Sterilization and Disinfection Orientation

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Course description
Qualified medical support staff, who are properly trained, are expected to provide sterilization and disinfection of re-usable medical devices. Completion of this course qualifies staff to perform sterilization and disinfection of re-usable medical devices.

Organization mission
Our mission is to foster community well-being in partnership with our patients by providing excellent, accessible, family-centered medical, dental and behavioral health care.

Organization vision
Our Vision is to offer available, respectful, quality health care to those we serve. Our Values are our respect for human dignity, highest quality of care and compassion.

Clinical education philosophy
Our clinical education philosophy represents attitudes, values, and beliefs of the organization. The clinical education department is committed to providing relevant evidence-based learning to all healthcare staff that expresses diversity, equity, and inclusion. The education department utilizes multi-modal methods for delivering curriculum that maintains a learner-centered environment. The department strives to develop connections between healthcare staff and the community through professional development.

Learning Outcomes
1. Define sterilization, disinfection, and cleaning related to sterilization and disinfection processes
2. Differentiate between germicides and antiseptics
3. Differentiate between critical, semicritical, and noncritical items.
4. Identify the five steps of sterilization / disinfection.
5. Identify accepted methods for loading steam sterilizers.
6. Demonstrate disinfection of medical instruments
7. Demonstrate inspection of instruments.
8. Demonstrate autoclave operations.

Prerequisite skills / experience:
- Licensed Nurses, or any Medical Support Staff approved by the Chief Medical Officer
- Completion of Medical Assistant orientation or Nursing Staff orientation

Learning activities
- **Service learning** – Learners will utilize La Familia Medical sterilization and disinfection related protocols to perform sterilization and disinfection. The trainer will facilitate discovery learning and critical reflection to ensure the learner understands concepts sterilization and disinfection that are safe.

- **Demonstration / Return demonstration** – The learner will orient with a peer who is qualified to perform the sterilization and disinfection. The learner will complete all tasks on the Sterilization and Disinfection Orientation checklist demonstrating competency and their confidence to apply the competencies their job.

Learner assessment

- Test – Staff will take the Guidelines for Disinfection and Sterilization in Healthcare Facilitates test. Staff will remediate until they pass with 100%. The test is open book with no time limit.
- Competency – Sterilization and Disinfection Orientation Checklist is required to be completed in its entirety.

Clinical education and learner expectations

- Clinical educator or other assigned trainer
    - Ensures staff has access to the current LFMC medication refill protocol
    - Ensures staff has access to the Telephone Protocols for Nurses handbook
    - Administers medication refill protocol familiarization test
    - Conducts scenario-based learning activity
    - Ensures staff member is familiar with telephone triage skills assessment
    - Validates all training requirements have been fulfilled
- Preceptor or other assigned staff
    - Observe the staff member correctly perform 10 telephone triage calls
    - Utilize Triage Skills assessment
    - Perform summative feedback
    - Validates clinical competency
    - Addresses questions or concerns regarding eCW
- Staff member:
    - Complete all training requirements

References

Rutala, W., Weber, D. (2008). Guideline for disinfection and sterilization in healthcare facilitites, 2008. https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

Test: Guidelines for Disinfection and Sterilization in Healthcare Facilities

1. Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods.
    a. True
    b. False
2. Disinfection describes a process that eliminates many or all pathogenic microorganisms.
    a. True
    b. False
3. Factors that affect the efficacy of both disinfection and sterilization include: (select all that apply).
    a. Prior cleaning of the object
    b. Organic and inorganic load present
    c. Type and level of microbial contamination
    d. Physical nature of the object
4. Cleaning is the removal of:
    a. Gauze wraps
    b. Packaging
    c. Visible soil
    d. Gloves
5. Cleaning is accomplished by:
    a. Manually or mechanically using water with detergents or enzymatic products
    b. Steam under pressure
    c. Dry heat
    d. Hydrogen peroxide gas plasma
6. A germicide is an agent that can kill microorganisms.
    a. True
    b. False
7. Antiseptics are germicides applied to living tissue and skin.
    a. True
    b. False
8. Disinfectants are antimicrobials applied only to inanimate objects.
    a. True
    b. False
9. Examples of disinfectants include: (select all that apply)
    a. Cavi-wipes
    b. Chlorine bleach
    c. Hand sanitizer
    d. Skin moisturizer
10. In general, antiseptics are used only on the skin and not for surface disinfection.
    a. True
    b. False
11. In general …
    a. Antiseptics are used only on surface disinfection.
    b. Antiseptics are used only on the skin.
    c. Disinfectants injure skin and other tissues

    d. Disinfectants are safe for skin application
12. Critical items confer a high risk for infection
    a. True
    b. False
13. Sterilization of objects that enter sterile tissue or the vascular system is optional.
    a. True
    b. False
14. Any microbial contamination that is not eradicated through sterilization could transmit disease.
    a. True
    b. False
15. Semi critical items contact mucous membranes or nonintact skin.
    a. True
    b. False
16. Semi critical items only require low-level disinfection because they only come in contact with mucous membranes.
    a. True
    b. False
17. High-level disinfection is defined as complete elimination of all microorganisms
    a. True
    b. False
18. Meticulous cleaning must precede any high-level disinfection or sterilization process.
    a. Only if the item is to be re-used
    b. Only on new instruments
    c. As a precaution only
    d. Always
19. Items can be rinsed and flushed using _____ after high-level disinfection to prevent contamination with organisms in tap water.
    a. Distilled water
    b. Hydrogen peroxide
    c. Sterile water
    d. Tap water
20. Noncritical items are those that come in contact with intact skin but not mucous membranes.
    a. True
    b. False
21. The sterility of items coming in contact with _____ skin is "not critical."
    a. Broken
    b. Wounded
    c. Healing
    d. Intact
22. What is the order of steps involved in disinfection and sterilization with a chemical sterilant?
    a. Disinfect, rinse, dry, store, clean
    b. Clean, disinfect, rinse, dry, store
    c. Rinse, dry, store, clean, disinfect
    d. Dry, clean, disinfect, rinse, store

23. Sterilization destroys most microorganisms on the surface of an article or in a fluid to prevent disease transmission associated with the use of that item.
    a. True
    b. False
24. Medical devices that have contact with sterile body tissues or fluids are considered critical items.
    a. True
    b. False
25. Of all the methods available for sterilization, dry heat is the most widely used and the most dependable.
    a. True
    b. False
26. The basic principle of steam sterilization, as accomplished in an autoclave, is to expose each item to: (select all that apply)direct steam contact at the required temperature and pressure for the specified time.
    a. Direct steam contact at the required time
    b. Direct steam contact at the required temperature
    c. Direct steam contact
    d. Direct steam contact for the required pressure
27. What are the four parameters of steam sterilization?
    a. Pressure, humidity, temperature, and time
    b. Steam, pressure, cleanliness, and temperature
    c. Steam, pressure, biological marker, cleanliness
    d. Steam, pressure, temperature, and time
28. The ideal steam for sterilizations is
    a. Dry steam
    b. Dry saturated steam
    c. Moist dry steam
    d. Moist saturated steam
29. Pressure serves as a means to obtain the _____ temperatures necessary to quickly kill microorganisms.
    a. Low
    b. Medium
    c. High
    d. Moist
30. The two common steam-sterilizing temperatures are
    a. 131°C (2678°F) and 122°C (251.6°F).
    b. 101°C (213.8°F) and 142°C (287.6°F).
    c. 121°C (250°F) and 132°C (270°F).
    d. 141°C (285.8°F) and 122°C (252.6°F).
31. The minimum exposure time for sterilization of healthcare supplies are ____ minutes at ____ ^{o}C (___^{o}F).
    a. 30 minutes, 121^{o}C, 250^{o}F
    b. 20 minutes, 121^{o}C, 250^{o}F

   c. 30 minutes, 250°C, 121°F
   d. 30 minutes, 100°C, 200°F
32. The autoclave is a type of dry heat sterilizer.
   a. True
   b. False
33. Hinged instruments must be remained closed prior to sterilization.
   a. True
   b. False
34. Devices with concave surfaces should be positioned to facilitate drainage of water.
   a. True
   b. False
35. Items with removable parts should remain assembled.
   a. True
   b. False
36. All items to be sterilized should be arranged so most surfaces will be _____ exposed to the sterilizing agent.
   a. Somewhat
   b. Mostly
   c. Directly
   d. Indirectly
37. Following the sterilization process, medical and surgical devices must be handled using aseptic technique in order to prevent contamination.
   a. True
   b. False
38. Instruments that are damaged, cracked, chipped, etc. should be removed from service.
   a. True
   b. False
39. Disinfectants are interchangeable, and incorrect concentrations and inappropriate disinfectants can result in excessive costs.
   a. True
   b. False
40. Thorough cleaning is required before high-level disinfection of sterilization because inorganic and organic materials may interfere with the sterilization process.
   a. True
   b. False

Sterilization and Disinfection Guidelines

Open Book Reference

Introduction

In the United States, approximately 46.5 million surgical procedures and even more invasive medical procedures—including approximately 5 million gastrointestinal endoscopies—are performed each year. [2] Each procedure involves contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogens that can lead to infection. Failure to properly disinfect or sterilize equipment carries not only risk associated with breach of host barriers but also risk for person-to-person transmission (e.g., hepatitis B virus) and transmission of environmental pathogens (e.g., *Pseudomonas aeruginosa*).

Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Because sterilization of all patient-care items is not necessary, health-care policies must identify, primarily on the basis of the items' intended use, whether cleaning, disinfection, or sterilization is indicated.

Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization. [3-6] Failure to comply with scientifically-based guidelines has led to numerous outbreaks. [6-12] This guideline presents a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes; the approach is based on well-designed studies assessing the efficacy (through laboratory investigations) and effectiveness (through clinical studies) of disinfection and sterilization procedures.

Methods

This guideline resulted from a review of all MEDLINE articles in English listed under the MeSH headings of *disinfection* or *sterilization* (focusing on health-care equipment and supplies) from January 1980 through August 2006. References listed in these articles also were reviewed. Selected articles published before 1980 were reviewed and, if still relevant, included in the guideline. The three major peer-reviewed journals in infection control—*American Journal of Infection Control, Infection Control and Hospital Epidemiology,* and *Journal of Hospital Infection*—were searched for relevant articles published from January 1990 through August 2006. Abstracts presented at the annual meetings of the Society for Healthcare Epidemiology of America and Association for professionals in Infection Control and Epidemiology, Inc. during 1997–2006 also were reviewed; however, abstracts were not used to support the recommendations.

Definition of Terms

Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, EtO gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health-care facilities. Sterilization is intended to convey an absolute meaning; unfortunately, however, some health professionals and the technical and commercial literature refer to "disinfection" as "sterilization" and items as "partially sterile." When chemicals are used to destroy all forms of microbiologic life, they can be called chemical sterilants. These same germicides used for shorter exposure periods also can be part of the disinfection process (i.e., high-level disinfection).

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects (Tables 1 and 2). In health-care settings, objects usually are disinfected by liquid chemicals or wet pasteurization. Each of the various factors that affect the efficacy of

disinfection can nullify or limit the efficacy of the process.

Factors that affect the efficacy of both disinfection and sterilization include prior cleaning of the object; organic and inorganic load present; type and level of microbial contamination; concentration of and exposure time to the germicide; physical nature of the object (e.g., crevices, hinges, and lumens); presence of biofilms; temperature and pH of the disinfection process; and in some cases, relative humidity of the sterilization process (e.g., ethylene oxide).

Unlike sterilization, disinfection is not sporicidal. A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called *chemical sterilants*. At similar concentrations but with shorter exposure periods (e.g., 20 minutes for 2% glutaraldehyde), these same disinfectants will kill all microorganisms except large numbers of bacterial spores; they are called *high-level disinfectants*. *Low-level disinfectants* can kill most vegetative bacteria, some fungi, and some viruses in a practical period of time (≤10 minutes). *Intermediate-level disinfectants* might be cidal for mycobacteria, vegetative bacteria, most viruses, and most fungi but do not necessarily kill bacterial spores. Germicides differ markedly, primarily in their antimicrobial spectrum and rapidity of action.

Cleaning is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. *Decontamination* removes pathogenic microorganisms from objects so they are safe to handle, use, or discard.

Terms with the suffix *cide* or *cidal* for killing action also are commonly used. For example, a germicide is an agent that can kill microorganisms, particularly pathogenic organisms (“germs”). The term *germicide* includes both antiseptics and disinfectants. *Antiseptics* are germicides applied to living tissue and skin; *disinfectants* are antimicrobials applied only to inanimate objects. In general, antiseptics are used only on the skin and not for surface disinfection, and disinfectants are not used for skin antisepsis because they can injure skin and other tissues. Virucide, fungicide, bactericide, sporicide, and tuberculocide can kill the type of microorganism identified by the prefix. For example, a bactericide is an agent that kills bacteria. [13-18]

A Rational Approach to Disinfection and Sterilization

More than 30 years ago, Earle H. Spaulding devised a rational approach to disinfection and sterilization of patient-care items and equipment.[14] This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization. [1, 13, 15, 17, 19, 20] Spaulding believed the nature of disinfection could be understood readily if instruments and items for patient care were categorized as critical, semicritical, and noncritical according to the degree of risk for infection involved in use of the items. The CDC *Guideline for Handwashing and Hospital Environmental Control* [21], *Guidelines for the Prevention of Transmission of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) to Health-Care and Public-Safety Workers*[22], and *Guideline for Environmental Infection Control in Health-Care Facilities*[23] employ this terminology.

Critical Items

Critical items confer a high risk for infection if they are contaminated with any microorganism. Thus, objects that enter sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. Most of the items in this category should be purchased as sterile or be sterilized with steam if possible. Heat-sensitive objects can be treated with EtO, hydrogen peroxide gas plasma; or if other methods are unsuitable, by liquid chemical sterilants. Germicides categorized as chemical sterilants include ≥2.4% glutaraldehyde-based formulations, 0.95% glutaraldehyde with 1.64% phenol/phenate, 7.5% stabilized hydrogen peroxide, 7.35% hydrogen peroxide with 0.23% peracetic acid, 0.2% peracetic acid, and 0.08% peracetic acid with 1.0% hydrogen peroxide. Liquid chemical sterilants reliably produce sterility only if cleaning precedes treatment and if proper guidelines are followed regarding concentration, contact time, temperature, and pH.

Semicritical Items

Semicritical items contact mucous membranes or nonintact skin. This category includes respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades [24], esophageal manometry probes, cystoscopes **[25]**, anorectal manometry catheters, and diaphragm fitting rings. These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are permissible. Intact mucous membranes, such as those of the lungs and the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria, and viruses. Semicritical items minimally require high-level disinfection using chemical disinfectants. Glutaraldehyde, hydrogen peroxide, *ortho*-phthalaldehyde, and peracetic acid with hydrogen peroxide are cleared by the Food and Drug Administration (FDA) and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met (Table 1). When a disinfectant is selected for use with certain patient-care items, the chemical compatibility after extended use with the items to be disinfected also must be considered.

High-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The FDA definition of high-level disinfection is a sterilant used for a shorter contact time to achieve a 6-$\log_{10}$ kill of an appropriate *Mycobacterium* species. Cleaning followed by high-level disinfection should eliminate enough pathogens to prevent transmission of infection. [26, 27]

Laparoscopes and arthroscopes entering sterile tissue ideally should be sterilized between patients. However, in the United States, this equipment sometimes undergoes only high-level disinfection between patients. [28-30] As with flexible endoscopes, these devices can be difficult to clean and high-level disinfect

or sterilize because of intricate device design (e.g., long narrow lumens, hinges). Meticulous cleaning must precede any high-level disinfection or sterilization process. Although sterilization is preferred, no reports have been published of outbreaks resulting from high-level disinfection of these scopes when they are properly cleaned and high-level disinfected. Newer models of these instruments can withstand steam sterilization that for critical items would be preferable to high-level disinfection.

Rinsing endoscopes and flushing channels with sterile water, filtered water, or tap water will prevent adverse effects associated with disinfectant retained in the endoscope (e.g., disinfectant-induced colitis). Items can be rinsed and flushed using sterile water after high-level disinfection to prevent contamination with organisms in tap water, such as nontuberculous mycobacteria, [10, 31, 32] *Legionella*, [33-35] or gram-negative bacilli such as *Pseudomonas*. [1, 17, 36-38] Alternatively, a tapwater or filtered water (0.2μ filter) rinse should be followed by an alcohol rinse and forced air drying. [28, 38-40] Forced-air drying markedly reduces bacterial contamination of stored endoscopes, most likely by removing the wet environment favorable for bacterial growth. [39] After rinsing, items should be dried and stored (e.g., packaged) in a manner that protects them from recontamination.

