CLEANING, DISINFECTION, AND STERILIZATION PROCEDURES

Steam sterilizers, or autoclaves, are the most economical sterilization process.

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The golden rule in infection control is "keep it clean." "It" refers to any exposed surface, from a technician's hand to a thermometer to an examination table. Following the correct guidelines to remove visible dirt and invisible microorganisms is the most important step in preventing transmission of pathogens.[a] *Knowing the correct level of disinfection for patient care equipment helps protect not only patients but also the veterinary staff.*

SURFACE PREPARATION

Before a piece of equipment can be used on a patient, its surface must be cleaned. There are three levels of surface cleaning.

- **Basic cleaning** is the removal of all foreign material (e.g., grease, oil, dust, soil, organic debris) and many microorganisms from the surface of tables, floors, monitoring equipment, thermometers, and surgical equipment through the use of soap or a general detergent and water.
- **Disinfection** is the process that eliminates most pathogenic organisms (e.g., bacteria, mycobacteria, fungi) from inanimate objects. Disinfectants are chemical compounds that are generally diluted with water and applied according to the manufacturer's directions. Most disinfectants do not eliminate bacterial spores and are not effective on surfaces that have not been cleaned of organic material.
- **Sterilization** is a process that kills all forms of microbial life on inanimate objects and requires special equipment. It is not effective on objects contaminated with organic material.

CLASSIFICATION OF PATIENT USE ITEMS

Before an item is put into use, the appropriate level of disinfection should be established for it. Referring to the Spaulding classification[b] helps in determining "the appropriate level of processing for preparing instruments and other patient care items based on the risk of infection."[1]

According to this system, items are classified as follows:

- **Critical items** are those that enter sterile tissue or the vascular system. Examples are surgical instruments, implants, needles, cardiac and urinary catheters, and cutting endoscopic accessories that break the mucosal barrier and the endoscopes through which they are used. These items need to be sterilized.
- **Semicritical items** come in contact with nonintact skin or mucous membranes. Examples are anesthesia equipment, bronchoscopes, and gastrointestinal scopes. These items should receive a minimum of high-level disinfection immediately (or up to 15 minutes) before use.
- **Noncritical items** come in contact with intact skin only. Examples are pressure cuffs, cages, linens, and carts. These items should receive intermediate- or low-level disinfection.

CLEANING

Good cleaning practice is essential. Cleaning with soap or detergent and water removes organic material (e.g., blood, urine, feces) that can protect microorganisms by providing a physical barrier that prevents contact with a disinfectant. A detergent that is compatible with the surface being cleaned

[a]For more information about infection control, see "Principles of Infection Control" on page 136 of the March 2006 issue.

[b]The Spaulding classification system was developed by Earle H. Spaulding, PhD, and helps health care professionals determine the level of disinfection needed for particular items based on how the items are used.

should be chosen. A commercially prepared combination of anionic/nonionic detergents is the best choice. These detergents have good emulsifiers and good penetration, do not bind to metallic ions that are generally found in hard water, and have reduced foaming properties. They are usually alkaline, with a pH greater than 7. When cleaning any surface, pay special attention to the inside of corners, cracks, and joints, which can collect dirt and microorganisms. Specific cleaning of surgical instruments is discussed later.

DISINFECTION

Disinfectants are chosen depending on the level of disinfection needed: high, intermediate, or low.

- **High-level disinfection** kills all vegetative microorganisms (e.g., bacteria, mycobacteria, fungi, viruses) and some bacterial spores. It is also tuberculocidal.
- **Intermediate-level disinfection** kills most viruses, most fungi, and all vegetative pathogenic bacteria but does not kill spores.
- **Low-level disinfection** kills some vegetative bacteria, some fungi, and lipid viruses. It is ineffective against spores and nonlipid viruses and is not tuberculocidal.

