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Disinfection and Sterilization

A Review of the Basics

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Special Digital Issue on Disinfection & Sterilization *April 2012*

editor'sLETTER

Getting Back to Basics

Getting back to basics is never a bad idea, even as the sophistication of disinfection and sterilization processes escalates. That's why we decided to pull together some information from industry guidelines as a companion piece to an existing comprehensive report, "Best Practices for High-Level Disinfection and Sterilization of Endoscopes," which is available for download on the ICT website in a special immersion center designed to provide a repository for information on disinfection and sterilization.

We have included an article on best practices for immediate-use sterilization, as well as consulted several industry experts for their perspectives that can help infection preventionists and sterile processing professionals stay on top of the prevention of medical device-related infections.

Until next time,
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Disinfection and Sterilization

A Review of the Basics

EDITOR'S NOTE: For a comprehensive report on disinfection and sterilization, visit: http://www.infectioncontroltoday.com/reports/2012/02/high-level-disinfection.aspx

For the purposes of reviewing the basics, here are some main points from the Centers for Disease Control and Prevention (CDC)'s guideline on disinfection and sterilization (CDC, 2008).

Medical devices are labeled by the manufacturer as either reusable or single-use, and reusable medical equipment such as endoscopes come with instructions for cleaning, disinfection and/or sterilization. All reusable medical devices must be cleaned and maintained according to the manufacturer's instructions to prevent patient-to-patient transmission of infectious agents.

The Spaulding Classification is a traditional approach that has been used to determine the level of disinfection or sterilization required for reusable medical devices, based upon the degree of risk for transmitting infections if the device is contaminated at the time of use.

- Critical items (such as surgical instruments) are objects that enter sterile tissue or the vascular system and must be sterile prior to use.

- Semi-critical items (such as endoscopes used for upper endoscopy and colonoscopy) contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse.

- Noncritical items (such as blood pressure cuffs) are those that may come in contact with intact skin but not mucous membranes and should undergo low- or intermediate-level disinfection depending on the nature and degree of contamination.

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Most importantly, cleaning to remove organic material must always precede disinfection or sterilization because residual debris reduces the effectiveness of the disinfection and sterilization processes.

Healthcare facilities should establish policies and procedures for containing, transporting and handling equipment that may be contaminated with blood, body fluids and other potentially infectious materials. Manufacturer's instructions for reprocessing any reusable medical equipment in the facility should be readily available and used to establish clear and appropriate policies and procedures. Instructions should be posted at the site where equipment reprocessing is performed. Responsibility for cleaning, disinfection and/or sterilization of medical equipment should be assigned to healthcare workers with training in the required reprocessing steps and in the appropriate use of personal protective equipment (PPE) necessary for handling of contaminated equipment. Competencies of healthcare workers responsible for reprocessing of equipment should be documented initially upon assignment of those duties, whenever new equipment is introduced, and periodically (such as semi-annually).

Key recommendations for cleaning, disinfection, and/or sterilization of medical equipment in ambulatory care settings:

1. Facilities should ensure that reusable medical equipment (e.g., blood glucose meters and other point-of-care devices, surgical instruments, endoscopes) is cleaned and reprocessed appropriately prior to use on another patient

2. Reusable medical equipment must be cleaned and reprocessed (disinfection or sterilization) and maintained according to the manufacturer's instructions. If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use

3. Assign responsibilities for reprocessing of medical equipment to healthcare workers with appropriate training

a. Maintain copies of the manufacturer's instructions for reprocessing of equipment in use at the facility; post instructions at locations where reprocessing is performed

b. Observe procedures to document competencies of healthcare workers responsible for equipment reprocessing upon assignment of those duties, whenever new equipment is introduced, and on an ongoing periodic basis (e.g., quarterly)

4. Ensure that healthcare workers have access to and wear appropriate PPE when handling and reprocessing contaminated patient equipment

Source: Centers for Disease Control and Prevention (CDC). Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care]

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Cleaning to remove organic material must always precede disinfection or sterilization because residual debris reduces the effectiveness of the disinfection and sterilization processes.

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

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

The most common types of mechanical or automatic cleaners are ultrasonic cleaners, washer-decontaminators, washer-disinfectors, and washer-sterilizers. Ultrasonic cleaning removes soil by cavitation and implosion in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold particulate matter to surfaces. Bacterial contamination can be present in used ultrasonic cleaning solutions (and other used detergent solutions) because these solutions generally do not make antibacterial label claims. Even though ultrasound alone does not significantly inactivate bacteria, sonication can act synergistically to increase the cidal efficacy of a disinfectant. Users of ultrasonic cleaners should be aware that the cleaning fluid could result in endotoxin contamination of surgical instruments, which could cause severe inflammatory reactions. Washer-sterilizers

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are modified steam sterilizers that clean by filling the chamber with water and detergent through which steam passes to provide agitation. Instruments are subsequently rinsed and subjected to a short steam-sterilization cycle. Another washer-sterilizer employs rotating spray arms for a wash cycle followed by a steam sterilization cycle at 285 degrees F. Washer-decontaminators/disinfectors act like a dishwasher that uses a combination of water circulation and detergents to remove soil. These units sometimes have a cycle that subjects the instruments to a heat process (e.g., 93 degrees C for 10 minutes). Washer-disinfectors are generally computer-controlled units for cleaning, disinfecting, and drying solid and hollow surgical and medical equipment. In one study, cleaning (measured as 5–6 log10 reduction) was achieved on surfaces that had adequate contact with the water flow in the machine. Detailed information about cleaning and preparing supplies for terminal sterilization is provided by professional organizations 453, 454 and books 455. Studies have shown that manual and mechanical cleaning of endoscopes achieves approximately a 4-log10 reduction of contaminating organisms; thus cleaning alone effectively reduces the number of microorganisms on contaminated equipment.

For instrument cleaning, a neutral or near-neutral pH detergent solution commonly is used because such solutions generally provide the best material compatibility profile and good soil removal. Enzymes, usually proteases, sometimes are added to neutral pH solutions to assist in removing organic material. Enzymes in these formulations attack proteins that make up a large portion of common soil (e.g., blood, pus). Cleaning solutions also can contain lipases (enzymes active on fats) and amylases (enzymes active on starches). Enzymatic cleaners are not disinfectants, and proteinaceous enzymes can be inactivated by germicides. As with all chemicals, enzymes must be rinsed from the equipment or adverse reactions (e.g., fever, residual amounts of high-level disinfectants, proteinaceous residue) could result. Enzyme solutions should be used in accordance with manufacturer's instructions, which include proper dilution of the enzymatic detergent and contact with equipment for the amount of time specified on the label. Detergent enzymes can result in asthma or other allergic effects in users. Neutral pH detergent solutions that contain enzymes are compatible with metals and other materials used in medical

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instruments and are the best choice for cleaning delicate medical instruments, especially flexible endoscopes. Alkaline-based cleaning agents are used for processing medical devices because they efficiently dissolve protein and fat residues; however, they can be corrosive. Some data demonstrate that enzymatic cleaners are more effective than neutral detergents in removing microorganisms from surfaces but two more recent studies found no difference in cleaning efficiency between enzymatic and alkaline-based cleaners.

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

Disinfectants are not interchangeable, and incorrect concentrations and inappropriate disinfectants can result in excessive costs. Because occupational diseases among cleaning personnel have been associated with use of several disinfectants (e.g., formaldehyde, glutaraldehyde, and chlorine), precautions (e.g., gloves and proper ventilation) should be used to minimize exposure. The preferred method of control is elimination of the chemical (through engineering controls or substitution) or relocation of the worker.

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

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

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

For additional information on disinfectants and sterilization methods, consult the Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, from the CDC.

CDC RECOMMENDATIONS

Disinfection and sterilization-related recommendations from the CDC include the following:

Cleaning of Patient-Care Devices

a. In hospitals, perform most cleaning, disinfection, and sterilization of patient-care devices in a central processing department in order to more easily control quality.

b. Meticulously clean patient-care items with water and detergent, or with water

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and enzymatic cleaners before high-level disinfection or sterilization procedures.

i. Remove visible organic residue (e.g., residue of blood and tissue) and inorganic salts with cleaning. Use cleaning agents that are capable of removing visible organic and inorganic residues.

ii. Clean medical devices as soon as practical after use (e.g., at the point of use) because soiled materials become dried onto the instruments. Dried or baked materials on the instrument make the removal process more difficult and the disinfection or sterilization process less effective or ineffective.

c. Perform either manual cleaning (i.e., using friction) or mechanical cleaning (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizers).

d. If using an automatic washer/disinfector, ensure that the unit is used in accordance with the manufacturer's recommendations. Category

e. Ensure that the detergents or enzymatic cleaners selected are compatible with the metals and other materials used in medical instruments. Ensure that the rinse step is adequate for removing cleaning residues to levels that will not interfere with subsequent disinfection/sterilization processes.

f. Inspect equipment surfaces for breaks in integrity that would impair either cleaning or disinfection/sterilization. Discard or repair equipment that no longer functions as intended or cannot be properly cleaned, and disinfected or sterilized.

Indications for Sterilization, High-Level Disinfection, and Low-Level Disinfection

a. Before use on each patient, sterilize critical medical and surgical devices and instruments that enter normally sterile tissue or the vascular system or through which a sterile body fluid flows (e.g., blood).

b. Provide, at a minimum, high-level disinfection for semicritical patient-care equipment (e.g., gastrointestinal endoscopes, endotracheal tubes, anesthesia breathing circuits, and respiratory therapy equipment) that touches either mucous membranes or nonintact skin.

c. Perform low-level disinfection for noncritical patient-care surfaces (e.g., bedrails, over-the-bed table) and equipment (e.g., blood pressure cuff) that touch intact skin.

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Selection and Use of Low-Level Disinfectants for Noncritical Patient-Care Devices

a. Process noncritical patient-care devices using a disinfectant and the concentration of germicide indicated.

b. Disinfect noncritical medical devices (e.g., blood pressure cuff) with an EPA-registered hospital disinfectant using the label's safety precautions and use directions. Most EPA-registered hospital disinfectants have a label contact time of 10 minutes. However, multiple scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens with a contact time of at least 1 minute. By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability from any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA.

c. Ensure that, at a minimum, noncritical patient-care devices are disinfected when visibly soiled and on a regular basis (such as after use on each patient or once daily or once weekly).

d. If dedicated, disposable devices are not available, disinfect noncritical patient-care equipment after using it on a patient who is on contact precautions before using this equipment on another patient.

High-Level Disinfection of Endoscopes

a. To detect damaged endoscopes, test each flexible endoscope for leaks as part of each reprocessing cycle. Remove from clinical use any instrument that fails the leak test, and repair this instrument.

b. Immediately after use, meticulously clean the endoscope with an enzymatic cleaner that is compatible with the endoscope. Cleaning is necessary before both automated and manual disinfection.

c. Disconnect and disassemble endoscopic components (e.g., suction valves) as completely as possible and completely immerse all components in the enzymatic cleaner. Steam sterilize these components if they are heat stable.

d. Flush and brush all accessible channels to remove all organic (e.g., blood, tissue) and other residue. Clean the external surfaces and accessories of the devices by using a soft cloth or sponge or brushes. Continue brushing until no debris appears on the brush.

e. Use cleaning brushes appropriate for the size of the endoscope channel or port (e.g., bristles should contact surfaces). Cleaning items (e.g., brushes, cloth) should be disposable or, if they are not disposable, they should be thoroughly cleaned and either high-level disinfected or sterilized after each use.

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f. Discard enzymatic cleaners (or detergents) after each use because they are not microbicidal and, therefore, will not retard microbial growth.

g. Process endoscopes (e.g., arthroscopes, cystoscope, laparoscopes) that pass through normally sterile tissues using a sterilization procedure before each use; if this is not feasible, provide at least high-level disinfection. High-level disinfection of arthroscopes, laparoscopes and cytoscopes should be followed by a sterile water rinse.

h. Phase out endoscopes that are critical items (e.g., arthroscopes, laparoscopes) but cannot be steam sterilized. Replace these endoscopes with steam sterilizable instruments when feasible.

i. Mechanically clean reusable accessories inserted into endoscopes (e.g., biopsy forceps or other cutting instruments) that break the mucosal barrier (e.g., ultrasonically clean biopsy forceps) and then sterilize these items between each patient.

j. Use ultrasonic cleaning of reusable endoscopic accessories to remove soil and organic material from hard-to-clean areas.

k. Process endoscopes and accessories that contact mucous membranes as semicritical items, and use at least high-level disinfection after use on each patient.

l. Use an FDA-cleared sterilant or high-level disinfectant for sterilization or high-level disinfection.

m. After cleaning, use formulations containing glutaraldehyde, glutaraldehyde with phenol/phenate, ortho-phthalaldehyde, hydrogen peroxide, and both hydrogen peroxide and peracetic acid to achieve high-level disinfection followed by rinsing and drying (see Table 1 for recommended concentrations).

n. Extend exposure times beyond the minimum effective time for disinfecting semicritical patient-care equipment cautiously and conservatively because extended exposure to a high-level disinfectant is more likely to damage delicate and intricate instruments such as flexible endoscopes. The exposure times vary among the Food and Drug Administration (FDA)-cleared high-level disinfectants.

o. Federal regulations are to follow the FDA-cleared label claim for high-level disinfectants. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 25 degrees C range from 20-90 minutes, depending upon the product based on three tier testing which includes

> Meticulously clean patient-care items with water and detergent, or with water and enzymatic cleaners before high-level disinfection or sterilization procedures.

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AOAC sporicidal tests, simulated use testing with mycobacterial and in-use testing.

p. Several scientific studies and professional organizations support the efficacy of >2% glutaraldehyde for 20 minutes at 20 degrees C; that efficacy assumes adequate cleaning prior to disinfection, whereas te FDA-cleared label claim incorporates an added margin of safety to accommodate possible lapses in cleaning practices. Facilities that have chosen to apply the 20 minute duration at 20ºC degrees have done so based on the IA recommendation in the July 2003 SHEA position paper, "Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes."

q. When using FDA-cleared high-level disinfectants, use manufacturers' recommended exposure conditions. Certain products may require a shorter exposure time (e.g., 0.55% ortho-phthalaldehyde for 12 minutes at 20 degrees C, 7.35% hydrogen peroxide plus 0.23% peracetic acid for 15 minutes at 20 degrees C) than glutaraldehyde at room temperature because of their rapid inactivation of mycobacteria or reduced exposure time because of increased mycobactericidal activity at elevated temperature (e.g., 2.5% glutaraldehyde at 5 minutes at 35 degrees C).

r. Select a disinfectant or chemical sterilant that is compatible with the device that is being reprocessed. Avoid using reprocessing chemicals on an endoscope if the endoscope manufacturer warns against using these chemicals because of functional damage (with or without cosmetic damage).

s. Completely immerse the endoscope in the high-level disinfectant, and ensure all channels are perfused. As soon as is feasible, phase out nonimmersible endoscopes.

t. After high-level disinfection, rinse endoscopes and flush channels with sterile water, filtered water, or tap water to prevent adverse effects on patients associated with disinfectant retained in the endoscope (e.g., disinfectant induced colitis). Follow this water rinse with a rinse with 70 percent to 90 percent ethyl or isopropyl alcohol.

u. After flushing all channels with alcohol, purge the channels using forced air to reduce the likelihood of contamination of the endoscope by waterborne pathogens and to facilitate drying.

v. Hang endoscopes in a vertical position to facilitate drying.

w. Store endoscopes in a manner that will protect them from damage or contamination.

x. Sterilize or high-level disinfect both the water bottle used to provide intraprocedural flush solution and its connecting tube at least once daily. After sterilizing or high-level disinfecting the water bottle, fill it with sterile water.

y. Maintain a log for each procedure and record the following: patient's name and

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medical record number (if available), procedure, date, endoscopist, system used to reprocess the endoscope (if more than one system could be used in the reprocessing area), and serial number or other identifier of the endoscope used.

z. Design facilities where endoscopes are used and disinfected to provide a safe environment for healthcare workers and patients. Use air-exchange equipment (e.g., the ventilation system, out-exhaust ducts) to minimize exposure of all persons to potentially toxic vapors (e.g., glutaraldehyde vapor). Do not exceed the allowable limits of the vapor concentration of the chemical sterilant or high-level disinfectant (e.g., those of ACGIH and OSHA).

aa. Routinely test the liquid sterilant/high-level disinfectant to ensure minimal effective concentration of the active ingredient. Check the solution each day of use (or more frequently) using the appropriate chemical indicator (e.g., glutaraldehyde chemical indicator to test minimal effective concentration of glutaraldehyde) and document the results of this testing. Discard the solution if the chemical indicator shows the concentration is less than the minimum effective concentration. Do not use the liquid sterilant/high-level disinfectant beyond the reuse-life recommended by the manufacturer (e.g., 14 days for ortho-phthalaldehyde).

bb. Provide personnel assigned to reprocess endoscopes with device-specific reprocessing instructions to ensure proper cleaning and high-level disinfection or sterilization. Require competency testing on a regular basis (e.g., beginning of employment, annually) of all personnel who reprocess endoscopes.

cc. Educate all personnel who use chemicals about the possible biologic, chemical, and environmental hazards of performing procedures that require disinfectants.

dd. Make PPE (e.g., gloves, gowns, eyewear, face mask or shields, respiratory protection devices) available and use these items appropriately to protect workers from exposure to both chemicals and microorganisms (e.g., HBV).

ee. If using an automated endoscope reprocessor (AER), place the endoscope in the reprocessor and attach all channel connectors according to the AER manufacturer's instructions to ensure exposure of all internal surfaces to the high-level disinfectant/chemical sterilant.

ff. If using an AER, ensure the endoscope can be effectively reprocessed in the AER. Also, ensure any required manual cleaning/disinfecting steps are performed

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(e.g., elevator wire channel of duodenoscopes might not be effectively disinfected by most AERs).

gg. Review the FDA advisories and the scientific literature for reports of deficiencies that can lead to infection because design flaws and improper operation and practices have compromised the effectiveness of AERs.

hh. Develop protocols to ensure that users can readily identify an endoscope that has been properly processed and is ready for patient use.

ii. Do not use the carrying case designed to transport clean and reprocessed endoscopes outside of the healthcare environment to store an endoscope or to transport the instrument within the healthcare environment.

jj. No recommendation is made about routinely performing microbiologic testing of either endoscopes or rinse water for quality assurance purposes.

kk. If environmental microbiologic testing is conducted, use standard microbiologic techniques.

ll. If a cluster of endoscopy-related infections occurs, investigate potential routes of transmission (e.g., person-to-person, common source) and reservoirs.

mm. Report outbreaks of endoscope-related infections to persons responsible for institutional infection control and risk management and to FDA. Notify the local and the state health departments, CDC, and the manufacturer(s).

nn. No recommendation is made regarding the reprocessing of an endoscope again immediately before use if that endoscope has been processed after use according to the recommendations in this guideline. Unresolved issue.

oo. Compare the reprocessing instructions provided by both the endoscope's and the AER's manufacturer's instructions and resolve any conflicting recommendations.

Editor's note: For more updated guidance, see: Petersen BT, et al. Multi-society Guideline on Reprocessing Flexible GI Endoscopes: 2011. Gastrointestinal Endoscopy. Vol. 73, No. 6. 2011.

Factors That Affect the Efficacy of Disinfection and Sterilization

The activity of germicides against microorganisms depends on a number of factors, some of which are intrinsic qualities of the organism, others of which are the chemical and external physical environment. Awareness of these factors should lead to better use of disinfection and sterilization processes, and they are reviewed here.

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The location of microorganisms also must be considered when factors affecting the efficacy of germicides are assessed.

1. Number and location of microorganisms

All other conditions remaining constant, the larger the number of microbes, the more time a germicide needs to destroy all of them. Spaulding illustrated this relation when he employed identical test conditions and demonstrated that it took 30 minutes to kill 10 B. atrophaeus (formerly Bacillus subtilis) spores but three hours to kill 100,000 Bacillus atrophaeus spores. This reinforces the need for scrupulous cleaning of medical instruments before disinfection and sterilization. Reducing the number of microorganisms that must be inactivated through meticulous cleaning, increases the margin of safety when the germicide is used according to the labeling and shortens the exposure time required to kill the entire microbial load.

The location of microorganisms also must be considered when factors affecting the efficacy of germicides are assessed. Medical instruments with multiple pieces must be disassembled and equipment such as endoscopes that have crevices, joints, and channels are more difficult to disinfect than are flat- surface equipment because penetration of the disinfectant of all parts of the equipment is more difficult. Only surfaces that directly contact the germicide will be disinfected, so there must be no air pockets and the equipment must be completely immersed for the entire exposure period. Manufacturers should be encouraged to produce equipment engineered for ease of cleaning and disinfection.

2. Innate resistance of microorganisms

Microorganisms vary greatly in their resistance to chemical germicides and sterilization processes. Intrinsic resistance mechanisms in microorganisms to disinfectants vary. For example, spores are resistant to disinfectants because the spore coat and cortex act as a barrier, mycobacteria have a waxy cell wall that prevents disinfectant entry, and gram-negative bacteria possess an outer membrane that acts as a barrier to the uptake of disinfectants. Implicit in all disinfection strategies is the consideration that the most resistant microbial subpopulation controls the sterilization or disinfection time, meaning that in order to destroy the most resistant types of microorganisms (such as bacterial spores), the user needs to employ exposure times and a concentration of germicide needed to achieve complete destruction. Except for prions, bacterial spores possess the highest innate resistance to chemical germicides, followed by coccidia (e.g., Cryptosporidium), mycobacteria (e.g., M. tuberculosis), nonlipid

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or small viruses (e.g., poliovirus, and coxsackievirus), fungi (e.g., Aspergillus, and Candida), vegetative bacteria (e.g., Staphylococcus, and Pseudomonas) and lipid or medium-size viruses (e.g., herpes, and HIV). The germicidal resistance exhibited by Gram-positive and Gram-negative bacteria is similar with some exceptions (P. aeruginosa shows greater resistance to some disinfectants). P. aeruginosa also is significantly more resistant to a variety of disinfectants in its "naturally occurring" state than are cells subcultured on laboratory media.

3. Concentration and potency of disinfectants

With other variables constant, and with one exception (iodophors), the more concentrated the disinfectant, the greater its efficacy and the shorter the time necessary to achieve microbial kill. Generally not recognized, however, is that all disinfectants are not similarly affected by concentration adjustments. For example, quaternary ammonium compounds and phenol have a concentration exponent of 1 and 6, respectively; thus, halving the concentration of a quaternary ammonium compound requires doubling its disinfecting time, but halving the concentration of a phenol solution requires a 64-fold (i.e., 26) increase in its disinfecting time. Considering the length of the disinfection time, which depends on the potency of the germicide, also is important. This was illustrated by Spaulding who demonstrated using the mucin-loop test that 70 percent isopropyl alcohol destroyed 104 M. tuberculosis in 5 minutes, whereas a simultaneous test with 3 percent phenolic required two to three hours to achieve the same level of microbial kill.

4. Physical and chemical factors

Several physical and chemical factors also influence disinfectant procedures: temperature, pH, relative humidity, and water hardness. For example, the activity of most disinfectants increases as the temperature increases, but some exceptions exist. Furthermore, too great an increase in temperature causes the disinfectant to degrade and weakens its germicidal activity and thus might produce a potential health hazard.

An increase in pH improves the antimicrobial activity of some disinfectants (such as glutaraldehyde, quaternary ammonium compounds) but decreases the antimicrobial activity of others (such as phenols, hypochlorites and iodine). The pH influences the antimicrobial activity by altering the disinfectant molecule or the cell surface.

Relative humidity is the single most important factor influencing the activity of

gaseous disinfectants/sterilants, such as EtO, chlorine dioxide, and formaldehyde.

Water hardness (i.e., high concentration of divalent cations) reduces the rate of kill of certain disinfectants because divalent cations (e.g., magnesium, calcium) in the hard water interact with the disinfectant to form insoluble precipitates.

5. Organic and inorganic matter

Organic matter in the form of serum, blood, pus, or fecal or lubricant material can interfere with the antimicrobial activity of disinfectants in at least two ways. Most commonly, interference occurs by a chemical reaction between the germicide and the organic matter resulting in a complex that is less germicidal or non-germicidal, leaving less of the active germicide available for attacking microorganisms. Chlorine and iodine disinfectants, in particular, are prone to such interaction. Alternatively, organic material can protect microorganisms from attack by acting as a physical barrier.

Several physical and chemical factors also influence disinfectant procedures: temperature, pH, relative humidity, and water hardness.

6. Duration of exposure

Items must be exposed to the germicide for the appropriate minimum contact time. Multiple investigators have demonstrated the effectiveness of low-level disinfectants against vegetative bacteria (e.g., Listeria, E. coli, Salmonella, VRE, MRSA), yeasts (e.g., Candida), mycobacteria (e.g., M. tuberculosis), and viruses (e.g., poliovirus) at exposure times of 30–60 seconds. By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

All lumens and channels of endoscopic instruments must contact the disinfectant. Air pockets interfere with the disinfection process, and items that float on the disinfectant will not be disinfected. The disinfectant must be introduced reliably

into the internal channels of the device. The exact times for disinfecting medical items are somewhat elusive because of the effect of the aforementioned factors on disinfection efficacy. Certain contact times have proved reliable, but, in general, longer contact times are more effective than shorter contact times.

Microorganisms may be protected from disinfectants by production of thick masses of cells and extracellular materials, or biofilms. Biofilms are microbial communities that are tightly attached to surfaces and cannot be easily removed. Once these masses form, microbes within them can be resistant to disinfectants by multiple mechanisms, including physical characteristics of older biofilms, genotypic variation of the bacteria, microbial production of neutralizing enzymes, and physiologic gradients within the biofilm (e.g., pH). Bacteria within biofilms are up to 1,000 times more resistant to antimicrobials than are the same bacteria in suspension. Although new decontamination methods are being investigated for removing biofilms, chlorine and monochloramines can effectively inactivate biofilm bacteria. Investigators have hypothesized that the glycocalyx-like cellular masses on the interior walls of polyvinyl chloride pipe would protect embedded organisms from some disinfectants and be a reservoir for continuous contamination. Biofilms have been found in whirlpools, dental unit waterlines, and numerous medical devices (e.g., contact lenses, pacemakers, hemodialysis systems, urinary catheters, central venous catheters, endoscopes). Their presence can have serious implications for immunocompromised patients and patients who have indwelling medical devices. Some enzymes and detergents can degrade biofilms or reduce numbers of viable bacteria within a biofilm, but no products are EPA-registered or FDA-cleared for this purpose.

Microorganisms may be protected from disinfectants by production of thick masses of cells and extracellular materials, or biofilms.

Reference:
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Immediate-Use Steam Sterilization

Best Practices

By Trish L. Stoutzenberger

Immediate-use steam sterilization, formerly referred to as flash sterilization, is currently a topic getting much attention by operating room and sterile processing personnel across the country. As a sterile processing manager of a large facility, I am keenly aware of the challenges involved with following best practices and guidelines to perform the complex procedure of sterilizing instruments for immediate use. The Joint Commission received intense training in the entire process just last year and the surveyors will be certain to visit the operating room sub-sterile during their annual survey.

EDITOR'S NOTE: This article originally appeared in the December 2011 print issue of Infection Control Today magazine.

When performed correctly and when deemed appropriate, immediate-use steam sterilization is an effective and safe way to sterilize critical medical devices for a surgical procedure (CDC, 2008). However, this process is complex and requires a facility to consistently follow all the necessary steps each time to ensure the sterility of the instruments to the point of use. There can be no margin of error. Improper technique can result in the use of contaminated instruments in surgery resulting in serious consequences including surgical site infections (SSI). It is because of this risk that all operating rooms should reduce their reliance upon and use of this process.

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Facilities should take action and increase their surgical instrument inventory, employ a scheduling conflict mechanism, improve communications between the operating room and sterile processing personnel, and educate all those involved with immediate-use steam sterilization.

Issues and Concerns

The serious consequence of an SSI is the No. 1 concern of improper use of immediate-use steam sterilization. According to the CDC, SSIs affect 2 percent to 5 percent of all patients undergoing surgery. That is equal to about 300,000 patients each year. Patients with an SSI have a 3 percent mortality rate. In addition, SSIs can increase of hospital length of stay for up to seven to 10 days. The increase hospital stay equates to increase costs of $3,000 to $29,000 per SSI with upwards of $10 billion annually (CDC, 2011). There are many causes of SSIs, and proper sterilization is just one factor of prevention. Nonetheless, it is an important factor as facilities continue to strive to reduce its number of hospital acquired infections.

The obstacle for facilities to reduce risk of SSIs is lack of education and understanding of current processes. In early 2011, a multi-society position statement addressing immediate-use steam sterilization of surgical instruments was released by American Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), and several other national organizations. This statement stressed the importance of education for the personnel directly involved in reprocessing of surgical instruments to the point of use. Furthermore, surgical and sterile processing personnel should be knowledgeable regarding the different types of steam sterilization cycles, standards and practices, cleaning, decontamination and rinsing processes, and correct aseptic transfer from the sterilizer to the point of use (AORN, 2011a).

The last major concern, which is also addressed in the position statement, is manufacturer's instructions for use. The world of surgery is now more technologically advanced. That new technology introduces more complex instruments and more complex manufacturer's instructions. A facility is required to follow those instructions as the manufacturers perform the quality testing of their instruments and they determine which steam cycles are successful. The problem is that their instructions do not always match the cycles available of a flash sterilizer in an operating room. If a facility chooses to sterilize an instrument tray without following these instructions, the sterility of the instruments is in question and they are putting their patients at risk.

When performed correctly and when deemed appropriate, immediate-use steam sterilization is an effective and safe way to sterilize critical medical devices for a surgical procedure. However, this process is complex and requires a facility to consistently follow all the necessary steps each time to ensure the sterility of the instruments to the point of use.

Standards and Guidelines

Although standards are voluntary, facilities should strive for best practice. AORN and AAMI standards are written as achievable practices for most facilities. According to AORN standards, immediate-use steam sterilization should only be used in selected clinical situations. Those situations include the following:

- When a one-of-a-kind instrument has been contaminated and needs to be replaced to the sterile field immediately.
- When an item has dropped on the floor and is needed to continue a surgical procedure.
- When specific instruments are needed for an emergency procedure.
- When there is no other sterilization alternative (AORN, 2011b).

AAMI ST 79 is a comprehensive document covering recommended practices for steam sterilization. The document states that immediate-use steam sterilization can be performed when deemed appropriate and when all of the following conditions are met:

- The device manufacturer's written instructions on cycle times, exposure times, temperature settings and dry times are followed.
- Items are dissembled and thoroughly cleaned with detergent and water to remove soil, blood, body fats and other substances.
- Lumens are brushed and flushed under the water with cleaning solution and rinsed thoroughly.
- Items are placed in a closed sterilization container or tray, validated for immediate-use sterilization, in a manner that allows steam contact and aseptic transfer to the operating room (American National Standard, 2010).

In addition, the multi-society position statement addresses the instances when immediate-use steam sterilization should never be performed. Immediate-

use sterilization should not be performed on the following devices:

- Implants, except in a documented emergency situation when no other option is available.
- Post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease (CJD) or similar disorders.
- Devices or loads that have not been validated with the specific cycle employed.
- Devices that are sold sterile and intended for single-use only (AORN, 2011a).

Solutions

Immediate-use steam sterilization can be a safe and effective process if used correctly. However, it should not be used as a matter of convenience. Steps should be taken to reduce the reliance and use of this process. The first appropriate response is to increase the surgical instrument inventory to levels that match the case load. Inadequate inventory is not an excuse for excessive use of immediate-use sterilization. However, as capital budgets are decreasing, this may not be an option for many facilities. A better and more efficient model would be to improve asset management and use the conflict scheduling mechanism. Facilities should not simply over-ride scheduling conflicts and manage resources on the day of surgery. In addition, there needs to be adequate turn over time built into the system in order for the sterile processing department (SPD) to terminally process the instruments.

Immediate-use steam sterilization can be a safe and effective process if used correctly. However, it should not be used as a matter of convenience.

The most important function of any high-level operation in the hospital is communication. Teams should be communicating and planning for the unexpected. No two days are alike in surgery, and the teams in the operating room (OR) and SPD must communicate with each other to ensure the patient's needs are met. The OR must inform the SPD if their surgeries are advancing ahead of schedule so together they can plan for the quick turnover of instrument resources. SPD staff must then communicate whether the turnover expectations can truly be delivered.

The final and most important solution to avoid excessive use is through education. Physicians, nurses, surgical technologists and management should understand

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the correct processes and the associated risks involved with immediate-use steam sterilization. Physicians are charged with the responsibility to do no harm, and nurses protect the rights as well as the dignity of their patients. They cannot do their job without the correct information.

Immediate-use steam sterilization is a critical aspect of delivering care to the patient during surgery. The serious consequences of SSIs can result from improper sterilized instruments used on patients. The best ways to deliver sterile instruments to patients every time are to know when to use the process, follow the correct procedures with well educated staff, and to ensure the availability of instruments before the need to use the sterilizer in the operating room. The teams in the OR and SPD should work together to address these issues and do what is ultimately safe for the patient.

Trish L. Stoutzenberger, ST, CRCST, CHL, is sterile processing manager for Lancaster General Hospital in Lancaster, Pa.

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Disinfection and Sterilization Advice from the Expert:

A Q&A with Barbara Trattler

ICT spoke with Barbara Trattler, RN, MPA, CNOR, CNA, director of clinical education for Advanced Sterilization Products, regarding some best practices for high-level disinfection and sterilization.

Q: What are some of the most common mistakes made by sterile processing professionals regarding high-level disinfection (HLD) and sterilization?

A: It seems that sterile processing departments (SPDs) continue to struggle with the volume of instruments requiring rapid reprocessing turnaround time, and this can potentially cause mistakes. I believe SPD departments have many opportunities to improve productivity with the resources they have. Reducing the number of separately wrapped instruments by containing instruments in sets and utilizing containers are two examples of how SPD professionals can improve productivity, increase efficiency and reduce cost in reprocessing practices. However, changes like these require a true partnership and collaboration with operating room (OR) personnel.

Increasingly, SPD departments are assuming responsibility for HLD practices for the facility as well – which could require additional training and expertise when it comes to flexible endoscopes. One option facilities can consider is the STERRAD® NX® System, offering terminal sterilization with packaged instruments that are dry and can be used immediately or stored for later use. This means busy ORs and surgery centers are able to start ahead and stay ahead, beginning the day with instruments that have already been packaged, processed and stored. This eliminates the waiting or rushing that can be experienced with other reprocessing methods.

Another option is the EVOTECH® Endoscope Cleaner and Reprocessor (ECR), which makes endoscope reprocessing a fully automated process. Technology like the EVOTECH® ECR makes labor-intensive and time-consuming manual endoscope reprocessing a thing of the past.

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Q: When mistakes are made, can they be attributed to knowledge gaps or implementation gaps, and how can these be remedied?

A: It is critical that SPD leaders ensure the information they are providing staff is clear and easy to understand, which can help avoid gaps in implementation. Enhanced communication and collaboration between SPD and the other departments in the facility helps to ensure there is compliance with best practices and standards throughout the facility. Over the past year particularly, I have seen SPD managers take ownership for their expertise and drive best practices in terminal sterilization and high-level disinfection throughout their facilities. Ongoing education in any facility is critical, and I encourage healthcare professionals to work with their sterilization or HLD manufacturer to determine what educational opportunities they provide.

Q: What are the differences between sterilization and liquid chemical sterilant processing?

A: Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Although the terms are similar, a liquid chemical sterilant processor is not a sterilizer. Liquid chemical sterilants do not convey a sterility assurance level of 10^{-6} that is required for sterilizers.

Liquid chemical sterilants comply with guidelines for HLD of semi-critical (e.g., endoscopes) medical devices or for sterilization of critical or semi-critical devices that are heat-sensitive or incompatible with traditional sterilization methods. There is a two-part process:

- Devices treated with a chemical germicide
- Devices rinsed to remove chemical residues, resulting in a wet end product

Alternatively, terminal sterilization delivers a sterility assurance level of 10^{-6}

- Devices are wrapped, providing a sterile barrier
- Devices are not immersed in liquid, resulting in a dry end product

Q: What are some best practices relating to sterility assurance?

A: As discussed previously, it's important to remember that a sterilized device is one that meets the sterility assurance level of 10^{-6}. Biological indicators (BIs) are the gold standard for sterility because they provide the verification needed to confirm that a sterilization cycle reached a sterility assurance level of 10^{-6}. A BI is the only

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direct measure of the lethality of the sterilization process so it is important for the user to understand what the quality monitors are for each system they own and whether a sterility assurance level of 10^{-6} is verified as part of the sterilization process. Liquid chemical sterilant processing systems are not sterilizers. They comply with the regulatory standards of HLDs and do not provide a sterility assurance level of 10^{-6}.

One of the biggest challenges regarding sterility assurance is ensuring staff is properly trained and competent in the tasks involved with instrument reprocessing. This includes decontamination, packaging, loading, handling and storage. It is critical that all steps are followed correctly, or else sterility will be compromised. I always recommend that facilities have the manufacturer's instructions for use (IFU) easily accessible at all times. The IFU will provide the guidance needed for how to clean the device, package and choose the correct cycle on a validated sterilization modality. When using a sterilizer, be sure to look at all quality monitors. This includes physical monitors (e.g., temperature, pressure and time), chemical indicators (CI) and BIs. All three play an important role in assuring sterility. In addition, if your sterilizer has the feature of electronically documenting all of the instruments that are included in the cycle, use it. If a problem occurs, it will be much easier to identify the source.

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At ASP, we recognize that staff education is key to both addressing sterility assurance challenges and ensuring a user's success. ASP makes it a priority to provide its customers with educational tools that address these types of common challenges. In fact, I have recently been a part of developing the ASP STERRAD® NX® System tutorial series, which is comprised of video installments that discuss a variety of topics related to best practices in sterilization. Given the importance of sterility assurance, we have dedicated one of the chapters to monitoring and documentation in order to assure sterility. We have also created the STERRAD® Sterility Guide (SSG) – an easy-to-use, online tool available 24 hours a day, seven days a week. The SSG is designed to provide STERRAD® Systems customers with an up-to-date list of devices that fall within cleared sterility claims. With just a few clicks of the mouse, users can quickly determine if a device is listed on the SSG.

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Q: What best practices do you recommend for the use of AERs?

A: Historically, the HLD process has meant a manual, time-consuming method. Endoscopes reprocessed appropriately—in accordance with reprocessing and infection-control guidelines—pose virtually no risk of transmitting patient-borne or environmental microorganisms. However, numerous studies of manual reprocessing indicate there is widespread difficulty in achieving recommended standards for manual cleaning and great variability in the manual cleaning performed.

Reprocessing technologies have evolved to help reduce manual endoscope cleaning practices, which can potentially increase the risk of human error and exposure to infectious organisms. The use of automatic endoscope reprocessors (AERs) has helped replace some manual reprocessing practices. Now, endoscope cleaner and reprocessors (ECRs) are available, which are fully automated HLD systems that eliminate the need for manual cleaning.*

Reprocessing technologies have evolved to help reduce manual endoscope cleaning practices, which can potentially increase the risk of human error and exposure to infectious organisms.

More and more, SPDs are using the EVOTECH® Endoscope Cleaner and Reprocessor (ECR) technology in the OR. The EVOTECH® ECR offers quick turnaround time, allowing users to focus more on their patients and less on reprocessing. The dual independent basins of the EVOTECH® ECR offer cleaning* and reprocessing of flexible endoscopes in 33 minutes or less.

The EVOTECH® ECR also offers complete monitoring of critical cycle parameters including minimum effective concentration or MEC, block detection, temperature, pressure and time, ensuring compliance throughout the process. The onboard MEC monitor of EVOTECH® ECR assures the amount of CIDEX® OPA•C Solution in use is correct for each cycle and endoscope, while eliminating the need for test strips and reducing worker exposure to chemicals. In addition, each endoscope channel is connected to a separate pump for proper perfusion based on endoscope make and model, allowing for automatic leak and blockage detection. This ensures the EVOTECH® ECR can maintain positive pressure in the endoscope to avoid fluid invasion and damage to the endoscope during reprocessing.

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Lastly, the EVOTECH® ECR printer provides a complete record of all key information including endoscope, operator, physician and patient data, as well as cycle information process start and end times, MEC status, disinfection time, leak test information and cycle stage times.

*Does not eliminate bedside pre-cleaning. Manual cleaning of medical devices (endoscopes) is not required prior to placement in the EVOTECH® ECR when selecting those cycles that contain a wash stage.

Q: Which guidelines are most critical to follow? The recently updated multi-society guidelines for reprocessing flexible scopes address a few issues such as hang time and microbial surveillance testing – can you comment on these and any other issues that may be confusing, controversial or unresolved?

A: There are many guidelines supporting best practices in flexible endoscope reprocessing, and it is important for each facility to review all of the scientific data and recommended practices available. This knowledge will allow facilities to develop policies and procedures ideal for their facilities.

At ASP, we have a team of clinical education consultants that can provide education training – and we also have resources available. ASP recently launched the Professional Education & Learning Solutions website (http://www.ASPJJ.com/us/prof-ed), which houses recent research, standards and regulations online in one central location.

Q: How can sterile processing departments and infection control departments work together to improve practices?

A: Both SPD staff and the infection preventionists have core competencies in various areas of infection prevention that can be shared to develop helpful tools and protocols for working together. The SPD staff has an opportunity to educate the infection preventionist on the process and standards in instrument reprocessing and what challenges they face to meet the demands of a busy OR schedule. The infection preventionist has expertise in surveillance and process and can assist and support the SPD in making changes to provide the highest standard of care in instrument reprocessing in the facility. I recommend that the SPD and the facility's infection preventionist work to take a collaborative approach to infection prevention, leveraging each other's expertise to benefit the patients we serve.

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Microbiology Issues, Biocompatibility are Key to Disinfection and Sterilization

A Q&A with Charles Roberts

ICT spoke with Charles Roberts, MS, RM (AAM), director of research, microbiology and chemistry for Advanced Sterilization Products, regarding the importance of following manufacturers' instructions for use and other critical considerations.

Q: Biocompatibility may not be something that is easily understood by many working in infection prevention and sterile processing – what should these professionals know as it relates to their work?

A: Biocompatibility is a measure of how a device or instrument will react with the human body. Ideally, a device should be relatively inert and not elicit any undesirable reaction in the patient. This depends on many factors, including the type of materials used in the construction of the device and the presence of chemicals that can leach out of materials or other residues that may be present after reprocessing. It is very important to follow the Instructions for Use (IFU), from both the device manufacturer and the manufacturer of any reprocessing equipment or chemicals, especially instructions for rinsing, to prevent any undesirable reaction in the patient.

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Q: As a microbiologist, what do you wish infection preventionists knew more about when it comes to proper disinfection and sterilization practices?

A: As a microbiologist, I can't emphasize enough the importance of device cleaning before disinfection or sterilization. Whether chemical or physical methods are employed for disinfection or sterilization, if the killing agent cannot come into direct contact with the microorganisms, there is a risk that the microorganisms can survive the process. Additionally, the cleaning process alone before disinfection or sterilization can greatly reduce the numbers of microorganisms contaminating a device. This provides for an even greater margin of safety.

Q: What are your suggestions for sorting through all of the choices when it comes to the selection of the right high-level disinfection system/AER or sterilizer?

A: Effective, reproducible cleaning is the first, critical step in reprocessing and a machine that can automate this task, taking away human variability, is a big advantage. Also, consider the compatibility of the process with materials commonly used in the construction of medical devices. When thinking about temperature-sensitive materials like plastics and electronic components, other processes must be considered, such as low-temperature, hydrogen peroxide gas plasma sterilization technology. Low-temperature, hydrogen peroxide gas plasma sterilization systems offer the advantage of fast processing times and safety as the break-down products of hydrogen peroxide are water and oxygen.

As a microbiologist, I can't emphasize enough the importance of device cleaning before disinfection or sterilization. Whether chemical or physical methods are employed for disinfection or sterilization, if the killing agent cannot come into direct contact with the microorganisms, there is a risk that the microorganisms can survive the process.

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