Some items that may come in contact with nonintact skin for a brief period of time (i.e., hydrotherapy tanks, bed side rails) are usually considered noncritical surfaces and are disinfected with intermediate-level disinfectants (i.e., phenolic, iodophor, alcohol, chlorine) [23]. Since hydrotherapy tanks have been associated with spread of infection, some facilities have chosen to disinfect them with recommended levels of chlorine [23, 41].

In the past, high-level disinfection was recommended for mouthpieces and spirometry tubing (e.g., glutaraldehyde) but cleaning the interior surfaces of the spirometers was considered unnecessary. [42] This was based on a study that showed that mouthpieces and spirometry tubing become contaminated with microorganisms but there was no bacterial contamination of the surfaces inside the spirometers. Filters have been used to prevent contamination of this equipment distal to the filter; such filters and the proximal mouthpiece are changed between patients.

Noncritical Items

Noncritical items are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is "not critical." In this guideline, noncritical items are divided into noncritical patient care items and noncritical environmental surfaces [43, 44]. Examples of noncritical patient-care items are bedpans, blood pressure cuffs, crutches and computers [45]. In contrast to critical and some semicritical items, most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. Virtually no risk has been documented for transmission of infectious agents to patients through noncritical items [37] when they are used as noncritical items and do not contact non-intact skin and/or mucous membranes. Table 1 lists several low-level disinfectants that may be used for noncritical items. Most Environmental Protection Agency (EPA)-registered disinfectants have a 10-minute label claim. However, multiple investigators have demonstrated the effectiveness of these disinfectants against vegetative bacteria (e.g., *Listeria*, *Escherichia coli*, *Salmonella*, vancomycin-resistant Enterococci, methicillin-resistant *Staphylococcus aureus*), yeasts (e.g., *Candida*), mycobacteria (e.g., *Mycobacterium tuberculosis*), and viruses (e.g. poliovirus) at exposure times of 30–60 seconds[46-64] Federal law requires all applicable label instructions on EPA-registered products to be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use, and disposal). If the user selects exposure conditions (e.g., exposure time) that differ from those on the EPA-registered products label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) [65].

Noncritcal environmental surfaces include bed rails, some food utensils, bedside tables, patient furniture and floors. Noncritical environmental surfaces frequently touched by hand (e.g., bedside tables,

bed rails) potentially could contribute to secondary transmission by contaminating hands of health-care workers or by contacting medical equipment that subsequently contacts patients [13, 46-48, 51, 66, 67]. Mops and reusable cleaning cloths are regularly used to achieve low-level disinfection on environmental surfaces. However, they often are not adequately cleaned and disinfected, and if the water-disinfectant mixture is not changed regularly (e.g., after every three to four rooms, at no longer than 60-minute intervals), the mopping procedure actually can spread heavy microbial contamination throughout the health-care facility [68]. In one study, standard laundering provided acceptable decontamination of heavily contaminated mopheads but chemical disinfection with a phenolic was less effective. [68] Frequent laundering of mops (e.g., daily), therefore, is recommended. Single-use disposable towels impregnated with a disinfectant also can be used for low-level disinfection when spot-cleaning of noncritical surfaces is needed[45].

Changes in Disinfection and Sterilization Since 1981

The Table in the CDC *Guideline for Environmental Control* prepared in 1981 as a guide to the appropriate selection and use of disinfectants has undergone several important changes (Table 1).[15] **First**, formaldehyde-alcohol has been deleted as a recommended chemical sterilant or high-level disinfectant because it is irritating and toxic and not commonly used. **Second**, several new chemical sterilants have been added, including hydrogen peroxide, peracetic acid [58, 69, 70], and peracetic acid and hydrogen peroxide in combination. **Third**, 3% phenolics and iodophors have been deleted as high-level disinfectants because of their unproven efficacy against bacterial spores, *M. tuberculosis,* and/or some fungi. [55, 71] **Fourth**, isopropyl alcohol and ethyl alcohol have been excluded as high-level disinfectants [15] because of their inability to inactivate bacterial spores and because of the inability of isopropyl alcohol to inactivate hydrophilic viruses (i.e., poliovirus, coxsackie virus).[72] **Fifth**, a 1:16 dilution of 2.0% glutaraldehyde-7.05% phenol-1.20% sodium phenate (which contained 0.125% glutaraldehyde, 0.440% phenol, and 0.075% sodium phenate when diluted) has been deleted as a high-level disinfectant because this product was removed from the marketplace in December 1991 because of a lack of bactericidal activity in the presence of organic matter; a lack of fungicidal, tuberculocidal and sporicidal activity; and reduced virucidal activity.[49, 55, 56, 71, 73-79] **Sixth**, the exposure time required to achieve high-level disinfection has been changed from 10-30 minutes to 12 minutes or more depending on the FDA-cleared label claim and the scientific literature. [27, 55, 69, 76, 80-84] A glutaraldehyde and an ortho-phthalaldehyde have an FDA-cleared label claim of 5 minutes when used at 35°C and 25°C, respectively, in an automated endoscope reprocessor with FDA-cleared capability to maintain the solution at the appropriate temperature. [85]

In addition, many new subjects have been added to the guideline. These include inactivation of emerging pathogens, bioterrorist agents, and bloodborne pathogens; toxicologic, environmental, and occupational concerns associated with disinfection and sterilization practices; disinfection of patient-care equipment used in ambulatory and home care; inactivation of antibiotic-resistant bacteria; new sterilization processes, such as hydrogen peroxide gas plasma and liquid peracetic acid; and disinfection of complex medical instruments (e.g., endoscopes).

Disinfection of Healthcare Equipment

Concerns about Implementing the Spaulding Scheme

One problem with implementing the aforementioned scheme is oversimplification. For example, the scheme does not consider problems with reprocessing of complicated medical equipment that often is heat-sensitive or problems of inactivating certain types of infectious agents (e.g., prions, such as Creutzfeldt-Jakob disease [CJD] agent). Thus, in some situations, choosing a method of disinfection remains difficult, even after consideration of the categories of risk to patients. This is true particularly for a few medical devices (e.g., arthroscopes, laparoscopes) in the critical category because of controversy about whether they should be sterilized or high-level disinfected. [28, 86] Heat-stable scopes (e.g., many rigid scopes) should be steam sterilized. Some of these items cannot be steam sterilized because they are heat-sensitive; additionally, sterilization using ethylene oxide (EtO) can be too time-consuming for routine use between patients (new technologies, such as hydrogen peroxide gas plasma and peracetic acid reprocessor, provide faster cycle times). However, evidence that sterilization of these items improves patient care by reducing the infection risk is lacking[29, 87-91]. Many newer models of these instruments can withstand steam sterilization, which for critical items is the preferred method.

Another problem with implementing the Spaulding scheme is processing of an instrument in the semicritical category (e.g., endoscope) that would be used in conjunction with a critical instrument that contacts sterile body tissues. For example, is an endoscope used for upper gastrointestinal tract investigation still a semicritical item when used with sterile biopsy forceps or in a patient who is bleeding heavily from esophageal varices? Provided that high-level disinfection is achieved, and all microorganisms except bacterial spores have been removed from the endoscope, the device should not represent an infection risk and should remain in the semicritical category [92-94] . Infection with spore-forming bacteria has not been reported from appropriately high-level disinfected endoscopes.

An additional problem with implementation of the Spaulding system is that the optimal contact time for high-level disinfection has not been defined or varies among professional organizations, resulting in different strategies for disinfecting different types of semicritical items (e.g., endoscopes, applanation tonometers, endocavitary transducers, cryosurgical instruments, and diaphragm fitting rings). Until simpler and effective alternatives are identified for device disinfection in clinical settings, following this guideline, other CDC guidelines [1, 22, 95, 96] and FDA-cleared instructions for the liquid chemical sterilants/high-level disinfectants would be prudent.

Reprocessing of Endoscopes

Physicians use endoscopes to diagnose and treat numerous medical disorders. Even though endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine and the incidence of infection associated with their use reportedly is very low (about 1 in 1.8 million procedures) [97], more healthcare–associated outbreaks have been linked to contaminated endoscopes than to any other medical device [6-8, 12, 98]. To prevent the spread of health-care–associated infections, all heat-sensitive endoscopes (e.g., gastrointestinal endoscopes, bronchoscopes, nasopharygoscopes) must be properly cleaned and, at a minimum, subjected to high-level disinfection after each use. High-level disinfection can be expected to destroy all microorganisms, although when high numbers of bacterial spores are present, a few spores might survive.