Common Disinfectants

There are many disinfectants on the market, each with advantages and disadvantages. They are categorized as alcohols, aldehydes, biguanides, halogens (hypochlorites and iodine compounds), oxidizing agents, phenols, and quaternary ammonium compounds based on their chemical characteristics. Some disinfectants can be used for different levels of disinfection or even for sterilization, depending on their exposure time or concentration. For example, exposing an item to 2.5% glutaraldehyde for 45 minutes at 77˚F (25˚C) results in high-level disinfection; exposure for 10 hours at 77˚F (25˚C) results in sterilization.

Considerations in Choosing a Disinfectant

- How long does it take to achieve the desired level of disinfection? Some compounds can achieve high-level disinfection in only 10 minutes but need 10 hours to sterilize.
- How will the disinfectant react with equipment surfaces? Some are corrosive to certain materials, some will stain, and some will leave a residue.
- How toxic is the disinfectant, and will it harm the patient or staff if they are exposed to it?
- How stable is the disinfectant in its concentrated and diluted forms?
- Is the disinfectant inactivated by organic material?
- Does water hardness affect the efficacy of the disinfectant?
- Does soap or detergent affect the efficacy of the disinfectant?

Rules of Chemical Disinfection

- All items must be thoroughly cleaned first to remove any organic material.
- Only surfaces in direct contact with the solution are disinfected.
- Items should be dry before being submerged in solution to avoid diluting the solution.
- Disinfectants are designed for inanimate objects and are damaging to the skin; therefore, gloves should be worn when using these products.
- Items should be allowed to air dry after the disinfection process.

The following are some examples of types of disinfectants[2]:

- **High-level disinfectants:** Aldehydes (e.g., glutaraldehyde, ortho-phthalaldehyde)
- **Intermediate-level disinfectants:** Sodium hypochlorite and isopropyl alcohol
- **Low-level disinfectants:** Quaternary ammonium compounds, hydrogen peroxide, and sometimes phenols

For any disinfectant to be effective, it must be used according to the manufacturer's recommendations for concentration, temperature, and contact time. Concentration and contact time are critical to achieving the desired outcome. Most disinfectants should be diluted only with water. Always check the label for appropriate dilution/mixing instructions. Disinfectants work best when they are diluted just before use. It is not safe to assume that a disinfectant has an indefinite shelf life once it has been diluted. Check with the manufacturer for specific product information. Once a disinfectant is diluted, it is ready to use. Disinfectants can be sprayed or wiped onto a surface or used for mopping floors.

STERILIZATION

Preparation

Before an item is sterilized, it must be cleaned in order to remove any organic material. This is necessary not only to ensure effective sterilization but also to reduce the bioburden. *Bioburden* is the microbiologic load in or on an object that may be capable of producing an infection. Cleaning should take place promptly after an item is used. If organic material is left to dry, it will be much more difficult to remove. To enhance the longevity of surgical equipment, instruments, and rigid scopes or endoscopes, follow the manufacturer's recommendations for cleaning and sterilization.

Packing

Surgical packs must be assembled and wrapped in a material that allows

Steps for Preparing an Instrument for Sterilization

- **Soak the instrument in an enzymatic cleaner** after use. This starts the process of loosening and removing the organic material.
- **Disassemble the instrument**, if necessary. The more complex the instrument, the more difficult it is to clean and reduce the bioburden. Therefore, complex equipment should be disassembled for cleaning.
- **Manually remove visible organic material.** Clean lumens with brushes and scrub serrations, teeth, jaws, and hinges.
- **Place the instrument in an ultrasonic cleaner** (if available).
- Thoroughly **rinse the instrument** and **flush lumens** with water.
- **Reassemble the instrument**, if necessary, and inspect it.
- **Allow the instrument to dry** thoroughly.

contact between the sterilant and the item(s) and provides a barrier to microorganisms. Cloth or nonwoven wrap is used to wrap trays, gowns, and surgical linens. Peel pouches for instruments come in a variety of sizes and paper/plastic combinations. The size of the pouch used should be appropriate for that particular item. Peel pouches are not made for heavy or bulky items; therefore, these items should be wrapped in cloth or nonwoven wrap.

