Sterilization and Disinfection of Patient-care Items in Oral Healthcare Settings

Course Author(s): Michaell A. Huber, DDS
CE Credits: 1 hour
Intended Audience: Dentists, Dental Hygienists, Dental Assistants, Dental Students, Dental Hygiene Students, Dental Assistant Students
Date Course Online: 06/01/2015
Last Revision Date: 11/28/2023
Course Expiration Date: 11/27/2026
Cost: Free
Method: Self-instructional
AGD Subject Code(s): 148

Online Course: *www.dentalcare.com/en-us/ce-courses/ce474*

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Conflict of Interest Disclosure Statement

- Dr. Huber is a member of the dentalcare.com Advisory Board and has no relevant financial relationships to disclose.

Introduction

Participants in this course will be introduced to evidence-based recommendations for the preferred methods of transporting, cleaning, sterilizing or disinfecting patient-care items essential for an effective infection control/exposure control strategy in oral healthcare settings.

Course Contents

Overview

During the course of diagnostic and therapeutic services in oral healthcare settings, instruments and other devices come in contact with the patient's skin, mucous membranes, sterile tissues, and body fluids. Failure to properly sterilize, or minimally disinfect, patient-care items carries the risk of healthcare-associated transmission of infectious diseases. This course presents evidence-based information for the preferred methods of transporting, cleaning, sterilizing and disinfecting patient-care items in oral healthcare settings.

Learning Objectives

Upon completion of this course, the dental professional should be able to:

- Discuss the rational for sterilization and disinfection.
- Discuss and select appropriate methods of sterilization and disinfection.
- Discuss and implement appropriate processing of reusable patient-care items.
- Discuss and implement appropriate quality assurance measures.
- Discuss and implement appropriate procedures in case of sterilization failure.

Introduction

During the course of diagnostic and therapeutic services in oral healthcare settings, patient-care items come in contact with the patient's skin, mucous membranes, sterile tissues, and body fluids. Failure to comply with evidence-based guidelines to properly sterilize or disinfect instruments and other patient-care devices carries the risk of healthcare-associated transmission of pathogenic organisms (e.g., HBV, HCV, HIV, SARS-CoV-2).[1-5]

Sterilization is a validated process that destroys all forms of microbial life (Table 1). The term is intended to convey an absolute meaning, although the probability of the presence of pathogenic and other organisms can never be reduced to zero. ***Disinfection*** defines a process that is less lethal than sterilization, i.e., disinfection destroys some, but not all recognized pathogens and it does not predictably eliminate bacterial spores (Table 1).

In healthcare facilities, sterilization is carried out by physical and chemical methods. In oral healthcare settings, the primary sterilizing methods are steam under pressure and dry heat. For heat-sensitive patient-care instruments and other devices the principal agents used for sterilization or disinfection are germicides, i.e., chemical sterilants and high-level, intermediate-level, and low-level disinfectants (Table 1).

The term ***germicide*** refers to both disinfectants and antiseptics. ***Disinfectants*** are germicides that are applied to inanimate objects such

Table 1. Sterilization vs. levels of disinfection by type of microorganism.[2,3]

Disinfection level	Bacterial spores (e.g., *Bacillus* species)	Mycobacteria (e.g., *M. tuberculosis*)	Nonlipid or small viruses (e.g., polio)	Fungi (e.g., *Aspergillus Candida* species)	Vegetative Bacteria (e.g., *S. aureus*)	Lipid or medium-sized viruses (e.g., HBV, HIV)
Sterilization processes	+	+	+	+	+	+
High-level disinfection	+/-	+	+	+	+	+
Intermediate-level disinfection	-	+	+/-	+	+	+
Low-level disinfection	-	-	+/-	+/-	+	+

as instruments and other devices and environmental surfaces. ***Antiseptics*** are germicides applied to skin and other living tissue (e.g., oral mucosa). Disinfectants are not intended for tissue antisepsis because they are toxic to skin and other tissues and antiseptics are not intended for disinfection of patient-care items.

With prolonged exposure times, ***chemical sterilants*** kill all forms of microbial life, including bacterial spores. At similar concentrations, but with shorter exposure times, the same chemicals are classified as disinfectants. ***High-level disinfectants*** kill all pathogens but not all bacterial spores. ***Intermediate-level disinfectants*** kill mycobacteria, vegetative bacteria, most viruses and fungi, but not bacterial spores. ***Low-level disinfectants*** kill most vegetative bacteria and some viruses and fungi.

Visible soil (e.g., organic matter and salts) on instruments interferes with microbial inactivation during sterilization and disinfection processes. ***Cleaning*** is the removal of visible soil and is typically accomplished using water and a detergent or an enzymatic product to remove contaminants. ***Detergents*** are compounds with both hydophilic and lipophilic parts - the term “soap” is often used to refer to such products.

Practical Approach to Sterilization and Disinfection

A practical approach to sterilization and disinfection was proposed by Earle H. Spaulding nearly 50 years ago. The concept is so clear and logical that with minor refinement, to this day, it serves as the basis for successful sterilization and disinfection strategies. According to Spaulding, patient-care items can be categorized as *critical*, *semi-critical* and *non-critical* predicated on the degree of risk for healthcare-associated transmission of infectious diseases with their use.