Because of the types of body cavities they enter, flexible endoscopes acquire high levels of microbial contamination (bioburden) during each use [99]. For example, the bioburden found on flexible gastrointestinal endoscopes after use has ranged from 10^5 colony forming units (CFU)/mL to 10^{10} CFU/mL, with the highest levels found in the suction channels [99-102]. The average load on bronchoscopes before cleaning was 6.4×10^4 CFU/mL. Cleaning reduces the level of microbial contamination by 4–6 $\log_{10}$ [83, 103]. Using human immunovirus (HIV)-contaminated endoscopes, several investigators have shown that cleaning completely eliminates the microbial contamination on the scopes [104, 105]. Similarly, other investigators found that EtO sterilization or soaking in 2% glutaraldehyde for 20 minutes was effective only when the device first was properly cleaned [106].

FDA maintains a list of cleared liquid chemical sterilants and high-level disinfectants that can be used to reprocess heat-sensitive medical devices, such as flexible endoscopes [This link is no longer active: http://www.fda.gov/cdrh/ode/germlab.html. The current version of this document may differ from original version:FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices - March 2015] (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm). At this time, the FDA-cleared and marketed formulations include: ≥2.4% glutaraldehyde, 0.55% *ortho*-phthalaldehyde (OPA), 0.95% glutaraldehyde with 1.64% phenol/phenate, 7.35% hydrogen peroxide with 0.23% peracetic acid, 1.0% hydrogen peroxide with 0.08% peracetic acid, and 7.5% hydrogen peroxide [85]. These products have excellent antimicrobial activity; however, some oxidizing chemicals (e.g., 7.5% hydrogen peroxide, and 1.0% hydrogen peroxide with 0.08% peracetic acid [latter product is no longer marketed]) reportedly have caused cosmetic and functional damage to endoscopes [69]. Users should check with device manufacturers for information about germicide compatibility with their device. If the germicide is FDA-cleared, then it is safe when used according to label directions; however, professionals should review the scientific literature for newly available data regarding human safety or materials compatibility. EtO sterilization of flexible endoscopes is infrequent because it requires a lengthy processing and aeration time (e.g., 12 hours) and is a potential hazard to staff and patients. The two products most commonly used for reprocessing endoscopes in the United States are glutaraldehyde and an automated, liquid chemical sterilization process that uses peracetic acid [107]. The American Society for Gastrointestinal Endoscopy (ASGE) recommends glutaraldehyde solutions that do not contain surfactants because the soapy residues of surfactants are difficult to remove during rinsing [108]. *ortho*-phthalaldehyde has begun to replace glutaraldehyde in many health-care facilities because it has several potential advantages over glutaraldehyde: is not known to irritate the eyes and nasal passages, does not require activation or exposure monitoring, and has a 12-minute high-level disinfection claim in the United States [69]. Disinfectants that are not FDA-cleared and should not be used for reprocessing endoscopes include iodophors, chlorine solutions, alcohols, quaternary ammonium compounds, and phenolics. These solutions might still be in use outside the United States, but their use should be strongly discouraged because of lack of proven efficacy against all microorganisms or materials incompatibility.

FDA clearance of the contact conditions listed on germicide labeling is based on the manufacturer's test results [This link is no longer active: http://www.fda.gov/cdrh/ode/germlab.html. The current version of this document may differ from original version:FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices - March 2015 (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm)]. Manufacturers test the product under worst-case conditions for germicide formulation (i.e., minimum recommended concentration of the active ingredient), and include organic soil. Typically manufacturers use 5% serum as the organic soil and hard water as examples of organic and inorganic challenges. The soil represents the organic loading to which the device is exposed during actual use and that would remain on the device in the absence of cleaning. This method ensures that the contact conditions completely eliminate the test mycobacteria (e.g., 10^5 to 10^6 *Mycobacteria tuberculosis* in organic soil and dried on a scope) if inoculated in the most difficult areas for the disinfectant to penetrate and contact in the absence of cleaning and thus provides a margin of safety [109]. For 2.4% glutaraldehyde that requires a 45-minute immersion at 25˚C to achieve high-level disinfection (i.e., 100% kill of *M. tuberculosis*). FDA itself does not conduct testing but relies solely on the disinfectant manufacturer's data. Data suggest that *M. tuberculosis* levels can be reduced by at least 8 $\log_{10}$ with cleaning (4 $\log_{10}$) [83, 101, 102, 110], followed by chemical disinfection for 20 minutes at 20°C (4 to 6 $\log_{10}$) [83, 93, 111, 112]. On the basis of these data, APIC [113], the Society of Gastroenterology Nurses and Associates (SGNA) [38, 114, 115], the ASGE [108], American College of Chest Physicians [12], and a multi-society guideline [116] recommend alternative contact conditions with 2% glutaraldehyde to achieve high-level disinfection (e.g., that equipment be immersed in 2% glutaraldehyde at 20°C for at least 20 minutes for high-level disinfection). Federal regulations are to follow the FDA-cleared label claim for high-level disinfectants. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 25°C range from 20-90 minutes, depending upon the product based on three tier testing which includes AOAC sporicidal tests, simulated use testing with mycobacterial and in-use testing. The studies supporting the efficacy of >2% glutaraldehyde for 20 minutes at 20ºC assume adequate cleaning prior to disinfection, whereas the FDA-cleared label claim incorporates an

added margin of safety to accommodate possible lapses in cleaning practices. Facilities that have chosen to apply the 20 minute duration at 20ºC have done so based on the IA recommendation in the July 2003 SHEA position paper, "Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes"[19, 57, 83, 94, 108, 111, 116-121].

⚠ **Flexible GI Endoscope Reprocessing Update [June 2011]:** Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011 (http://www.asge.org/uploadedFiles/Publications_and_Products/Practice_Guidelines/Multisociety%20guideline%20on%20reprocessing%20flexible%20gastrointestinal.pdf [PDF - 547KB]).

Flexible endoscopes are particularly difficult to disinfect [122] and easy to damage because of their intricate design and delicate materials. [123] Meticulous cleaning must precede any sterilization or high-level disinfection of these instruments. Failure to perform good cleaning can result in sterilization or disinfection failure, and outbreaks of infection can occur. Several studies have demonstrated the importance of cleaning in experimental studies with the duck hepatitis B virus (HBV) [106, 124], HIV [125]and *Helicobacter pylori*. [126]

An examination of health-care–associated infections related only to endoscopes through July 1992 found 281 infections transmitted by gastrointestinal endoscopy and 96 transmitted by bronchoscopy. The clinical spectrum ranged from asymptomatic colonization to death. *Salmonella* species and *Pseudomonas aeruginosa* repeatedly were identified as causative agents of infections transmitted by gastrointestinal endoscopy, and *M. tuberculosis*, atypical mycobacteria, and *P. aeruginosa* were the most common causes of infections transmitted by bronchoscopy [12]. Major reasons for transmission were inadequate cleaning, improper selection of a disinfecting agent, and failure to follow recommended cleaning and disinfection procedures [6, 8, 37, 98], and flaws in endoscope design [127, 128] or automated endoscope reprocessors. [7, 98] Failure to follow established guidelines has continued to result in infections associated with gastrointestinal endoscopes [8] and bronchoscopes [7, 12]. Potential device-associated problems should be reported to the FDA Center for Devices and Radiologic Health. One multistate investigation found that 23.9% of the bacterial cultures from the internal channels of 71 gastrointestinal endoscopes grew ≥100,000 colonies of bacteria after completion of all disinfection and sterilization procedures (nine of 25 facilities were using a product that has been removed from the marketplace [six facilities using 1:16 glutaraldehyde phenate], is not FDA-cleared as a high-level disinfectant [an iodophor] or no disinfecting agent) and before use on the next patient[129]. The incidence of postendoscopic procedure infections from an improperly processed endoscope has not been rigorously assessed.