When a surgical pack is assembled, its presentation and use should be considered. The contents of the pack should be presented in a sterile fashion. For example, items should be placed in peel pouches so that the grasping end (the handle or ring) is presented first when the package is opened. The envelope fold is the most commonly used method of wrapping a tray for sterile presentation.

All surgical packs and pouches should be labeled with their contents and date of sterilization. However, sterility is event related, not time related. Contamination does not occur on the last day of the label. Items that are packaged appropriately, handled minimally, rotated to ensure that the oldest sterile product is used first, and stored in an environment that is clean and free of moisture and excess heat or cold (preferably in a closed cabinet at 60˚F to 75˚F [15˚C to 24˚C]), are considered sterile unless the packaging is compromised. Events that compromise sterility are excessive handling leading to seal breakage; punctures, tears, or other loss of package integrity; moisture penetration; and mishandling or dropping the package or tray.

Choosing a Sterilization Process

The ability of an instrument or piece of equipment to withstand heat is the major determining factor in the choice of a sterilization process. Some common sterilization processors are steam sterilizers (autoclaves), ethylene oxide (EO) sterilizers, gas plasma sterilizers, and peracetic acid processors.

Steam Sterilizers

Steam sterilization is the most common and economical sterilization process. Most steam sterilizers are classified as gravity displacement sterilizers. In this type of sterilizer, steam enters the top of the sterilization chamber and, as the pressure increases, pushes the air to the bottom of the chamber into a drain line. A sensor in the drain monitors the temperature in the chamber. When the steam reaches a set temperature, the sterilization cycle begins.[3] During this cycle, the contents of the packages are subjected to steam under pressure for a specified period. When the sterilization cycle is complete, the steam shuts off, the drain opens, and the steam exits through the drain.

An accepted standard cycle for sterilization of wrapped items in a gravity sterilizer is 15 to 20 minutes of sterili-

Rules of Sterilization

- The sterilizer must be properly designed and used at the correct temperature and sterilant concentration.[a]
- The bioburden of the items to be sterilized must be low.
- All surfaces must be in contact with the sterilant for an adequate amount of time.[a]

[a]American Society for Healthcare Central Service Professionals: *Training Manual for Central Service Technicians*, ed 3. Chicago, American Hospital Association, 1997.

zation time at 270˚F to 274˚F (132˚C to 134˚C) under 30 to 32 psi, with a drying time of 30 minutes. A lower-temperature sterilization cycle is 30 minutes of sterilization time at 250˚F (121˚C) under 18 to 20 psi, with a drying time of 45 minutes. "Flash" sterilization is used only in emergency situations. The item is placed, unwrapped, in a perforated metal tray in a gravity displacement sterilizer. The typical flash cycle is 270˚F to 275˚F (132˚C to 135˚C) for 3 minutes (for a single item without a lumen) to 10 minutes (for individual items with lumens or for nitrogen gas–driven or specialized battery-driven power equipment), with a 1-minute drying time. When removed from the sterilizer, the tray will be very hot and may contain some residual moisture. Transporting the tray aseptically to the sterile field is difficult because it collects dust and microorganisms on the way. Implants should never be flash sterilized because all cycle parameters cannot be verified.