Critical Patient-care Items

During the course of their intended use, critical items penetrate soft and hard tissues or the vascular system and confer a high degree of risk for infection if contaminated with pathogens.[2-4] In oral healthcare settings critical items such as surgical instruments, periodontal

scalers, scalpel blades, burs, and explorers present the greatest risk of transmitting infection. Heat-tolerant critical items must be sterilized by a U.S. Food and Drug Administration (FDA)-cleared heat sterilizer.[2,3] Heat-sensitive critical items may be sterilized by a low-temperature sterilization process or by an FDA-registered chemical sterilant.[2,3,6]

Semi-critical Patient-care Items

During the course of their intended use, semi-critical items contact, but do not penetrate nonintact skin or mucous membrane.[2-4] In oral healthcare settings semi-critical items such as mouth mirrors, amalgam condensers, reusable dental impression trays, cheek retractors, dental handpieces, air-water syringes and orthodontic pliers confer a lower risk of infection. Heat-tolerant semi-critical items, including all dental handpieces, must be heat sterilized.[2,3] Heat-sensitive semi-critical items must minimally undergo high-level disinfection with an FDA-registered chemical sterilant used as a high-level disinfectant.[2,3,6]

Non-critical Patient-care Items

During the course of their intended use, non-critical items (also known as clinical contact surfaces) come in contact with intact skin but not mucous membranes.[2-4] 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 oral healthcare settings non-critical items such as radiographic equipment, blood pressure cuffs, facebows, pulse oximeters, examination and curing lights, and computers pose the least risk of transmission of infection.

Because cleaning and disinfection of non-critical items and clinical contact surfaces can be difficult or damaging to their surfaces, disposable barrier protection is the preferred infection control method during their use.[2-4] When non-critical items become visibly soiled, they must be cleaned and disinfected using a U.S. Environmental Protection Agency (EPA)-registered hospital-level disinfectant with tuberculocidal claim.[2-4,7-9] The use of EPA-registered products (Box A), consistent with their labeling, complies with Occupational Safety and Health Administration (OSHA) requirements.[1,7]

Methods of Sterilization and Disinfection

Heat tolerant critical and semi-critical items must be sterilized by steam, unsaturated chemical vapor, or dry heat.[2,3] Heat-sensitive critical items can be sterilized by ethylene oxide, hydrogen peroxide gas plasma; or by immersing them in liquid chemical germicides registered by the FDA as chemical sterilants.[2,3,6] Heat-sensitive semi-critical items minimally must undergo high-level disinfection with a chemical sterilant used as a high-level disinfectant. Non-critical items (clinical contact surfaces), when visibly soiled, must be disinfected with an EPA-registered hospital level intermediate-level disinfectant.[2-4,7-9]

Steam Sterilization

Steam sterilization (autoclaving) is the most dependable and economical process. It is the most widely used method for wrapped and unwrapped critical and semi-critical items that are not heat and/or moisture sensitive. To kill microorganisms, steam sterilization requires exposure of each item to direct steam contact at a specified temperature and pressure for a defined period. There are two basic types of steam sterilizers: gravity displacement and high-speed prevacuum.

Most tabletop sterilizers used in oral healthcare settings are gravity displacement sterilizers. In gravity displacement sterilizers, steam is admitted through steam lines, a steam generator or self-generation of steam within the chamber. Unsaturated air is forced out of the chamber through a vent in the chamber wall. Errors in packaging items or overloading the sterilizer chamber can result in cool air pockets and sterilization failure.

High-speed prevacuum sterilizers are fitted with a pump to create a vacuum in the chamber and to ensure air removal from the sterilizing chamber before the chamber is pressurized with steam. In comparison to gravity displacement, this technology allows for faster and more positive steam penetration throughout the entire load. Prevacuum sterilizers should be tested daily for adequate air removal (see Quality Assurance). Residual air in the chamber can lead to sterilization failure.[2,3]

Box A. Classification of EPA-registered disinfectants.[7]

List A: EPA's Registered Antimicrobial Products as Sterilizers.
List B: EPA Registered Tuberculocide Products Effective Against *Mycobacterium tuberculosis*.
List C: EPA's Registered Antimicrobial Products Effective Against the Human HIV-1 Virus.
List D: EPA's Registered Antimicrobial Products Effective Against Human HIV-1 and Hepatitis B Virus.
List E: EPA's Registered Antimicrobial Products Effective Against *Mycobacterium tuberculosis*, Human HIV-1 and Hepatitis B Virus.
List F: EPA's Registered Antimicrobial Products Effective Against Hepatitis C Virus.
List G: EPA's Registered Antimicrobial Products Effective Against Norovirus.
List H: EPA's Registered Antimicrobial Products Effective Against Methicillin Resistant *Staphylococcus aureus* (MRSA) and Vancomycin Resistant *Enterococcus faecalis* or *faecium* (VRE).
List J: EPA's Registered Antimicrobial Products for Medical Waste Treatment.
List K: EPA's Registered Antimicrobial Products Effective Against Clostridium Difficile Spores.
List L: EPA's Registered Antimicrobial Products That Meet the CDC Criteria for Use Against the Ebola virus.
List M: EPA's Registered Antimicrobial Products with Label Claims for Avian (Bird) Flu Disinfectants.
List N: Disinfectants for Use Against SARS-CoV-2.

Unsaturated Chemical-Vapor Sterilization

Unsaturated chemical-vapor sterilization involves heating a chemical solution, primarily alcohol with 0.23% formaldehyde, in a closed pressurized chamber. This method causes less corrosion of carbon steel instruments (e.g., dental burs) than steam sterilization because less water is present during the cycle. However, instruments must be dry before sterilizing; and federal, state and local authorities must be consulted for hazardous waste disposal requirements of the solution.[2,3]

Dry-heat Sterilization

Dry heat may be used to sterilize patient-care items that might be damaged by moist heat (e.g., burs and certain orthodontic instruments). Although dry heat has the

advantages of low operating cost and being noncorrosive, it is a prolonged process and the high temperatures required are not suitable for the sterilization of many instruments and devices. There are two types of dry-heat sterilizers used in dentistry: static-air and forced-air types.