Automated endoscope reprocessors (AER) offer several advantages over manual reprocessing: they automate and standardize several important reprocessing steps[130-132], reduce the likelihood that an essential reprocessing step will be skipped, and reduce personnel exposure to high-level disinfectants or chemical sterilants. Failure of AERs has been linked to outbreaks of infections [133] or colonization [7, 134], and the AER water filtration system might not be able to reliably provide "sterile" or bacteria-free rinse water[135, 136]. Establishment of correct connectors between the AER and the device is critical to ensure complete flow of disinfectants and rinse water [7, 137]. In addition, some endoscopes such as the duodenoscopes (e.g., endoscopic retrograde cholangiopancreatography [ERCP]) contain features (e.g., elevator-wire channel) that require a flushing pressure that is not achieved by most AERs and must be reprocessed manually using a 2- to 5-mL syringe, until new duodenoscopes equipped with a wider elevator-channel that AERs can reliably reprocess become available [132]. Outbreaks involving removable endoscope parts [138, 139] such as suction valves and endoscopic accessories designed to be inserted through flexible endoscopes such as biopsy forceps emphasize the importance of cleaning to remove all foreign matter before high-level disinfection or sterilization. [140] Some types of valves are now available as single-use, disposable products (e.g., bronchoscope valves) or steam sterilizable products (e.g., gastrointestinal endoscope valves).

AERs need further development and redesign [7, 141], as do endoscopes [123, 142], so that they do not represent a potential source of infectious agents. Endoscopes employing disposable components (e.g., protective barrier devices or sheaths) might provide an alternative to conventional liquid chemical high-level disinfection/sterilization[143, 144]. Another new technology is a swallowable camera-in-a-capsule that travels through the digestive tract and transmits color pictures of the small intestine to a receiver worn outside the body. This capsule currently does not replace colonoscopies.

Published recommendations for cleaning and disinfecting endoscopic equipment should be strictly followed [12, 38, 108, 113-116, 145-148]. Unfortunately, audits have shown that personnel do not consistently adhere to guidelines on reprocessing [149-151] and outbreaks of infection continue to occur. [152-154] To ensure reprocessing personnel are properly trained, each person who reprocesses endoscopic instruments should receive initial and annual competency testing [38, 155].

In general, endoscope disinfection or sterilization with a liquid chemical sterilant involves five steps after leak testing:

1. Clean: mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion).
2. Disinfect: immerse endoscope in high-level disinfectant (or chemical sterilant) and perfuse (eliminates air pockets and ensures contact of the germicide with the internal channels) disinfectant into all accessible channels, such as the suction/biopsy channel and air/water channel and expose for a time recommended for specific products.
3. Rinse: rinse the endoscope and all channels with sterile water, filtered water (commonly used with AERs) or tap water (i.e., high-quality potable water that meets federal clean water standards at the point of use).
4. Dry: rinse the insertion tube and inner channels with alcohol, and dry with forced air after disinfection and before storage.
5. Store: store the endoscope in a way that prevents recontamination and promotes drying (e.g., hung vertically).

Drying the endoscope (steps 3 and 4) is essential to greatly reduce the chance of recontamination of the endoscope by microorganisms that can be present in the rinse water [116, 156]. One study demonstrated that reprocessed endoscopes (i.e., air/water channel, suction/biopsy channel) generally were negative (100% after 24 hours; 90% after 7 days [1 CFU of coagulase-negative *Staphylococcus* in one channel]) for bacterial growth when stored by hanging vertically in a ventilated cabinet[157]. Other investigators found all endoscopes were bacteria-free immediately after high-level disinfection, and only four of 135 scopes were positive during the subsequent 5-day assessment (skin bacteria cultured from endoscope surfaces). All flush-through samples remained sterile [158]. Because tapwater can contain low levels of microorganisms[159], some researchers have suggested that only sterile water (which can be prohibitively expensive) [160] or AER filtered water be used. The suggestion to use only sterile water or filtered water is not consistent with published guidelines that allow tapwater with an alcohol rinse and forced air-drying [38, 108, 113] or the scientific literature. [39, 93] In addition, no evidence of disease transmission has been found when a tap water rinse is followed by an alcohol rinse and forced-air drying. AERs produce filtered water by passage through a bacterial filter (e.g., 0.2 μ). Filtered rinse water was identified as a source of bacterial contamination in a study that cultured the accessory and suction channels of endoscopes and the internal chambers of AERs during 1996–2001 and reported 8.7% of samples collected during 1996–1998 had bacterial growth, with 54% being *Pseudomonas* species. After a system of hot water flushing of the piping (60°C for 60 minutes daily) was introduced, the frequency of positive cultures fell to approximately 2% with only rare isolation of >10 CFU/mL [161]. In addition to the endoscope reprocessing steps, a protocol should be developed that ensures the user knows whether an endoscope has been appropriately cleaned and disinfected (e.g., using a room or cabinet for processed endoscopes only) or has not been reprocessed. When users leave endoscopes on movable carts, confusion can result about whether the endoscope has been processed. Although one guideline recommended endoscopes (e.g., duodenoscopes) be reprocessed immediately before use [147], other guidelines do not require this activity [38, 108, 115] and except for the Association of periOperative Registered Nurses (AORN), professional organizations do not recommended that reprocessing be repeated as long as the original processing is done correctly. As part of a quality assurance program, healthcare facility personnel can consider random bacterial surveillance cultures of processed endoscopes to ensure high-level disinfection or sterilization[7, 162-164] . Reprocessed endoscopes should be free of microbial pathogens except for small numbers of relatively avirulent microbes that represent exogenous environmental contamination (e.g., coagulase-negative *Staphylococcus*, *Bacillus* species, diphtheroids). Although recommendations exist for the final rinse water used during endoscope

Cleaning

Cleaning is the removal of foreign material (e.g., soil, and organic material) from objects and is normally accomplished using water with detergents or enzymatic products. Thorough cleaning is required before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. Also, if soiled materials dry or bake onto the instruments, the removal process becomes more difficult and the disinfection or sterilization process less effective or ineffective. Surgical instruments should be presoaked or rinsed to prevent drying of blood and to soften or remove blood from the instruments.

Cleaning is done manually in use areas without mechanical units (e.g., ultrasonic cleaners or washer-disinfectors) or for fragile or difficult-to-clean instruments. With manual cleaning, the two essential components are friction and fluidics. Friction (e.g., rubbing/scrubbing the soiled area with a brush) is an old and dependable method. Fluidics (i.e., fluids under pressure) is used to remove soil and debris from internal channels after brushing and when the design does not allow passage of a brush through a channel [445]. When a washer-disinfector is used, care should be taken in loading instruments: hinged instruments should be opened fully to allow adequate contact with the detergent solution; stacking of instruments in washers should be avoided; and instruments should be disassembled as much as possible.

The most common types of mechanical or automatic cleaners are ultrasonic cleaners, washer-decontaminators, washer-disinfectors, and washer-sterilizers. Ultrasonic cleaning removes soil by cavitation and implosion in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces. Bacterial contamination can be present in used ultrasonic cleaning solutions (and other used detergent solutions) because these solutions generally do not make antibacterial label claims [446]. Even though ultrasound alone does not significantly inactivate bacteria, sonication can act synergistically to increase the cidal efficacy of a disinfectant [447]. Users of ultrasonic cleaners should be aware that the cleaning fluid could result in endotoxin contamination of surgical instruments, which could cause severe inflammatory reactions [448]. Washer-sterilizers are modified steam sterilizers that clean by filling the chamber with water and detergent through which steam passes to provide agitation. Instruments are subsequently rinsed and subjected to a short steam-sterilization cycle. Another washer-sterilizer employs rotating spray arms for a wash cycle followed by a steam sterilization cycle at 285°F [449, 450]. Washer-decontaminators/disinfectors act like a dishwasher that uses a combination of water circulation and detergents to remove soil. These units sometimes have a cycle that subjects the instruments to a heat process (e.g., 93ºC for 10 minutes) [451]. Washer-disinfectors are generally computer-controlled units for cleaning, disinfecting, and drying solid and hollow surgical and medical equipment. In one study, cleaning (measured as 5–6 $\log_{10}$ reduction) was achieved on surfaces that had adequate contact with the water flow in the machine [452]. Detailed information about cleaning and preparing supplies for terminal sterilization is provided by professional organizations [453, 454] and books [455]. Studies have shown that manual and mechanical cleaning of endoscopes achieves approximately a 4-$\log_{10}$ reduction of contaminating organisms [83, 104, 456, 457]. Thus, cleaning alone effectively reduces the number of microorganisms on contaminated equipment. In a quantitative analysis of residual protein contamination of reprocessed surgical instruments, median levels of residual protein contamination per instrument for five trays were 267, 260, 163, 456, and 756 µg [458]. In another study, the median amount of protein from reprocessed surgical instruments from different hospitals ranged from 8 µg to 91 µg [459]. When manual methods were compared with automated methods for cleaning reusable accessory devices used for minimally invasive surgical procedures, the automated method was more efficient for cleaning biopsy forceps and ported and nonported laparoscopic devices and achieved a >99% reduction in soil parameters (i.e., protein, carbohydrate, hemoglobin) in the ported and nonported laparoscopic devices [460, 461]