Dynamic air removal sterilizers use a vacuum system to pull the air from the chamber. This shortens the cycle time from that of a gravity sterilizer. It is critical to test the performance of the vacuum system. For this, a Bowie-Dick test is routinely conducted. The Bowie-Dick test is named after its inventors, who found that if the vacuum system did not remove all the air from the sterilization chamber and there was only one package present, an air bubble would form in the center of the package. The Bowie-Dick test indicates how efficiently the vacuum system is working and detects the presence of air leaks in the sterilizer. However, it does not determine whether sterilization parameters have been met. To run the test, a handmade or commercially prepared Bowie-Dick test pack is placed horizontally on the bottom of an empty sterilizer cart, near the door and over the drain. This pack contains a piece of paper imprinted with heat-sensitive ink. A special cycle is run, with an exposure time of more than 3 minutes but less than 4 minutes, a temperature no greater than 273˚F (134˚C), and no drying time. The pack is then removed from the sterilizer and opened. If the entire sheet of test paper has changed uniformly in color, the sterilizer is working satisfactorily. If air remains trapped in the pack, the center of the test sheet will not be as dark as the rest of the test paper. This is an unsatisfactory result. If the area around the outer edge of the paper is lighter than the rest of the pattern, there may be a problem with the gasket around the sterilizer door.

Improper loading and incorrect preparation of packs can affect the ability of a steam sterilizer to remove air from the chamber and the ability of the steam to penetrate the load. Following the manufacturer's recommendations on pack density and load placement is critical to achieving sterilization. For each sterilizer, follow the manufacturer's recommendations for each cycle.

Ethylene Oxide Sterilizers

EO sterilizers are used for temperature-sensitive devices. EO readily penetrates packaging materials and diffuses rapidly to come into surface contact with all items in the load. The same type of packaging used for steam can be used for EO. EO is classified as a known carcinogen, is extremely flammable in its pure form, and requires hours to sterilize and aerate items. EO sterilizers are expensive to maintain. The cycle time depends on the humidity, temperature, density, and type of material being sterilized. A typical cycle is 120˚F to 140˚F (49˚C to 60˚C) at 20% to 40% humidity for 2.5 hours of sterilization time, with 12 to 18 hours of aeration time. A typical product used in EO sterilizers contains 10% EO and 90% carrier gas (e.g., chlorodifluoromethane, chlorotetrafluoroethane). Some EO sterilizers use smaller amounts of 100% EO and require less aeration time.

Gas Plasma Sterilizers

Gas plasma sterilizers are also used for temperature-sensitive devices. In these sterilizers, a precursor gas or vapor of hydrogen peroxide enters the sterilization chamber under low vacuum. This gas is exposed to an electromagnetic field (microwave or radio frequency) that generates electrons and free radicals that have biocidal properties. When the electromagnetic field and precursor gas stop, a vacuum removes any residual gas in the chamber and filtered air is introduced. The precursor gas breaks down into water, oxygen, hydrogen, and argon. A typical cycle is 105˚F to 135˚F (40˚C to 57˚C) for a total time of only 75 minutes. All items must be wrapped in special cellulose-based materials (Tyvek-Mylar pouches or polypropylene fabric). There are limits to the length and lumen diameter of items that can be sterilized using gas plasma.

Peracetic Acid Systems

Peracetic acid processors are used for temperature-sensitive devices that can be exposed to peracetic acid. The sterilant comes in a powder concentrate that is automatically diluted with sterile water in the processor. The items are exposed to the sterilant for 12 minutes and then are given four sterile water rinses. The total cycle time is about 30 minutes. Because

rigid and flexible endoscopes can be safely immersed and have a variety of trays and adapters, this is the preferred method of sterilization for these items. Proper leak testing, cleaning, and drying of the device are critical to obtaining sterilization. The sterilant must come into contact with all surfaces of the device for it to be rendered sterile.

Monitoring the Sterilization Process

Regardless of the sterilization process used, sterilizers must be regularly tested to ensure that all the parameters of sterilization (e.g., adequate temperature) are being met. There are three types of monitors and tests: mechanical, chemical, and biologic. Together, these monitors and tests provide assurance that each item processed is actually sterile.

Mechanical or electronic controls measure the duration of exposure to the sterilant and are often built into the sterilizer itself. An example is the gauge or recorder on a steam sterilizer that verifies that the correct time, temperature, and pressure were achieved at the monitoring site (usually in the drain), not inside a package.

