The care and maintenance of surgical instruments and equipment is generally one of the many job duties of veterinary technicians. Media reports about antibiotic-resistant infections that abound in human medicine should serve as a way to raise awareness about healthcare-associated (nosocomial) infections (HAIs) in veterinary medicine. Iatrogenic surgical site infections can prolong recovery, increase patient morbidity and mortality, and lead to unnecessary costs for clients. Today’s veterinary technicians are uniquely poised to make a difference in the lives of animal patients, in part by ensuring that proper protocols and procedures are in place to help prevent perioperative infections.

Any successful infection control program must consist of a multipronged approach, which may incorporate issues such as perioperative antibiotic use, choice of antiseptics and disinfectants, atraumatic hair removal during surgical patient preparation clipping, best practices for prepping and draping, and proper housekeeping methods in addition to sterile processing.

**DISINFECTION VERSUS STERILIZATION**

What is the difference between disinfection and sterilization?

Sterilization is defined as the destruction of all microbial life, whereas disinfection involves the use of a chemical sterilant/agent to eliminate virtually all recognized pathogenic microorganisms, but not necessarily all types of microorganisms (e.g., bacterial endospores) present on inanimate objects.

There are three levels of disinfection: high, intermediate, and low. The high-level disinfection (HLD) process kills all vegetative microorganisms, mycobacteria, lipid and nonlipid viruses, fungal spores, and some bacterial spores. Intermediate-level disinfection kills mycobacteria, most viruses and bacteria, and is registered by the Environmental Protection Agency (EPA) as a “tuberculocide.” Low-level disinfection kills some viruses and bacteria.

Almost 40 years ago, Dr. E. H. Spaulding established a categorization system for medical devices based on the risk of infection associated with their use. This classification system has been embraced by the US Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) and is used by many professional medical organizations to choose disinfection or sterilization protocols for various medical devices. Medical devices are assigned to one of three categories:

1. Sterile
2. Sterilized
3. Disinfected
Veterinary technicians play a key role in ensuring that medical devices are clean and functional before HLD and sterilization, and much can be learned from the mistakes made in human medicine.

→ Critical: A device that enters normally sterile tissue or the vascular system where blood flows. These devices (e.g., surgical instruments, needles, intravenous catheters) should undergo sterilization.
→ Semicritical: A device that comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissues (e.g., laryngoscopes, thermometers, flexible endoscopes). These devices should receive, minimally, HLD.
→ Noncritical: A device that ordinarily does not come into contact with the patient or touches only intact skin (e.g., bedpans, blood pressure cuffs, stethoscopes). These devices should be cleaned by low-level disinfection.

GOALS OF STERILE PROCESSING
Adequate sterile processing depends on the performance of people, processes, and equipment to achieve the highest level of sterility assurance. Therefore, the goals for individuals participating in a sterile processing program include:
→ Ensuring that every item in each load is sterile
→ Minimizing the risk of HAIs
→ Meeting regulatory requirements by emulating human sterility practices and standards
→ Maintaining personal integrity
→ Undergoing periodic training, education, and process review
→ Ensuring quality outcomes

In short, assuming that all steps throughout the sterilization process are working simply because they are being performed correctly is just not good enough.

Inconsistent processes and/or equipment malfunction can jeopardize the goals of sterile processing. Susan Flynn, BESc, CSPDT (Central Sterile Processing and Distribution Technician), explains that human error accounts for approximately 85% of processing-related issues, much more so than utility (e.g., poor steam quality) and equipment problems. Therefore, each facility should strive to ensure quality outcomes by implementing an evolving plan that continually improves while eliminating or minimizing waste.

QUALITY OUTCOMES MATTER!
Why care? According to USA Today, at least 100 endoscope-related infections have been reported in human patients in several major US cities, some of which were fatal. According to a US Senate report, major duodenoscope maker Olympus and the FDA failed to alert the US public that hundreds of patients were becoming infected with a so-called “superbug”—a drug-resistant bacterial strain (carbapenem-resistant Enterobacteriaceae) associated with a roughly 50% mortality rate—because of lapses in basic cleaning, disinfection, and sterilization of medical devices. On September 11, 2015, the CDC alerted healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices, citing noncompliance as a critical gap in patient safety. In other words, cleaning procedures conducted against the manufacturers’ instructions for use (IFU) resulted in a lapse in infection control.