For instrument cleaning, a neutral or near-neutral pH detergent solution commonly is used because such solutions generally provide the best material compatibility profile and good soil removal. Enzymes,

usually proteases, sometimes are added to neutral pH solutions to assist in removing organic material. Enzymes in these formulations attack proteins that make up a large portion of common soil (e.g., blood, pus). Cleaning solutions also can contain lipases (enzymes active on fats) and amylases (enzymes active on starches). Enzymatic cleaners are not disinfectants, and proteinaceous enzymes can be inactivated by germicides. As with all chemicals, enzymes must be rinsed from the equipment or adverse reactions (e.g., fever, residual amounts of high-level disinfectants, proteinaceous residue) could result [462, 463]. Enzyme solutions should be used in accordance with manufacturer's instructions, which include proper dilution of the enzymatic detergent and contact with equipment for the amount of time specified on the label [463]. Detergent enzymes can result in asthma or other allergic effects in users. Neutral pH detergent solutions that contain enzymes are compatible with metals and other materials used in medical instruments and are the best choice for cleaning delicate medical instruments, especially flexible endoscopes [457]. Alkaline-based cleaning agents are used for processing medical devices because they efficiently dissolve protein and fat residues [464]; however, they can be corrosive [457]. Some data demonstrate that enzymatic cleaners are more effective than neutral detergents [465, 466] in removing microorganisms from surfaces but two more recent studies found no difference in cleaning efficiency between enzymatic and alkaline-based cleaners [443, 464]. Another study found no significant difference between enzymatic and non-enzymatic cleaners in terms of microbial cleaning efficacy [467]. A new non-enzyme, hydrogen peroxide-based formulation (not FDA-cleared) was as effective as enzymatic cleaners in removing protein, blood, carbohydrate, and endotoxin from surface test carriers[468] In addition, this product effected a 5-$\log_{10}$ reduction in microbial loads with a 3-minute exposure at room temperature [468].

Although the effectiveness of high-level disinfection and sterilization mandates effective cleaning, no "real-time" tests exist that can be employed in a clinical setting to verify cleaning. If such tests were commercially available they could be used to ensure an adequate level of cleaning.[469-472] The only way to ensure adequate cleaning is to conduct a reprocessing verification test (e.g., microbiologic sampling), but this is not routinely recommended [473]. Validation of the cleaning processes in a laboratory-testing program is possible by microorganism detection, chemical detection for organic contaminants, radionuclide tagging, and chemical detection for specific ions [426, 471]. During the past few years, data have been published describing use of an artificial soil, protein, endotoxin, X-ray contrast medium, or blood to verify the manual or automated cleaning process [169, 452, 474-478] and adenosine triphosphate bioluminescence and microbiologic sampling to evaluate the effectiveness of environmental surface cleaning[170, 479]. At a minimum, all instruments should be individually inspected and be visibly clean.

Disinfection

Many disinfectants are used alone or in combinations (e.g., hydrogen peroxide and peracetic acid) in the health-care setting. These include alcohols, chlorine and chlorine compounds, formaldehyde, glutaraldehyde, *ortho*-phthalaldehyde, hydrogen peroxide, iodophors, peracetic acid, phenolics, and quaternary ammonium compounds. Commercial formulations based on these chemicals are considered unique products and must be registered with EPA or cleared by FDA. In most instances, a given product is designed for a specific purpose and is to be used in a certain manner. Therefore, users should read labels carefully to ensure the correct product is selected for the intended use and applied efficiently.

Disinfectants are not interchangeable, and incorrect concentrations and inappropriate disinfectants can result in excessive costs. Because occupational diseases among cleaning personnel have been associated with use of several disinfectants (e.g., formaldehyde, glutaraldehyde, and chlorine), precautions (e.g., gloves and proper ventilation) should be used to minimize exposure [318, 480, 481]. Asthma and reactive airway disease can occur in sensitized persons exposed to any airborne chemical, including germicides. Clinically important asthma can occur at levels below ceiling levels regulated by OSHA or recommended by NIOSH. The preferred method of control is elimination of the chemical (through engineering controls or substitution) or relocation of the worker.

The following overview of the performance characteristics of each provides users with sufficient information to select an appropriate disinfectant for any item and use it in the most efficient way.

Chemical Disinfectants

Alcohol

Overview. In the healthcare setting, “alcohol” refers to two water-soluble chemical compounds—ethyl alcohol and isopropyl alcohol—that have generally underrated germicidal characteristics [482]. FDA has not cleared any liquid chemical sterilant or high-level disinfectant with alcohol as the main active ingredient. These alcohols are rapidly bactericidal rather than bacteriostatic against vegetative forms of bacteria; they also are tuberculocidal, fungicidal, and virucidal but do not destroy bacterial spores. Their cidal activity drops sharply when diluted below 50% concentration, and the optimum bactericidal concentration is 60%–90% solutions in water (volume/volume) [483, 484].

Mode of Action. The most feasible explanation for the antimicrobial action of alcohol is denaturation of proteins. This mechanism is supported by the observation that absolute ethyl alcohol, a dehydrating agent, is less bactericidal than mixtures of alcohol and water because proteins are denatured more quickly in the presence of water [484, 485]. Protein denaturation also is consistent with observations that alcohol destroys the dehydrogenases of *Escherichia coli* [486], and that ethyl alcohol increases the lag phase of *Enterobacter aerogenes* [487] and that the lag phase effect could be reversed by adding certain amino acids. The bacteriostatic action was believed caused by inhibition of the production of metabolites essential for rapid cell division.

Microbicidal Activity. Methyl alcohol (methanol) has the weakest bactericidal action of the alcohols and thus seldom is used in healthcare [488]. The bactericidal activity of various concentrations of ethyl alcohol (ethanol) was examined against a variety of microorganisms in exposure periods ranging from 10 seconds to 1 hour [483]. *Pseudomonas aeruginosa* was killed in 10 seconds by all concentrations of ethanol from 30% to 100% (v/v), and *Serratia marcescens, E, coli* and *Salmonella typhosa* were killed in 10 seconds by all concentrations of ethanol from 40% to 100%. The gram-positive organisms *Staphylococcus aureus* and *Streptococcus pyogenes* were slightly more resistant, being killed in 10 seconds by ethyl alcohol concentrations of 60%–95%. Isopropyl alcohol (isopropanol) was slightly more bactericidal than ethyl alcohol for *E. coli* and *S. aureus* [489].

Ethyl alcohol, at concentrations of 60%–80%, is a potent virucidal agent inactivating all of the lipophilic viruses (e.g., herpes, vaccinia, and influenza virus) and many hydrophilic viruses (e.g.,

Sterilization

Most medical and surgical devices used in healthcare facilities are made of materials that are heat stable and therefore undergo heat, primarily steam, sterilization. However, since 1950, there has been an increase in medical devices and instruments made of materials (e.g., plastics) that require low-temperature sterilization. Ethylene oxide gas has been used since the 1950s for heat- and moisture-sensitive medical devices. Within the past 15 years, a number of new, low-temperature sterilization systems (e.g., hydrogen peroxide gas plasma, peracetic acid immersion, ozone) have been developed and are being used to sterilize medical devices. This section reviews sterilization technologies used in healthcare and makes recommendations for their optimum performance in the processing of medical devices [1, 18, 811-820].

Sterilization destroys all microorganisms on the surface of an article or in a fluid to prevent disease transmission associated with the use of that item. While the use of inadequately sterilized critical items represents a high risk of transmitting pathogens, documented transmission of pathogens associated with an inadequately sterilized critical item is exceedingly rare [821, 822]. This is likely due to the wide margin of safety associated with the sterilization processes used in healthcare facilities. The concept of what constitutes "sterile" is measured as a probability of sterility for each item to be sterilized. This probability is commonly referred to as the sterility assurance level (SAL) of the product and is defined as the probability of a single viable microorganism occurring on a product after sterilization. SAL is normally expressed a 10^{-n}. For example, if the probability of a spore surviving were one in one million, the SAL would be 10^{-6} [823, 824]. In short, a SAL is an estimate of lethality of the entire sterilization process and is a conservative calculation. Dual SALs (e.g., 10^{-3} SAL for blood culture tubes, drainage bags; 10^{-6} SAL for scalpels, implants) have been used in the United States for many years and the choice of a 10^{-6} SAL was strictly arbitrary and not associated with any adverse outcomes (e.g., patient infections) [823].