Chemical indicators react to one or more parameters of sterilization. Not all indicators show whether all the conditions for sterilization (i.e., time, temperature, and sterilant contact) were met. Typically, indicators are placed in the center of a pack or in a difficult area for the sterilant to reach. There are five classes of indicators[4]:

- **Class 1 — Process indicators** (e.g., autoclave tape used on the outside of a package). These indicators determine whether an item has been processed. Autoclave tape changes color when the tape is exposed to heat. It is used as an external indicator to differentiate between processed and unprocessed items; however, it does not indicate whether the contents are sterile.
- **Class 2 — Bowie-Dick indicators.**
- **Class 3 — Temperature-specific indicators.** These indicators are placed inside packs and reveal whether the center of the pack has achieved a specific temperature but not whether the items in the pack are sterile.
- **Class 4 — Multiparameter indicators.** These indicators respond to all the necessary parameters of sterilization by changing color or showing change along a wick, indicating a passed or failed test. They are also placed inside packs.
- **Class 5 — Process integrators.** These indicators are placed in the center of the packs and react to all parameters of sterilization over a specified range of sterilization cycles, verifying that all conditions for sterilization have been met and that the items in the packs are sterile.

Biologic indicators (BIs) are used to challenge the sterilization cycle. They provide the highest level of sterility assurance because they test the sterilizer's ability to kill highly resistant strains of organisms. A BI is a device that has been impregnated with a known number of specific spores that far exceed the number and resistance of microorganisms expected to be present on any item normally sterilized. The most easily used BIs are self-contained ampules. The bacteria commonly used in this type of indicator are *Geobacillus stearothermophilus* (for steam sterilizers, gas plasma sterilizers, and peracetic acid processors) and *Bacillus atrophaeus* (for EO sterilizers). BIs are placed inside a "standard" test pack made in-house or in a commercially available pack. The test pack can be part of a regular sterilization load. To test a gas plasma sterilizer, the BI is placed inside a Tyvek peel pouch. For a peracetic acid processor, the BI consists of a strip impregnated with *G. stearothermophilus* spores that is placed in a culture medium after it has been processed in a load or by itself in the processor.

The BI test pack is placed in the most difficult portion of the sterilizer to sterilize. In a steam sterilizer, the area directly above the drain is the weak spot; in an EO sterilizer, it is the center of the load. When testing a gas plasma sterilizer, the test pack is placed

on the back bottom shelf of the chamber with the Tyvek side facing up.

After the pack has undergone a typical sterilization cycle, the self-contained BI is activated by crushing the ampule, thereby releasing the spores into a dye-containing growth medium that is then incubated for 24 to 48 hours or up to 7 days, depending on the test organism. If a spore strip was used, it is placed in a separate tube of culture medium for incubation. The incubation temperature should be 133˚F (56˚C) for BIs used in steam sterilizers, gas plasma sterilizers, and peracetic acid processors and 99˚F (37˚C) for those used in EO sterilizers. If the spores were killed during the sterilization process, the growth medium will not change color. If viable spores are present, they will change the color of the medium. The recommendations of the Association for the Advancement of Medical Instrumentation are to test steam sterilizers with a BI once a week or when sterilizing any load that contains implants and to test EO sterilizers every cycle. The manufacturer recommends testing gas plasma and peracetic acid processors daily.[5] If the results of the BI are positive for viable spores, the sterilizer may be in need of servicing by the manufacturer. If the BI was part of a regular sterilization load, the items in the load will not be sterile and should not be used until they are resterilized. Routine maintenance, preventive maintenance, and scheduled maintenance and calibration of each sterilizer should be performed according to the manufacturer's manual.

CONCLUSION

Cleaning, disinfection, and sterilization are critical parts of veterinary practice. All procedures, from cleaning and disinfecting cages to monitoring the sterilization cycle, should have written protocols, and when an item is cleaned, what was done and how it was done should be documented. This helps all staff members to accomplish tasks in a uniform manner and to be responsible for maintaining the highest level of performance.

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