Shortly afterward, both the FDA Safety Commission and CDC raised a number of issues regarding sterilization and HLD in human healthcare facilities, including:
→ Are all reprocessing personnel properly trained or certified? Some states have laws that require reprocessing personnel to be certified and to complete minimum continuing education requirements (10+ units) annually. Personnel training may be provided by a full-time educator.
→ Are regular audits performed to observe compliance with reprocessing steps? Details regarding regular audits, training records, and annual competency documentation (including involvement of third-party contractors) are encouraged.
→ Are policies and procedures consistent with national standards? Policies and procedures should include a review of written IFU before purchasing, borrowing, or testing a new reusable medical device; require device

Susan Flynn, BESc, CSPDT, technical service specialist, 3M Health Care, Sterilization Assurance Group, St. Paul, MN, oral communication, April 2008.
manufacturers to update users with IFU changes; and be fully enforced (especially in regard to loaner surgical instrument trays, which are reusable surgical instruments that are not owned or stored in the healthcare facility).

→ Are all device manufacturers’ IFU available and accessible to reprocessing personnel? If not, users should consult the manufacturer’s website, sales representative, or onesourcedocs.com (fee charged for database access).

→ What happens if there are conflicting IFU? Conflicts surrounding the resources needed to comply with all reprocessing steps should be identified, including considerations of space, supplies, equipment, water quality, training, and environmental controls.

→ Is there enough time to comply with device IFU? All steps required to reprocess the item must be considered, including drying time, proper storage, and transportation to the point of use.

→ Is there documentation of compliance? Human healthcare facilities are obligated to document all reprocessing activities, including maintenance records (e.g., autoclaves, automated endoscope reprocessors, medical washers and washer-disinfectors, water treatment systems), sterilization records (physical, chemical, and biological indicator results), and records verifying that liquid chemical sterilant reprocessing duties contracted to third-party vendors and HLD liquid concentrations were tested and replaced appropriately. It is also important to ensure adequate environmental conditions during transportation and storage (e.g., control humidity, damage) to maintain sterility. If reprocessing duties are contracted to third-party vendors, it must be confirmed that they are approved or certified by the manufacturer to provide those services.

Notably, these guidelines are currently only for human healthcare. Similar guidelines have not yet been developed for the veterinary profession, although

FIGURE 1. SonoCheck (Healthmark). (A) Sonocheck tests the efficacy of cavitation energy in ultrasonic cleaners. The color of the test solution changes from dark green to amber to indicate effective cavitation energy. (B) For best results, Sonocheck test vials should be evenly distributed throughout the ultrasonic cleaner’s basket.
American Animal Hospital Association (AAHA) certification covers some areas of sterilization. It is up to the veterinary team to voluntarily improve practices through education.

**CLEANING AND VERIFICATION**

Ensuring that all items are “surgically clean” before HLD, liquid chemical sterilization (LCS), or other forms of sterilization (e.g., steam, ethylene oxide [EO], hydrogen peroxide gas plasma) plays a key role in ensuring quality outcomes, and its importance cannot be overemphasized. There are several ways to accomplish this goal. First and foremost is strict adherence to manufacturers’ IFU regarding device cleaning.

All surgical equipment and instrumentation (devices) should be meticulously washed either by hand or mechanically immediately after use. If surgical devices cannot be cleaned immediately, they should be kept moist until they can be cleaned, preferably using products approved for this purpose (e.g., Spectra-Soak; IMS Animal Health, spectrumveterinaryinstruments.com).

It is recommended that only detergents and enzymatic cleaners approved for surgical devices be used for washing, as per manufacturers’ IFU. Specific instrument-cleaning brushes should be used to access box locks, channels, or any other area considered difficult to clean.

All cannulated items (e.g., Frazier or Poole suction tips, endoscopic or arthroscopic equipment) should be cleaned using a 3-step process: flush (using copious amounts of water), brush (with an appropriate-diameter brush), and rinse. Using the correct brush size for the lumen is critical to create effective cleaning friction against the lumen walls. If the brush diameter is too large, bristles will bend backwards and will not scrub away debris. If the brush is too small, the limited friction and contact between the bristles and lumen walls prevent adequate cleaning.

Ultrasonic cleaning should be included as part of a comprehensive standardized cleaning process. Although not designed to eliminate all (gross) debris, ultrasonic cleaners remove more dried serum, whole blood, microorganisms, and other fine debris from less accessible surfaces than is possible with manual scrubbing alone. In fact, one study demonstrated that only 3 minutes of ultrasonic cleaning time eliminated 99.9% of residual blood on contaminated instruments. For optimum
performance, ultrasonic cleaning solutions should be de-gassed per the manufacturer’s IFU and changed daily (sooner if needed). After manual cleaning, items are placed in the ultrasonic cleaning basket with box locks in the open position. The basket should be two-thirds to three-quarters full; the tank should not be overfilled.

To confirm that the ultrasonic cleaner is creating adequate cavitation energy, the aluminum foil test (in which indentations in a piece of foil demonstrate cavitation energy) or a specific ultrasonic cleaner test (e.g., SonoCheck; Healthmark, hmark.com) should be performed on a regular basis (FIGURE 1).

Instruments removed from the ultrasonic cleaner should be rinsed thoroughly. Distilled water may be preferred over rinsing with hard water. Surgical devices must be completely dry, as water droplets can interfere with steam sterilization or dilute liquid chemical sterilants. The drying phase can be accelerated using high-pressure canned air (nitrogen) tanks. Hot air drying is contraindicated before EO sterilization.

Because not all contamination is visible to the naked eye, the thoroughness of cleaning can be assessed via keen visual inspection augmented by use of a magnifying glass and good light source (FIGURE 2). Surface stains can be differentiated from residual blood contamination by using commercially available peroxidase detection products such as HemoCheck-S (Healthmark; FIGURE 3), which quickly detects blood residue down to 0.1 mcg, or EndoCheck (Healthmark), designed for use with flexible endoscopes.

ProChek-II (Healthmark) detects residual amounts of protein (sensitive to 1 mcg) using clinical chemistry techniques evolved from the pyrogallol-red method.

Proper cleaning and preparation of surgical devices intended for LCS/HLD is imperative. Organic matter or residual moisture from the cleaning process can dilute or inactivate the active ingredients in sterilants/disinfectants and can interfere with direct contact to the device surfaces. Substances such as soap, detergent, cork, cotton, lint, cotton wool, cellulose sponges, and minerals found in hard water can also affect the efficacy or pH of some liquid chemical sterilants. Devices must be dried properly before further processing, as per manufacturers’ IFU.

**LIQUID CHEMICAL STERILANTS AND HIGH-LEVEL DISINFECTANTS**

Many liquid chemical sterilants and high-level disinfectants approved by the FDA are labeled for use in both sterilization and HLD, with sterilization requiring a longer contact time than HLD (BOX 1). The label conditions required for HLD to occur are the time and temperature needed to achieve a six-log reduction of an appropriate

![FIGURE 2. Careful visual inspection using a good light source and magnification is imperative to thoroughly assess the cleanliness of surgical devices before proceeding to the next phase of sterilization.](image)

![FIGURE 3. (A) Detecting microscopic levels of blood contamination on surgical instruments and equipment is simple when using a HemoCheck-S (Healthmark) test. (B) The green color change in the HemoCheck-S tube on the right demonstrates a positive result for residual blood contamination, while the clear test solution indicates blood was not the source of contamination on surgical instrument pictured left. Courtesy of Healthmark](image)
Mycobacterium species, when used as per manufacturers’ IFU. Most FDA-cleared LCS/HLD products that have labeled contact conditions for sterilization must pass the Association of Official Analytical Chemists Sporicidal Activity Test as a sterilant (i.e., they must pass the test perfectly). Devices must be completely submerged in the LCS/HLD solution (activated, diluted, or ready-to-use) for the specified time and temperature, and the sterilant/disinfectant must be at the correct concentration. The solution should be visually inspected before each use and discarded if precipitates are noted, even if the solution is within its usable life.

The concentration of the active ingredient in solutions should be monitored before each use. Because biologic and chemical indicators are generally not available or labeled for use with liquid chemical sterilants/high-level disinfectants, most manufacturers provide solution test strips or chemical monitoring devices for use with their products (FIGURE 4). The test strips monitor for the concentration of active ingredients. A thermometer and timer are used for physical monitoring and documentation of manual LCS/HLD processes for each cycle. Disposable water temperature verification strips are also available to help assess cycle efficacy. Upon completion of the LCS/HLD process, the sterilized/disinfected items are manually rinsed using aseptic technique as described in the CDC or Association for the Advancement of Medical Instrumentation (AAMI) standards, or according to the manufacturer’s IFU. If the device is not rinsed in sterile water, its sterility will be compromised.

Healthcare personnel must be advised of the hazards associated with the chemicals they work with, and they should be provided with education and safety procedures to ensure compliance, as per OSHA Hazard Communication Standard (29 CFR 1910.1200). In general, healthcare personnel should avoid direct contact with liquid chemical sterilants/high-level disinfectants. Personnel should wear appropriate personal protective equipment (PPE) to prevent skin and eye contact with the solutions (FIGURE 5). Furthermore, these solutions should be used in a well-ventilated area and kept covered to prevent inhalation exposure to the fumes. Recommended aeration or rinsing procedures must be followed after use of these chemical sterilants, as per the manufacturer’s IFU. Finally, each facility should designate and train a liquid chemical sterilant/
high-level disinfectant spill containment response team to ensure that spills can be cleaned up safely."

**STERILIZATION INDICATORS**

Six classes of chemical indicators (CIs) are used to assess parameters identified as being essential or critical to the sterilization process. The variables considered critical for effective sterilization may include different parameters based on the sterilization process being used. For example, steam sterilization parameters include time, temperature, and water (as delivered by saturated steam), but those considered critical for effective EO sterilization involve time, temperature, relative humidity, and EO concentration.1,2

Some CIs use a reactive ink technology that produces a chemical reaction driven by exposure to process variables and results in a color change. "Moving front" CIs possess tablets that melt in response to steam and temperature and wick down a paper path.

**Class 1** (process indicators): These are used externally as an exposure control (e.g., indicator tapes) on individual units to distinguish between processed and unprocessed units. Class 1 indicators are relatively simple and are designed to react to one or more of the critical process variables. Class 1 indicator tapes are agent specific, meaning that, for example, a class 1 steam indicator tape would not work as a class 1 indicator tape for an EO unit.

**Class 2** (test sterilizer performance during a specific test procedure, such as a Bowie–Dick test): Bowie–Dick testing can detect anomalies such as air leaks, inadequate air removal, inadequate steam penetration, or the presence of noncondensable gases (air or gases from boiler additives) in vacuum-assisted sterilizers.

**Class 3** (single-variable indicators): These are designed to react to one of the critical variables and indicate exposure

**FIGURE 6.** Class 5 (integrating) indicators are designed to react to all critical variables and are identified as the CI type providing the highest level of sterility assurance. To determine the efficacy of a steam sterilization cycle using a 3M Comply SteriGage (as shown), the black bar must wick into the ACCEPT zone.

**FIGURE 7.** As an alternative to running and incubating biologic indicator tests on site, sterilization monitoring service is available through outside companies such as SPS Medical. (Quarterly SPS Medical report pictured with class 5 indicators.)
to a sterilization process at a stated value (SV) of the chosen variable. Class 3 indicators may become obsolete.

**Class 4** (multi-variable indicators; usually paper strips): These are designed to react to 2 or more critical variables. This type of CI indicates exposure to a sterilization cycle at an SV of the chosen variables.

**Class 5** (integrating indicators): These are designed to react to all critical variables. The SVs for a class 5 indicator are equivalent to the performance requirements for biologic indicators (BIs). Their response must correlate to a BI at 3 time/temperature relationships: 250°F/121°C, 275°F/135°C, and one or more temperatures in between, such as 263°F/128°C. SVs must be listed on the product or provided on the label/IFU (FIGURE 6). Again, class 4 and 5 indicators for steam sterilization are different than class 4 and 5 indicators for EO.

**Class 6** (emulating indicators): These are cycle verification indicators that are designed to react to all critical variables for specified sterilization cycles. The SVs are generated from the critical variables of the specified sterilization process. Class 6 indicators are cycle specific and must pass an appropriate dry heat test; their response does not correlate to a BI.

BIs contain >100,000 viable spores of a highly resistant organism on a strip and therefore are considered the most reliable level of testing available. Using BIs during a sterilization cycle provides the only direct method of demonstrating lethality within that particular load.

BIs may also be used during low-temperature sterilization methods such as EO, hydrogen peroxide gas plasma, and ozone sterilization processes. Nonetheless, it is possible to have a negative BI and still have a CI failure elsewhere in the load.

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**BOX 1 Liquid Chemical Sterilants and High-Level Disinfectants**

**Glutaraldehyde solutions.** Glutaraldehyde is a major component of many LCS/HLD products. Two-percent glutaraldehyde in alkaline aqueous solution was discovered in the 1960s. Alkaline glutaraldehyde products are usually supplied in 2 parts and require mixing, while acid glutaraldehyde usually does not. Depending on the glutaraldehyde formulation and concentration, conditions for HLD generally range from 5–90 minutes at temperatures ranging from 20°C–35°C (68°F–95°F). The contact time for sterilization is 10 hours at temperatures ranging from 20°C–25°C (68°F–77°F) or 7 hours and 40 minutes at 35°C (95°F). However, recent evidence suggests that some types of microorganisms demonstrate resistance to the antimicrobial effects of glutaraldehyde and may not be inactivated by these solutions.

**Hydrogen peroxide solutions.** These ready-to-use HLD solutions are used primarily for heat-sensitive and submersible medical devices (e.g., flexible or rigid endoscopes.) Two-percent hydrogen peroxide lists contact conditions of 8 minutes at 20°C (68°F) and has a reuse life of 21 days at or above 1.5% concentration. Labeled for an HLD contact time of 30 minutes at 20°C (68°F), 7.5% hydrogen peroxide has a sterilization contact time of 6 hours at 20°C (68°F) with a similar 21-day reuse life if solution concentration remains above 6%.

**Ortho-phthalaldehyde (OPA) solutions.** OPA solutions are FDA approved for use as high-level disinfectants for reprocessing heat-sensitive medical devices. They are especially active against particular strains of mycobacteria, but some strains have shown a high level of resistance, as have some cyst and vegetative forms of protozoa. Products containing 0.55%–0.6% OPA have been approved for use as high-level disinfectants during manual reprocessing at 12 minutes and 20°C (68°F); the solution has a reuse life of 14 days. Use of OPA to process urologic instrumentation has been associated with anaphylactic-like reactions in humans with a history of bladder cancer.

**Peracetic acid–hydrogen peroxide solutions.** Peracetic acid solutions have strong microbial effects and a broad spectrum of activity and can be used for HLD and sterilization applications. Peracetic acid solutions can vary significantly, ranging from 35% peracetic acid and 6% hydrogen peroxide to 5% peracetic acid and 26% hydrogen peroxide. Based on composition, typical HLD contact times range from 5–30 minutes, with sterilization contact times of 6 minutes to 8 hours at 20°C (68°F). Ready-to-use formulations can be reusable for up to 14 days.

**Sodium hypochlorite solutions.** Bleach-type chemicals such as chlorine and chlorine-releasing agents (CRAs) have a long history of use for antisepsis of the skin, hands, and wounds, as well as for disinfection of hospitals, water, and sewage and textile bleaching. Sodium hypochlorite is the most commonly used CRA in healthcare facilities as a hard surface and environmental disinfectant. Sodium hypochlorite and related solutions rapidly lose effectiveness in the presence of organic matter (e.g., blood, feces, tissue). Although chlorine compounds are biocidal to a broad spectrum of microorganisms, most CRA preparations are not intended for HLD or sterilization of medical devices because of their highly corrosive effects.

Additional resources can be found on the FDA website: FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices (http://is.gd/vK7uV6).
Healthcare facilities can either process BIs on site using test vials and an incubator or contract with a sterilization monitoring service (FIGURE 7).

A process challenge device (PCD) is an item (pack/tray) designed to create a defined resistance to a sterilization process and is used to assess the performance of the sterilization process. For example, a Bowie–Dick test ensures the sterilizer is removing air efficiently in dynamic-air-removal (i.e., vacuum-assisted) steam sterilizers and detects trapped air within the sterilizer, which can compromise sterility. A PCD containing a BI is considered a BI challenge test pack/tray, whereas a PCD containing only a class 5 integrating indicator is considered a CI challenge test pack/tray. In large facilities, PCDs are often run at the beginning of each day.1,2,12

**CE Test Keys to Successful High-Level Disinfection And Sterilization Processes**

The article you have read is RACE approved for 1 hour of continuing education credit. To receive credit, take the approved test online at VetMedTeam.com/tvt.aspx. A $5 fee applies. Questions and answers online may differ from those below. Tests are valid for 2 years from the date of approval.

1. Which of the following products has been associated with bladder neoplasia in humans?
   a. Sodium hypochlorite
   b. OPA
   c. Glutaraldehyde
   d. Chlorhexidine

2. The most crucial step in the reprocessing of surgical devices for HLD or sterilization is
   a. thorough verification of the cleaning process.
   b. location of a class 3 chemical indicator.
   c. ensuring the usable shelf life for each liquid chemical sterilant is not exceeded.
   d. correct placement of the biologic indicator.

3. The efficacy of each batch of liquid chemical sterilant or HLD solution is determined by
   a. chemical indicators.
   b. solution temperature.
   c. agent-specific test strips.
   d. expiration dates.

4. When cleaning cannulated items, it is important to
   a. use a 3-step cleaning method: flush, flush, rinse.
   b. use approved pipe cleaners.
   c. use enzymatic cleaners.
   d. select a brush similar in diameter.

5. A Bowie–Dick test is an example of a
   a. class 1 indicator.
   b. process challenge device.
   c. cavitation energy test.
   d. residual protein assay.

6. The most common reason for failure of a sterile process is
   a. human error.
   b. poor service from third-party vendors.
   c. equipment malfunction.
   d. utility (e.g., water quality) issues.

7. The primary difference between an HLD process and sterilization with a liquid chemical depends on the
   a. concentration of the solution.
   b. acidity of the product used.
   c. contact time and temperature.
   d. presence or absence of residual organic matter.

8. Which of the following can be used to verify the presence of adequate cavitation energy in ultrasonic cleaning units?
   a. pyrogallol-red method
   b. solution-specific test strip
   c. aluminum foil test
   d. a peroxidase detection product

9. Which liquid chemical is the most commonly used chlorine-releasing agent in healthcare facilities for disinfection of hard surfaces?
   a. OPA
   b. glutaraldehyde
   c. peracetic acid compounds
   d. sodium hypochlorite

10. Reacting to all critical variables, this indicator's performance requirements are equivalent to those of a biologic indicator:
    a. Class 3
    b. Class 4
    c. Class 5
    d. Class 6
CONCLUSION
Veterinary technicians play a key role in ensuring that medical devices are clean and functional before HLD and sterilization, and much can be learned from the mistakes made in human medicine. Regularly updating hospital policies and procedures and verifying the efficacy of cleaning and sterilization processes can play a vital role in preventing HAIs during the pursuit of excellence in veterinary patient care.

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