Medical devices that have contact with sterile body tissues or fluids are considered critical items. These items should be sterile when used because any microbial contamination could result in disease transmission. Such items include surgical instruments, biopsy forceps, and implanted medical devices. If these items are heat resistant, the recommended sterilization process is steam sterilization, because it has the largest margin of safety due to its reliability, consistency, and lethality. However, reprocessing heat- and moisture-sensitive items requires use of a low-temperature sterilization technology (e.g., ethylene oxide, hydrogen peroxide gas plasma, peracetic acid) [825]. A summary of the advantages and disadvantages for commonly used sterilization technologies is presented in Table 6.

Steam Sterilization

Overview. Of all the methods available for sterilization, moist heat in the form of saturated steam under pressure is the most widely used and the most dependable. Steam sterilization is nontoxic, inexpensive [826], rapidly microbicidal, sporicidal, and rapidly heats and penetrates fabrics (Table 6) [827]. Like all sterilization processes, steam sterilization has some deleterious effects on some materials, including corrosion and combustion of lubricants associated with dental handpieces[212]; reduction in ability to transmit light associated with laryngoscopes[828]; and increased hardening time (5.6 fold) with plaster-cast [829].

The basic principle of steam sterilization, as accomplished in an autoclave, is to expose each item to direct steam contact at the required temperature and pressure for the specified time. Thus, there are four parameters of steam sterilization: steam, pressure, temperature, and time. The ideal steam for sterilization is dry saturated steam and entrained water (dryness fraction ≥97%)[813, 819]. Pressure serves as a means to obtain the high temperatures necessary to quickly kill microorganisms. Specific temperatures must be obtained to ensure the microbicidal activity. The two common steam-sterilizing temperatures are 121°C (250°F) and 132°C (270°F). These temperatures (and other high temperatures) [830] must be maintained for a minimal time to kill microorganisms. Recognized minimum exposure periods for sterilization of wrapped healthcare supplies are 30 minutes at 121°C (250°F) in a gravity displacement

sterilizer or 4 minutes at 132°C (270°C) in a prevacuum sterilizer (Table 7). At constant temperatures, sterilization times vary depending on the type of item (e.g., metal versus rubber, plastic, items with lumens), whether the item is wrapped or unwrapped, and the sterilizer type.

The two basic types of steam sterilizers (autoclaves) are the gravity displacement autoclave and the high-speed prevacuum sterilizer. In the former, steam is admitted at the top or the sides of the sterilizing chamber and, because the steam is lighter than air, forces air out the bottom of the chamber through the drain vent. The gravity displacement autoclaves are primarily used to process laboratory media, water, pharmaceutical products, regulated medical waste, and nonporous articles whose surfaces have direct steam contact. For gravity displacement sterilizers the penetration time into porous items is prolonged because of incomplete air elimination. This point is illustrated with the decontamination of 10 lbs of microbiological waste, which requires at least 45 minutes at 121°C because the entrapped air remaining in a load of waste greatly retards steam permeation and heating efficiency[831, 832]. The high-speed prevacuum sterilizers are similar to the gravity displacement sterilizers except they are fitted with a vacuum pump (or ejector) to ensure air removal from the sterilizing chamber and load before the steam is admitted. The advantage of using a vacuum pump is that there is nearly instantaneous steam penetration even into porous loads. The Bowie-Dick test is used to detect air leaks and inadequate air removal and consists of folded 100% cotton surgical towels that are clean and preconditioned. A commercially available Bowie-Dick-type test sheet should be placed in the center of the pack. The test pack should be placed horizontally in the front, bottom section of the sterilizer rack, near the door and over the drain, in an otherwise empty chamber and run at 134°C for 3.5 minutes[813, 819]. The test is used each day the vacuum-type steam sterilizer is used, before the first processed load. Air that is not removed from the chamber will interfere with steam contact. Smaller disposable test packs (or process challenge devices) have been devised to replace the stack of folded surgical towels for testing the efficacy of the vacuum system in a prevacuum sterilizer. [833] These devices are “designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process”[819, 834]. They should be representative of the load and simulate the greatest challenge to the load[835]. Sterilizer vacuum performance is acceptable if the sheet inside the test pack shows a uniform color change. Entrapped air will cause a spot to appear on the test sheet, due to the inability of the steam to reach the chemical indicator. If the sterilizer fails the Bowie-Dick test, do not use the sterilizer until it is inspected by the sterilizer maintenance personnel and passes the Bowie-Dick test[813, 819, 836].

Another design in steam sterilization is a steam flush-pressure pulsing process, which removes air rapidly by repeatedly alternating a steam flush and a pressure pulse above atmospheric pressure. Air is rapidly removed from the load as with the prevacuum sterilizer, but air leaks do not affect this process because the steam in the sterilizing chamber is always above atmospheric pressure. Typical sterilization temperatures and times are 132°C to 135°C with 3 to 4 minutes exposure time for porous loads and instruments[827, 837].

Like other sterilization systems, the steam cycle is monitored by mechanical, chemical, and biological monitors. Steam sterilizers usually are monitored using a printout (or graphically) by measuring temperature, the time at the temperature, and pressure. Typically, chemical indicators are affixed to the outside and incorporated into the pack to monitor the temperature or time and temperature. The effectiveness of steam sterilization is monitored with a biological indicator containing spores of *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*). Positive spore test results are a relatively rare event [838] and can be attributed to operator error, inadequate steam delivery[839], or equipment malfunction.

Portable (table-top) steam sterilizers are used in outpatient, dental, and rural clinics[840]. These sterilizers are designed for small instruments, such as hypodermic syringes and needles and dental instruments. The ability of the sterilizer to reach physical parameters necessary to achieve sterilization should be monitored by mechanical, chemical, and biological indicators.

are kept together, so that reassembly can be accomplished efficiently[811].

Investigators have described the degree of cleanliness by visual and microscopic examination. One study found 91% of the instruments to be clean visually but, when examined microscopically, 84% of the instruments had residual debris. Sites that contained residual debris included junctions between insulating sheaths and activating mechanisms of laparoscopic instruments and articulations and grooves of forceps. More research is needed to understand the clinical significance of these findings [960] and how to ensure proper cleaning.

Personnel working in the decontamination area should wear household-cleaning-type rubber or plastic gloves when handling or cleaning contaminated instruments and devices. Face masks, eye protection such as goggles or full-length faceshields, and appropriate gowns should be worn when exposure to blood and contaminated fluids may occur (e.g., when manually cleaning contaminated devices)[961]. Contaminated instruments are a source of microorganisms that could inoculate personnel through nonintact skin on the hands or through contact with the mucous membranes of eyes, nose, or mouth[214, 811, 813]. Reusable sharps that have been in contact with blood present a special hazard. Employees must not reach with their gloved hands into trays or containers that hold these sharps to retrieve them[214]. Rather, employees should use engineering controls (e.g., forceps) to retrieve these devices.

Packaging. Once items are cleaned, dried, and inspected, those requiring sterilization must be wrapped or placed in rigid containers and should be arranged in instrument trays/baskets according to the guidelines provided by the AAMI and other professional organizations[454, 811-814, 819, 836, 962]. These guidelines state that hinged instruments should be opened; items with removable parts should be disassembled unless the device manufacturer or researchers provide specific instructions or test data to the contrary[181]; complex instruments should be prepared and sterilized according to device manufacturer's instructions and test data; devices with concave surfaces should be positioned to facilitate drainage of water; heavy items should be positioned not to damage delicate items; and the weight of the instrument set should be based on the design and density of the instruments and the distribution of metal mass[811, 962]. While there is no longer a specified sterilization weight limit for surgical sets, heavy metal mass is a cause of wet packs (i.e., moisture inside the case and tray after completion of the sterilization cycle)[963]. Other parameters that may influence drying are the density of the wraps and the design of the set[964].