The static-air type is commonly called an oven-type sterilizer. Heating coils in the bottom or sides of the unit cause hot air to rise inside the chamber through natural convection. The forced-air type is also known as a rapid heat-transfer sterilizer. Heated air is circulated throughout the chamber at a high velocity, which permits more rapid transfer of energy from the air to the instruments, thereby reducing the time needed for sterilization.[2,3]

Low-temperature Sterilization

Low-temperature sterilization with ethylene oxide gas (ETO) is used extensively in larger health-care facilities. Its primary advantage is the ability to sterilize heat- and moisture-sensitive patient-care items with reduced deleterious effects. However, extended sterilization times of 10-48 hours and potential hazards to patients and oral healthcare personnel (OHCP) requiring stringent health and safety precautions make this method impractical for private-practice settings.[2,3]

Chemical Sterilants and Disinfectants

Heat-sensitive critical items must be cleaned and sterilized by immersing them for 3-12 hours in liquid germicides registered by the FDA as chemical sterilants. Heat-sensitive semi-critical items must minimally undergo high-level disinfection, i.e., they must be immersed in an FDA-registered chemical sterilant but for a shorter contact time (≥12 min.). The use of these chemicals is strictly limited for applications indicated in their label instructions.

Non-critical patient-care items (i.e., clinical contact surfaces), when visibly soiled, must be cleaned and disinfected (10-minute contact time for most products) using an EPA-registered intermediate-level disinfectant from List B (i.e., a hospital level disinfectant with tuberculocidal claim) or List E (i.e., a hospital disinfectant with a tuberculocidal and an HIV, HBV claim). The use of these chemicals is strictly limited for applications indicated in their label instructions.[2-8]

Processing Contaminated Reusable Patient-care Items

The recycling of instruments and other devices requires adequate space, specialized equipment, and qualified personnel. Correct transport, cleaning, packaging, sterilizer loading procedures, and sterilization or disinfection methods should be followed to ensure that patient-care items are adequately processed and safe for reuse on patients. OHCP should be provided ongoing training and the recycling processes should be monitored regularly (see Quality Assurance).

There should be a central processing area (CPA) of adequate size with four successive stations for (1) receiving and cleaning; (2) preparation and packaging; (3) sterilization or disinfection; and (4) storage of sterilized units (e.g., individual packs, peel pouches, containers, etc).[2,3] Each station should be physically separated to control traffic flow and to contain contaminants during the process. If physical separation is not practical, spatial separation might be satisfactory.

Transporting

Reusable contaminated patient-care items must be transported from the point of use to the CPA. To prevent exposure of OHCP to blood and other potentially infectious materials (OPIM) through percutaneous injury, contact with nonintact skin, or contact with mucous membranes (i.e., eyes, nose, or mouth), such items should be handled using appropriate personal protective equipment (PPE) and transported in sealed, leak proof containers displaying a biohazard symbol.[2,3]

Receiving and Cleaning

At the first station of the CPA, reusable instruments and other devices are received, sorted, and cleaned. Wearing appropriate PPE (e.g., mask, protective eyewear or face shield, heavy-duty utility gloves, and gown) cleaning should be done with minimal splashing and in a timely fashion. If visible debris (both organic and inorganic contaminants) is not removed,

it will interfere with microbial inactivation and compromise the sterilization and disinfection processes.

Factors to consider in selecting a cleaning method include (1) efficacy of the method, process, and equipment used; (2) compatibility with items to be cleaned; and (3) occupational health and exposure risks. The use of automated equipment (e.g., ultrasonic cleaner or washer/disinfector) is safer and more efficient than manual cleaning. It does not require presoaking or scrubbing of instruments, improves cleaning effectiveness, and decreases exposure to blood and OPIM.

Manual cleaning of instruments is discouraged. If the manual method is used, the instruments must be placed in a leak proof, puncture-resistant container and soaked with a detergent, a disinfectant/detergent, or an enzymatic cleaner to prevent drying of contaminants. To avoid percutaneous injury, when cleaning contaminated instruments and devices manually, OHCP should wear puncture resistant, heavy-duty utility gloves and use a long-handled brush.

In ultrasonic cleaners, waves of acoustic energy are propagated in aqueous solutions. The process disrupts, by cavitation and implosion, the bonds that hold particulate matter to instrument surfaces. Ultrasound alone does not predictably inactivate pathogens and manufacturers of ultrasonic cleaning solutions generally do not make antimicrobial label claims. Ultrasonic and other detergent cleaning solutions can contain microbial contaminants.

Washer-disinfectors are generally computer-controlled units for cleaning, disinfecting, and drying solid and hollow surgical and other medical/dental equipment. They act like dishwashers and use a combination of circulating water and detergents to remove soil. Some of these units also have a cycle that subjects the instruments to a heat process (e.g., 93ºC for 10 min.). Cleaning efficacy is dependent on adequate instrument contact with water/detergent flow in the machine.

Detergents with neutral pH generally provide the best material compatibility profile and good soil removal. Enzymes, usually proteases, sometimes are added to neutralize pH solutions to assist in removing organic material. Proteases in these formulations attack proteins that make up a large portion of common soil (e.g., blood and OPIM). Some cleaning solutions also contain lipases (enzymes that inactivate fat) and amylases (enzymes that inactivate starches).

Enzymatic cleaners are not disinfectants and proteinaceous enzymes can be inactivated by germicides. As with all chemicals, detergents and enzymes must be rinsed from instruments or adverse effects (e.g., fever, asthma and allergic reactions) could result. Cleaning solutions should be used in accordance with manufacturer's instructions, which include proper dilution of the enzymatic detergent and contact with instruments for the amount of time specified on the label.

After the instruments have been washed to remove detergent and enzyme residues, they must be inspected for cleanliness, integrity, and function. At this point, damaged instruments should be replaced and some instruments may have to be lubricated according to manufacturer's instruction. OHCP must never reach into trays or containers holding sharp instruments. A strainer-type basket should be used to hold instruments and forceps to remove items.[2,3]

Preparing and Packaging

At the second station of the CPA, the individual instruments may be placed in self-sealed or heat-sealed plastic and paper pouches; or they may be arranged in rigid or perforated trays/cassettes and wrapped. Complex instruments must be disassembled according to manufacturer's instructions and hinged instruments must be in an open, unlocked position. The packaging material must allow penetration of the sterilization agent to the items being sterilized.

For quality assurance, each instrument unit must have an internal indicator placed on the inside and, if the internal indicator cannot be seen, an external indicator must be applied to the outside (see Quality Assurance). The date and sterilizer number should also be noted

on each instrument unit. The packing material e.g., paper or plastic pouches and wraps must maintain the sterility of instruments during transport and storage.[2,3]

Sterilizing Wrapped Instruments

The third station of the CPA is the setting where the sterilizers and related supplies are located. There should be adequate space for loading and unloading. The area can also house the incubators essential for spore testing (see Quality Assurance) and storage space for sterile instrument units and disposable (single-use) items. Manufacturer and building-code specifications will determine placement and room ventilation requirements.

All instrument units to be sterilized should be placed in the sterilizer so that all surfaces will be directly exposed to the sterilizing agent. Loading must allow for free circulation of steam (or another sterilant) around each unit; perforated trays/cassettes should be placed so they are parallel to the shelf; non-perforated containers should be placed on their edge; peel-packs should be placed on edge and small items should be loosely placed in wire baskets.

The sterilization cycle must be monitored by physical, chemical, and biological indicators (see Quality Assurance). Follow manufacturer's recommendations regarding the physical parameters (e.g., time, temperature, and pressure) of the sterilizer and its compatibility with other indicators. Once the sterilization cycle is complete, allow the packs to cool and dry inside the chamber (Table 2). Hot packs act as wicks; absorbing moisture and bacteria from hands.[2,3]

Sterilizing Unwrapped Instruments

Flash sterilization is a method for sterilizing unwrapped patient-care items for immediate use. The time required depends on the type of sterilizer and the type of instrument (i.e., porous or nonporous) to be sterilized (Table 3). The unwrapped cycle in tabletop sterilizers is preprogrammed by the manufacturer to a specific time and temperature setting and can include a drying phase at the end to produce a dry instrument with much of the heat dissipated.

If the drying phase requirements are unclear, the operation manual or manufacturer of the sterilizer should be consulted. If the unwrapped sterilization cycle in a steam sterilizer does not include a drying phase or has only a minimal drying phase the items retrieved from the sterilizer will be hot and wet making aseptic transport to the point of use more difficult. For dry-heat and chemical-vapor sterilizers, a drying phase is not required.

Unwrapped sterilization method must meet four criteria: (1) the instruments must be thoroughly cleaned and dried prior to the cycle; (2) mechanical indicators must be checked and, at a minimum, a chemical indicator must be placed with the items to be sterilized; (3) care

Table 2. Minimum cycle times for steam sterilization.[3]

Type of sterilizer	Units	Exposure time at 250°F (121°C)	Exposure time at 270°F (132°C)	Drying time
Gravity displacement	Wrapped	30 min.	15 min.	15-30 min.
	Textile packs	30 min.	25 min.	15 min.
High-speed prevacuum	Wrapped instruments	N/A	4 min.	20-30 min.
	Textile packs	N/A	4 min.	5-20 min.

Table 3. Examples of drying time required for flash steam sterilization parameters.[3]

Type of sterilizer	Load type	Temperature	Drying time
Gravity displacement	Nonporous items only (e.g., metal instruments without lumens)	270°F (132°C)	3 min.
	Nonporous and porous items (e.g., rubber or plastic items, items with lumens sterilized together)	270°F (132°C)	10 min.
High-speed prevacuum	Nonporous items only (e.g., metal instruments without lumens)	270°F (132°C)	3 min.
	Nonporous and porous items (e.g., rubber or plastic items, items with lumens sterilized together)	270°F (132°C)	4 min.

should be taken to avoid thermal injury to OHCP or patients; and (4) items must be transported aseptically to the point of use. Unwrapped or flash sterilization of implantable items is not recommended.

Unwrapped sterile instruments and other devices exposed to air can become contaminated with dust, airborne organisms, and other contaminants before use on a patient and should never be stored. Critical items sterilized unwrapped must be transferred from the sterilizer to the point of use by an aseptic method for immediate use. Semi-critical items must be handled in a similar manner and should be used within a short time of sterilization.[2,3]

Sterilizing and High-level Disinfecting with Germicides

Chemical sterilants can cause tissue irritation (e.g., skin, eye, and respiratory tract) and reactive airway disease. To reduce toxicity, special precautions include the use of closed containers to limit vapor release; chemically resistant gloves and aprons, goggles, and face shields; and special ventilation (10 air exchanges per hour). The use of heat-sensitive critical and semi-critical items, when heat-tolerant or disposable alternatives are available, is generally discouraged.

Following sterilization or high-level disinfection, patient-care items must be (1) rinsed with sterile water after immersion to remove toxic or irritating residues; (2) handled using sterile gloves and dried with sterile towels; (3) delivered to the point of use in an aseptic manner; and (4) must be used immediately (the items processed cannot be stored). Finally, the efficacy of the sterilization or high-level disinfection process using germicides cannot be verified.

Federal law requires that label instructions on FDA and EPA-registered products be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use, and disposal). If the user selects exposure conditions that differ from those on an FDA or EPA-registered product's 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).[2,3,6,10]

Storing Sterilized Items

After the sterilization cycle is completed and the instrument units are dry and cool, inspect all packages for proper color change by visible chemical indicators. The units should then be stored in a clean, dry, closed cabinet. Storage practices for wrapped sterilized instruments should be event-related. Event-related practices recognize that packages remain sterile indefinitely, unless an event causes a package to become contaminated (e.g., torn, wet, or open packaging).

Prior to distribution to the point of use, the sterile instrument units should be inspected to verify barrier integrity and dryness. When the packaging is compromised (i.e., torn, wet, or open), the instruments should be re-cleaned, re-packaged in a new wrap, and re-sterilized. The date of sterilization and the sterilizer used, noted on the outside of the packaging material, should facilitate the retrieval of suspected instrument units in the event of a sterilization failure.[2,3]

Quality Assurance

Quality assurance of the sterilization process is predicated on the assessment of three types of indicators: physical, chemical, and biological. In combination, these indicators evaluate both the sterilizing conditions and the procedure's effectiveness. The results of physical, chemical, and biological monitoring must be documented in a sterilization monitoring record. Finally, as part of quality assurance, a maintenance record must also be kept on each sterilizer.

Physical Indicators

Monitoring physical indicators involves observing the gauges or displays on the sterilizer and recording the time, temperature, and pressure associated with each sterilization cycle for each load. Some sterilizers have recording devices that print out these parameters. Correct readings do not guaranty sterilization, but incorrect readings can be the first indication of a problem with the sterilization cycle and suggest the load may not be sterile.[2,3]

Chemical Indicators (Internal and External)

Chemical indicators (Table 4) use sensitive chemicals to assess critical variables (e.g., time, temperature, or steam saturation) during a sterilization cycle. They are applied either to the outside or placed on the inside of each instrument unit (e.g., packs, peel pouches, containers, etc). They do not prove that sterilization has been achieved, but they can provide an early indication of a problem and where in the sterilization process the problem might exist.[2,3]

Biological Indicators

Biological indicators (BIs), or spore tests, assess directly the killing of known highly resistant, nonpathogenic bacterial spores. *Geobacillus stearothermophilus* (*G. stearothermophilus*) spores test steam and unsaturated chemical vapor sterilizers. *Bacillus atrophaeus* (*B. atrophaeus*) spores test dry heat sterilizers. Bacterial spores in the test products are more resistant and are present in greater numbers than common microbial contaminants found on patient-care items.

In oral healthcare facilities, BIs should be processed with a load in all sterilizers at least weekly. However, a BI must be processed in every load containing an implant and the implant should be quarantined until the result of the spore test is known. BIs should be placed in the sterilizer in accordance with the manufacturer's directions. BIs come in three forms: spore strips, self-contained spore vials, and spore ampules.

Spore strips, small strips of thick filter paper covered with spores, are enclosed in glassine pouches. The pouches are placed into packages and processed. After processing, using an aseptic technique, the pouches are opened, and the strips are placed into a tube of sterile culture media for incubation (at a specified temperature for up to 7 days). No growth (a clear tube) indicates the test is negative. Growth (a cloudy tube) indicates the test is positive (i.e., sterilization failure).

Self-contained spore vials include a glass ampule of sterile media surrounded by a plastic vial with a spore strip inside. After processing, the BI is activated by crushing the vial (manually or with a device) to allow the culture media to come in contact with the spore strip. The vials are then incubated at the appropriate temperature for a maximum of 48 hours. Significant failures could be detected in ≤24 hours.

Some self-contained spore vials may include a pH indicator system in the glass ampule of the sterile media. The pH indicator in the growth media changes from purple to yellow with the generation of acid. Some spore vials can also be placed into a special incubator/reader, which delivers rapid results (in one hour). The readers displays a "red light" for positive results or a "green light" for negative results.

Table 4. Classification (non-hierarchical) of chemical indicators.[3]

Class 1: Process indicators.	
✓ Process indicators are applied to the outside of a unit. ✓ It is designed to react to one critical variable, usually temperature.	✓ A color change indicates that the unit has been directly exposed to the sterilization process and helps to distinguish between processed and unprocessed units. Examples: ProChek® ID Indicator Tape ProChek® ID Dry Heat Sticker
Class 2: Indicators for use in specific tests (e.g., air removal).	
✓ An air-removal indicator is positioned over the chamber drain of an otherwise empty sterilizer. ✓ It is designed to assess air removal from the chamber of a high-speed prevacuum sterilizer.	✓ An uneven color change indicates an inefficient air removal stage, an air leak, or non-condensable gases in the steam supply. Example: AirView™ Bowie-Dick Test Pack
Class 3: Single-parameter indicators.	
✓ Single-parameter indicators are placed on the inside of a unit. ✓ It is designed to react to one of the critical variables, either time or temperature.	✓ A color change indicates that the unit has been directly exposed to the chosen variable during the sterilization process. Example: ProChek® ID Paper Strip
Class 4: Multi-parameter indicators.	
✓ A multi-parameter indicator is placed on the inside of a unit. ✓ It is designed to react to two or more of the critical variables, usually time and temperature or time, temperature or steam.	✓ A color change indicates that the unit has been directly exposed to the chosen variables during the sterilization process. Examples: Sure-Check® Strips Sure-Check® Sterilization Pouches
Class 5: Integrating indicators.	
✓ An integrating integrator is placed on the inside of a unit. ✓ It is designed to react to all critical variables and to correlate to biological indicators (BIs).	✓ A color change indicates that the unit has been directly exposed to the chosen variables during the sterilization process. Examples: STEAM*Plus*™ Class 5 Integrator ProChek® S Class 5 Indicator

Glass ampules are available with *G. stearothermophilus* spores for use with steam processes. The ampules contain spores suspended in a culture broth solution. Since the spores and the media are mixed together, no vial crushing or activation is required after processing. A 48-hour incubation period is recommended, but growth usually occurs within 8-12 hours. Spore growth is evidenced by a yellow color change in the media along with visible turbidity at the bottom of the vial.

Biological testing may be accomplished in-office. Following the manufacturer's recommendations, the test BI (e.g., ConFirm® 10 In-Office Biological Monitoring System) is placed in a pack, pouch, tray, or cassette or in the sterilizer with unpackaged instruments. Test BIs from multiple sterilizers must be clearly identified. After processing, the test BI must be incubated (along with a positive control from the same lot but not processed through the sterilizer) within two hours (or refrigerated). Accurate records must be maintained (see Sterilization Monitoring Record).

Biological testing may also be accomplished by an independent entity. Following the manufacturer's recommendations, the test BI (e.g., ConFirm® Mail-in Biological Monitoring) is placed in a pack, pouch, tray, or cassette or in the sterilizer with unpackaged instruments. Test BIs from multiple sterilizers must be clearly identified. After processing, the test BI (along with a control BI from the same lot but not processed through the sterilizer) must be mailed within 24 hours to the testing agency. Documentation of test results must be provided by the testing agency.[2,3]

Sterilization Monitoring Record

Documentation (Box B), in the form of a log, is an absolute requirement of quality assurance. The sterilization monitoring record (SMR), the fourth component of quality assurance, provides evidence the monitoring process is ongoing and that the cycle parameters are being confirmed in a timely manner by all appropriate indicators. The SMR also provides a mechanism for determining if a recall is indicated and, in combination with the date and sterilizer number on each pack, the extent of the recall. Finally, the SMR establishes accountability.[2,3]

Sterilizer Maintenance Record

Manufacturers provide instructions for the operation and care of their products. In general, sterilization equipment must undergo daily and periodic maintenance to ensure accurate, reliable operation (Box C). A maintenance record, the fifth component of quality assurance, must be kept on each sterilizer. It should include the model and serial number, date of servicing, reason for the service (periodic, preventive, or sterilization failure), what was done, and the name or initial of the person performing the service.

Procedures to Follow in the Event of a Positive Spore Test

In case of a positive spore test, the sterilizer should be removed from service. All records of physical and chemical monitoring since the last negative BI test should be reviewed. If the physical (e.g., time, temperature, and pressure) and chemical (i.e., internal or external) indicators demonstrate the sterilizer is functioning correctly, a single positive spore test probably does not indicate sterilizer malfunction, consider the possibility of operator error.

Review cleaning, packaging, loading, and spore testing procedures with all persons who work with the sterilizer. In the absence of mechanical failure of the sterilizer unit, overloading, failure to provide adequate package separation and incorrect or excessive packaging material are all common reasons for a positive BI. Using the same cycle that produced the failure, the spore test should be repeated immediately after correctly loading the sterilizer.

If physical and chemical monitoring indicates adequate processing and the repeat spore test is negative the sterilizer can be put back into service. If packaging, loading, and operating procedures have been confirmed as performed correctly but the repeat BI test is positive, the sterilizer must remain out of

Box B. Essential requirements for documenting sterilization monitoring.

- ✓ Sterilizer identification number
  - In-office monitoring
    - Date a specific test was conducted
      - Daily Bowie-Dick test results (high-speed prevacuum)
      - Exposure time, temperature, and pressure for each load
      - Results of chemical indicators for each load
      - Weekly results of biological indicators (test BI and control BI)
        - Within 48 hours
        - Test BI: e.g., negative or (-)
        - Control BI: e.g., positive or (+)
    - Operator's name or initials
  - Mail-in biological monitoring
    - Reports from the testing agency must be maintained in the dental office and correlated to the in-office monitoring data
- ✓ All documentation of testing shall be maintained for a period of at least three years and shall be made immediately available upon request by appropriate authorities
  - Individual State Dental Board requirements may vary

Box C. Essential requirements for documenting sterilizer maintenance.

- ✓ Daily inspection and cleaning as specified in the manufacturer's instruction manual
  - e.g., cleaning of gaskets, chart pens, chamber drain screens and internal/external surfaces.
- ✓ Periodic preventive maintenance as specified in the manufacturer's instruction manual
  - e.g., periodic lubrication of parts and replacement of expendable parts such as steam traps.
- ✓ Periodic calibration as specified in the manufacturer's instruction manual
  - e.g., calibration of pressure and temperature gauges, timers, recording and control devices
- ✓ All documentation of maintenance shall be maintained for a period of at least three years
  - Individual State Dental Board requirements may vary
- ✓ All documentation of maintenance shall be immediately made available upon request by appropriate authorities
  - e.g., OSHA, State Dental Board

service until it has been inspected, repaired, and re-challenged with BI tests in three consecutive empty-chamber sterilization cycles.

A more conservative approach is to assume that a positive BI test is an indication of sterilizer malfunction. As a consequence, all items from suspect loads dating back to the last negative BI should be re-cleaned, re-wrapped, and re-sterilized.[1,2]

Summary

The ultimate goal of disinfection and sterilization procedures in oral healthcare facilities is to reduce the rate of healthcare-associated infections. Process-related recommendations are based on scientific evidence, theoretical rationale, applicability, and federal and state regulations. When used properly, disinfection and sterilization ensure the safety of critical, semi-critical and non-critical patient-care items.

Course Test Preview

To receive Continuing Education credit for this course, you must complete the online test. Please go to: *www.dentalcare.com/en-us/ce-courses/ce474/test*

1. Which statement is inaccurate with respect to sterilization and levels of disinfection?

A. Sterilization is a validated process that destroys all forms of microbial life.
B. High-level disinfection kills all pathogens but not all bacterial spores.
C. Intermediate-level disinfection kills mycobacteria, viruses, fungi, all vegetative bacteria, but not bacterial spores.
D. Low-level disinfection kills lipid or medium-sized viruses, some fungi, and vegetative bacteria.

2. Which component is not included in the Spaulding's approach to sterilization and disinfection?

A. During the course of their intended use, critical items penetrate soft and hard tissues or the vascular system.
B. During the course of their intended use, semi-critical items contact, but do not penetrate nonintact skin or mucous membranes.
C. During the course of their intended use, non-critical items come in contact with intact skin, but not mucous membranes.
D. During the delivery of care, the most important factor determining the risk of infection from contaminated instruments is the duration of exposure.

3. Which statement inaccurately describes the sterilizing process for heat tolerant patient-care items?

A. Heat-tolerant critical patient-care items must be sterilized by an FDA cleared heat sterilizer.
B. Heat-tolerant semi-critical patient-care items, including all dental handpieces, must be heat sterilized.
C. Heat-tolerant semi-critical items must undergo disinfection with an FDA-registered chemical sterilant used as a high level disinfectant.
D. Heat tolerant critical and semi-critical items must be sterilized by steam, unsaturated chemical vapor, or dry heat.

4. Which technique is incorrect when disinfecting heat sensitive critical or semi-critical, or non-critical patient-care items?

A. Heat-sensitive critical items must undergo intermediate-level disinfection using an FDA-registered chemical sterilant.
B. Non-critical items, when visibly soiled, must be disinfected with an EPA-registered hospital level intermediate-level disinfectant.
C. Heat-sensitive critical items can be sterilized by ethylene oxide or by immersing them in liquid chemical germicides registered by the FDA as chemical sterilants.
D. Unless visibly soiled, disposable barrier protection is the preferred infection control method for non-critical items.

5. Which statement incorrectly describes the use of steam sterilizers?

A. Steam sterilization is the most widely used method for critical and semi-critical items that are heat and moisture tolerant.
B. Steam sterilization requires exposure to direct steam contact at a specified temperature and pressure for a defined period of time.
C. Gravity displacement steam sterilizers should be tested daily for adequate air removal.
D. The majority of tabletop sterilizers used in oral healthcare settings are gravity displacement sterilizers.

6. Which is not a characteristic of unsaturated chemical-vapor sterilization?

A. Unsaturated chemical-vapor sterilization involves heating a chemical solution in a closed pressurized chamber.
B. The advantage of using unsaturated chemical-vapor sterilization is that the instruments do not have to be dry before sterilization.
C. When using an unsaturated chemical-vapor sterilizer federal, state and local authorities must be consulted for hazardous waste disposal requirements.
D. Unsaturated chemical-vapor sterilization causes less corrosion of carbon steel instruments than steam sterilization.

7. Which is an inaccurate description of the characteristics of dry heat sterilization?

A. Dry heat may be used to sterilize patient-care items that might be damaged by moist heat.
B. Dry heat has the advantages of low operating cost and being noncorrosive.
C. The high temperatures required for this prolonged sterilization process are not suitable for many instruments and devices.
D. The static-air type has the advantage a shorter sterilization cycle time compared to the forced-air type.

8. Which procedure is inaccurate when using chemical sterilants and disinfectants?

A. Heat-sensitive critical items must be cleaned and sterilized by immersing them for 3-12 hours in liquid germicides registered by the FDA as chemical sterilants.
B. Heat-sensitive semi-critical items must minimally undergo high-level disinfection by immersing in an FDA-registered chemical sterilant for 10-12 minutes.
C. Non-critical patient-care items, when visibly soiled, must be cleaned using an EPA-registered intermediate-level disinfectant with tuberculocidal claim.
D. Environmental surfaces in the dental office, when soiled with blood, must be cleaned using an EPA-registered intermediate-level disinfectant.

9. Which is not involved with the processing of contaminated reusable patient-care items?

A. There should be a central processing area (CPA) of adequate size with four successive stations for cleaning, packaging, sterilization and storage.
B. Within the CPA, each station should be physically separated to control traffic flow and to contain contaminants during the process.
C. If physical separation between stations is not practical, barriers must be installed to isolate the stations.
D. Reusable contaminated patient-care items must be transported from the point of use to the CPA in sealed, leak proof containers displaying a biohazard symbol.

10. Which cleaning approach for reusable instruments and other devices is inaccurate?

A. If visible organic and inorganic debris is not removed, it will interfere with microbial inactivation and compromise the sterilization and disinfection processes.
B. Factors to consider in selecting a cleaning method include efficacy, compatibility and occupational health and exposure risks.
C. Manual cleaning of instruments is preferred over the use of automated equipment (e.g., ultrasonic cleaner or washer/disinfector) because it is more efficient.
D. During manual cleaning, the instruments must be placed in a leak proof, puncture-resistant container and soaked with a detergent, a disinfectant/detergent, or an enzymatic cleaner.

11. Which is not a characteristic of detergents and enzymatic cleaners for reusable instruments?

A. Detergents with an acidic pH generally provide the best material compatibility profile and good soil removal.
B. Enzymes, usually proteases, sometimes are added to neutralize pH solutions to assist in removing organic material.
C. Some cleaning solutions also contain lipases (enzymes that inactivate fat) and amylases (enzymes that inactivate starches).
D. After cleaning, detergent and enzyme residues must be removed by washing the instruments.

12. Which is not recommended when preparing and packaging instruments?

A. Individual instruments should be placed in self-sealed or heat-sealed plastic and paper pouches or arranged in rigid or perforated trays/cassettes and wrapped.
B. Hinged instruments placed in various packs must be in a closed, locked position.
C. Each instrument unit must have an internal indicator placed on the inside and, if the internal indicator cannot be seen, an external indicator must be applied to the outside.
D. The packing material must maintain the sterility of instruments during transport and storage.

13. Which approach should be avoided when loading and uploading wrapped instruments for sterilization?

A. Perforated trays/cassettes should be placed so that they are parallel to the shelf.
B. Non-perforated containers should be placed on their edge.
C. Peel-packs should be placed on edge and small items should be loosely placed in wire baskets.
D. Once the sterilization cycle is complete, remove the packs to cool and dry outside the chamber.

14. Which is incorrect with respect to sterilizing and storing unwrapped instruments?

A. Unwrapped instruments must be thoroughly cleaned and dried prior to sterilization.
B. When sterilizing unwrapped instruments mechanical indicators must be checked, but there is no requirement to place a chemical indicator with the items.
C. Critical items sterilized unwrapped must be transferred from the sterilizer to the point of use by an aseptic method for immediate use.
D. Unwrapped sterile instruments can become contaminated with dust, airborne organisms, and other contaminants and should never be stored.

15. Which statement inaccurately describes sterilizing and high-level disinfecting with germicides?

A. Patient-care items must be rinsed with sterile water after immersion to remove toxic or irritating residues.
B. Patient-care items must be handled using sterile gloves, dried with sterile towels, and delivered to the point of use in an aseptic manner for immediate use.
C. The efficacy of the sterilization or high-level disinfection process using germicides is readily verifiable.
D. Federal law requires that label instructions on FDA and EPA-registered products be followed.

16. Which is an inaccurate statement regarding the storage of sterilized items?

A. After the sterilization cycle is completed and the instrument units are dry and cool, inspect all packages for proper color change by visible chemical indicators.
B. Instruments units should be stored in a clean, dry, closed cabinet.
C. Storage practices for wrapped sterilized instruments are time-related, i.e., wrapped instruments maintain their sterility for a specified time.
D. When the packaging is compromised (i.e., torn, wet, or open), the instruments should be re-cleaned, re-packaged in a new wrap, and re-sterilized.

17. Which statement does not accurately describe the quality assurance indicators of the sterilization process?

A. Monitoring physical indicators involves observing the gauges or displays on the sterilizer and recording the time, temperature, and pressure associated with each sterilization cycle for each load.
B. Chemical indicators use sensitive chemicals to assess critical variables (i.e., time, temperature, steam saturation) during a sterilization cycle and validate that sterilization has been achieved.
C. Biological indicators (BIs), or spore tests, assess directly the killing of known highly resistant, nonpathogenic bacterial spores.
D. The results of physical, chemical and biological monitoring must be documented in a sterilization monitoring record.

18. Which biological monitoring of the sterilization process is not recommended?

A. In oral healthcare facilities, BIs should be processed with a load in all sterilizers at least weekly.
B. A BI must be processed in every load containing an implant and the implant should be quarantined until the result of the spore test is known.
C. When biological testing is done in-office, the test BI must be incubated within two hours or refrigerated.
D. Bacillus atrophaeus are the types of spores that should be used to test steam sterilizers.

19. Which statement inaccurately describes the sterilization monitoring record (SMR)?

A. Documentation, in the form of a log, is an absolute requirement of quality assurance.
B. Mail-in biological monitoring reports are maintained by the testing agency and there is no requirement for separate recordkeeping in the dental office.
C. The SMR provides a mechanism for determining if a recall is indicated and, in combination with the date and sterilizer number on each pack, the extent of the recall.
D. The sterilization monitoring record and the sterilizer maintenance record shall be maintained for a specified period of time (state dental board requirements may vary).

20. Which procedure would be unnecessary in the event of a positive spore test?

A. In case of a positive spore test, the sterilizer should be removed from service and all records of physical and chemical monitoring since the last negative BI test should be reviewed.
B. If the physical and chemical indicators reveal the sterilizer is functioning correctly consider possible operator error, and using the same cycle that produced the failure, repeat the spore test immediately after correctly loading the sterilizer.
C. If packaging, loading, and operating procedures have been confirmed as performed correctly and the repeat BI test is negative, the sterilizer must remain out of service until it has been inspected, repaired, and re-tested with a confirmatory BI test.
D. All items sterilized from suspect loads dating back to the last negative BI test should be re-cleaned, wrapped, and re-sterilized.

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Additional Resources

- No Additional Resources Available.

About the Authors

Michaell A. Huber, DDS
Professor
Department of Comprehensive Dentistry
The University of Texas Health Science Center at San Antonio, School of Dentistry, San Antonio, Texas

Dr. Michaell A. Huber is an Adjunct Professor of Oral Medicine, Department of Comprehensive Dentistry, the UT Health School of Dentistry. He received his DDS from the UTHSCSA in 1980 and a Certificate in Oral Medicine from the National Naval Dental Center, Bethesda, Maryland in 1988. He is certified by the American Board of Oral Medicine. Dr. Huber served as Graduate Program Director in Oral Medicine at the National Naval Dental Center, Bethesda, Maryland. In addition he served as Specialty Leader for Oral Medicine to the Surgeon General of the United States Navy, Washington, DC; and Force Dental Officer, Naval Air Force Atlantic, Norfolk, Virginia.

Since joining the faculty in 2002, Dr. Huber has been teaching both pre-doctoral and graduate dental students at the UT Health School of Dentistry. In 2019 he was awarded the UT System Regents Outstanding Teaching Award. He is a Past President of the American Academy of Oral Medicine and is a member of the *dentalcare.com* Advisory Board. Dr. Huber has spoken before many local, state, and national professional organizations. He has published over 90 journal articles, book chapters, and online postings.

Phone: (210) 567-3360
Fax: (210) 567-3334

Email: huberm@uthscsa.edu