There are several choices in methods to maintain sterility of surgical instruments, including rigid containers, peel-open pouches (e.g., self-sealed or heat-sealed plastic and paper pouches), roll stock or reels (i.e., paper-plastic combinations of tubing designed to allow the user to cut and seal the ends to form a pouch) [454] and sterilization wraps (woven and nonwoven). Healthcare facilities may use all of these packaging options. The packaging material must allow penetration of the sterilant, provide protection against contact contamination during handling, provide an effective barrier to microbial penetration, and maintain the sterility of the processed item after sterilization [965]. An ideal sterilization wrap would successfully address barrier effectiveness, penetrability (i.e., allows sterilant to penetrate), aeration (e.g., allows ETO to dissipate), ease of use, drapeability, flexibility, puncture resistance, tear strength, toxicity, odor, waste disposal, linting, cost, and transparency[966]. Unacceptable packaging for use with ETO (e.g., foil, polyvinylchloride, and polyvinylidene chlorine [kitchen-type transparent wrap]) [814] or hydrogen peroxide gas plasma (e.g., linens and paper) should not be used to wrap medical items.

In central processing, double wrapping can be done sequentially or nonsequentially (i.e., simultaneous wrapping). Wrapping should be done in such a manner to avoid tenting and gapping. The sequential wrap uses two sheets of the standard sterilization wrap, one wrapped after the other. This procedure creates a package within a package. The nonsequential process uses two sheets wrapped at the same time so that the wrapping needs to be performed only once. This latter method provides multiple layers of protection of surgical instruments from contamination and saves time since wrapping is

done only once. Multiple layers are still common practice due to the rigors of handling within the facility even though the barrier efficacy of a single sheet of wrap has improved over the years[966]. Written and illustrated procedures for preparation of items to be packaged should be readily available and used by personnel when packaging procedures are performed[454].

Loading. All items to be sterilized should be arranged so all surfaces will be directly exposed to the sterilizing agent. Thus, loading procedures must allow for free circulation of steam (or another sterilant) around each item. Historically, it was recommended that muslin fabric packs should not exceed the maximal dimensions, weight, and density of 12 inches wide × 12 inches high × 20 inches long, 12 lbs, and 7.2 lbs per cubic foot, respectively. Due to the variety of textiles and metal/plastic containers on the market, the textile and metal/plastic container manufacturer and the sterilizer manufacturers should be consulted for instructions on pack preparation and density parameters[819].

There are several important basic principles for loading a sterilizer: allow for proper sterilant circulation; perforated trays should be placed so the tray is parallel to the shelf; nonperforated containers should be placed on their edge (e.g., basins); small items should be loosely placed in wire baskets; and peel packs should be placed on edge in perforated or mesh bottom racks or baskets[454, 811, 836].

Storage. Studies in the early 1970s suggested that wrapped surgical trays remained sterile for varying periods depending on the type of material used to wrap the trays. Safe storage times for sterile packs vary with the porosity of the wrapper and storage conditions (e.g., open versus closed cabinets). Heat-sealed, plastic peel-down pouches and wrapped packs sealed in 3-mil (3/1000 inch) polyethylene overwrap have been reported to be sterile for as long as 9 months after sterilization. The 3-mil polyethylene is applied after sterilization to extend the shelf life for infrequently used items[967]. Supplies wrapped in double-thickness muslin comprising four layers, or equivalent, remain sterile for at least 30 days. Any item that has been sterilized should not be used after the expiration date has been exceeded or if the sterilized package is wet, torn, or punctured.

Although some hospitals continue to date every sterilized product and use the time-related shelf-life practice, many hospitals have switched to an event-related shelf-life practice. This latter practice recognizes that the product should remain sterile until some event causes the item to become contaminated (e.g., tear in packaging, packaging becomes wet, seal is broken)[968]. Event-related factors that contribute to the contamination of a product include bioburden (i.e., the amount of contamination in the environment), air movement, traffic, location, humidity, insects, vermin, flooding, storage area space, open/closed shelving, temperature, and the properties of the wrap material[966, 969]. There are data that support the event-related shelf-life practice[970-972]. One study examined the effect of time on the sterile integrity of paper envelopes, peel pouches, and nylon sleeves. The most important finding was the absence of a trend toward an increased rate of contamination over time for any pack when placed in covered storage[971]. Another evaluated the effectiveness of event-related outdating by microbiologically testing sterilized items. During the 2-year study period, all of the items tested were sterile[972]. Thus, contamination of a sterile item is event-related and the probability of contamination increases with increased handling[973].

Following the sterilization process, medical and surgical devices must be handled using aseptic technique in order to prevent contamination. Sterile supplies should be stored far enough from the floor (8 to 10 inches), the ceiling (5 inches unless near a sprinkler head [18 inches from sprinkler head]), and the outside walls (2 inches) to allow for adequate air circulation, ease of cleaning, and compliance with local fire codes (e.g., supplies must be at least 18 inches from sprinkler heads). Medical and surgical supplies should not be stored under sinks or in other locations where they can become wet. Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces. Closed or covered cabinets are ideal but open shelving may be used for storage. Any package that has fallen or been dropped on the floor must be inspected for damage to the packaging and contents (if the items are breakable). If the package is heat-sealed in impervious plastic and the seal is

Name:	Position

Topic Sterilization and Disinfection Orientation

Performance Criteria	Trainer Initials
Cleaning	
1. Performs hand hygiene	
2. Applies appropriate PPE • Puncture resistant, heavy-duty gloves • Face shield • Eye protection • Gown or equivalent	
3. Removes debris (organic or inorganic) from instruments and devices • Wet cloth at point of use • Immerse in approved enzymatic solution	
4. Discard pre-cleaning solution after use	
Disinfection	
5. Perform hand hygiene	
6. Applies appropriate PPE • Puncture resistant, heavy-duty gloves • Face shield • Eye protection • Gown or equivalent	
7. Rinse instruments under cold running water	
8. Drain basket or utilize mechanical device to lift out instruments and devices	
9. Places instruments and devices in container LFMC approved detergent • Leaves hinged instrument in open position • Disassembles instruments with removable parts • Labels basin with product name and date mixed *(secondary label per EHS hazardous communication policy)* • Soaks instruments per manufacturer guidelines	
10. Scrubs all surfaces with scrub brush, pipe cleaners or other cleaning tools *(pay special attention to serrated edges, box locks and other hard to reach areas)* • Scrub while submerged in liquid detergent to prevent aerosolization of BBP • Replace brushes and cleaning tools weekly or as needed • DO NOT use metal brushes • Discards detergent after use	
11. Rinses instruments thoroughly in cool tap water • Allows to air dry completely (towels, etc. will leave lint)	

Performance Criteria	Trainer Initials
Inspection	
12. Checks instruments for the following prior to packaging • Hinged instruments for ease of opening and alignment of jaws and teeth • Sharp or semi-sharp instruments for sharpness • Cracks, chips, sharp edges or worn spots • Malleable instruments for dents and bends	
13. Removes from service ANY instrument with any defect and turns in to appropriate department for repair	
Peel Pack/Pouch	
14. Selects appropriate size package	
15. Places steam indicator in package ensuring it is visible from the outside of the pack/pouch	
16. Ensure all instruments are in the open position or disassembled to their smallest parts	
17. Protects sharp points with gauze or tip protectors	
18. Ensures open end of package is sealed evenly without wrinkles and excessive air *(air acts as a barrier to heat and steam)*	
19. Labels package using waterproof pen • Date of sterilization • Load # • Initials of person preparing package	
Autoclave	
20. Ensures weekly biological monitor result is on file and logged	
21. Describes procedure for biological monitoring referring to package directions	
22. Describes procedure for positive result	
23. Completes autoclave log each time autoclave is operated, monitored or maintenance is performed	
24. Follows manufacturer directions for loading and operation of autoclave	
25. Ensures packs are loaded in a manner that allows for free steam and air circulation	
26. Places all pouches in the same direction	
27. Sets autoclave controls for appropriate type of packaging	
28. NEVER use the “unwrapped” or “flash” cycles	
29. Articulates reasons for instrument recall/reserialization	

30. Makes appropriate notation on log
• Failed biological monitor
• Visible condensation
  ○ Repackages and re-sterilizes single package if only one
  ○ Repackages and re-sterilizes entire load of more than 1 package affected
• Steam indicators have not changed to appropriate color
• Package integrity concerns, compromised storage and handling conditions	

31. Verifies knowledge and performance of routine maintenance per manufacturer recommendations.	
32. Has appropriate autoclave cleaner and maintenance supplies	

Clinical Practice Validation

Topic Sterilization and Disinfection Orientation

Learning Activity / Assessment	Trainer Initials
Test: *Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008*	

I am confident I can apply these competencies to my job. I understand that it is my responsibility to seek guidance or clarify any questions or issues when performing these skills.
Employee Printed Name:
Employee Signature:
Date:
This employee has been evaluated and validated to perform the tasks outlined in this competency.
Trainer Printed Name:
Trainer Signature:
Date: