Disinfection and Sterilization In Healthcare Facilities

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INTRODUCTION

Each year in the United States there are approximately 46,500,000 surgical procedures and an even larger number of invasive medical procedures. For example, there are at least 5 million gastrointestinal endoscopies per year. Each of these procedures involves contact by a medical device or surgical instrument with a patient’s sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of infection. Failure to properly disinfect or sterilize equipment carries not only the risk associated with breach of the host barriers but the additional risk of person-to-person transmission (e.g., hepatitis B virus) and transmission of environmental pathogens (e.g., Pseudomonas aeruginosa).

Achieving disinfection and sterilization through the use of disinfectants and sterilization practices is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Since it is unnecessary to sterilize all patient-care items, healthcare policies must identify whether cleaning, disinfection, or sterilization is indicated based primarily on the items' intended use. Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization. Failure to comply with scientifically-based guidelines has led to numerous outbreaks. In this chapter, a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes is presented, based on well-designed studies assessing the efficacy (via laboratory investigations) and effectiveness (via clinical studies) of disinfection and sterilization procedures.

DEFINITION OF TERMS

Sterilization is the complete elimination or destruction of all forms of microbial life and is accomplished in healthcare facilities by either physical or chemical processes. Steam under pressure, dry heat, ethylene oxide (ETO) gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in healthcare facilities. Sterilization is intended to convey an absolute meaning, not a relative one. Unfortunately, some health professionals as well as the technical and commercial literature refer to "disinfection" as "sterilization" and items as "partially sterile." When chemicals are used for the purposes of destroying all forms of microbiological life, including fungal and bacterial spores, they may be called chemical sterilants. These same germicides used for shorter exposure periods may also be part of the disinfection process (i.e., high-level disinfection).

Disinfection describes a process that eliminates many or all-pathogenic microorganisms on inanimate objects with the exception of bacterial spores. Disinfection is usually accomplished by the use of liquid chemicals or wet pasteurization in healthcare settings. The efficacy of disinfection is affected by a number of factors, each of which may nullify or limit the efficacy of the process. Some of the factors that affect both disinfection and sterilization efficacy are the prior cleaning of the object; the organic and inorganic load present; the type and level of microbial contamination; the concentration of and exposure time to the germicide; the nature of the object (e.g., crevices, hinges, and lumens); the presence of biofilms; the temperature and pH of the disinfection process; and, in some cases, the relative humidity of the sterilization process (e.g., ethylene oxide).

By definition then, disinfection differs from sterilization by its lack of sporicidal property, but this is an oversimplification. A few disinfectants will kill spores with prolonged exposure times (3-12 hours) and are called chemical sterilants. At similar concentrations but with shorter exposure periods (e.g., 20 minutes for 2% glutaraldehyde) these same disinfectants will kill all microorganisms with the exception of large numbers of bacterial spores and are called high-level disinfectants. Low-level disinfectants may kill most vegetative bacteria, some fungi, and some viruses in a practical period of time (<10 minutes), whereas intermediate-level disinfectants may be cidal for mycobacteria, vegetative bacteria, most viruses, and most fungi but do not necessarily kill bacterial spores. The germicides differ markedly among themselves primarily in their antimicrobial spectrum and rapidity of action. Table 1 will be discussed later and consulted in this context.

Cleaning, on the other hand, is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces, and it normally is accomplished by manual or mechanical means using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization since inorganic and organic materials that remain on the surfaces of instruments interfere
with the effectiveness of these processes. Also, if the soiled materials become dried or baked 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. Decontamination is a procedure that removes pathogenic microorganisms from objects so they are safe to handle, use or discard.

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

A RATIONAL APPROACH TO DISINFECTION AND STERILIZATION

Over 30 years ago, Earle H. Spaulding devised a rational approach to disinfection and sterilization of patient-care items or equipment. This classification scheme is so clear and logical that it has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization. Spaulding believed that the nature of disinfection could be understood more readily if instruments and items for patient care were divided into three categories based on the degree of risk of infection involved in the use of the items. The three categories he described were critical, semicritical, and noncritical.

Critical Items

Critical items are so called because of the high risk of infection if such an item is contaminated with any microorganism, including bacterial spores. Thus, it is critical that objects that enter sterile tissue or the vascular system be sterile because any microbial contamination could result in disease transmission. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. Most of the items in this category should be purchased as sterile or be sterilized by steam sterilization if possible. If heat-sensitive, the object may be treated with ETO, hydrogen peroxide gas plasma, or by liquid chemical sterilants if other methods are unsuitable. Table 1 lists the sterilization processes that may be used for critical items and it lists several germicides categorized as chemical sterilants. The chemical sterilants include ≥2.4% glutaraldehyde-based formulations, 0.95% glutaraldehyde with 1.64% phenol/phenate, 7.5% stabilized hydrogen peroxide, 7.35% hydrogen peroxide with 0.23% peracetic acid, 0.2% peracetic acid, and 0.08% peracetic acid with 1.0% hydrogen peroxide. Liquid chemical sterilants can be relied upon to produce sterility only if cleaning, to eliminate organic and inorganic material, precedes treatment and if proper guidelines as to concentration, contact time, temperature, and pH are met.

Semicritical Items

Semicritical items are those that come in contact with mucous membranes or nonintact skin. Respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades, esophageal manometry probes, anorectal manometry catheters, and diaphragm fitting rings are included in this category. These medical devices should be free of all microorganisms, although small numbers of bacterial spores may be present. Intact mucous membranes, such as those of the lungs or the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms such as bacteria, mycobacteria, and viruses. Semicritical items minimally require high-level disinfection using chemical disinfectants (see Table 1). Glutaraldehyde, hydrogen peroxide, orthophthalaldehyde, and peracetic acid with hydrogen peroxide are cleared by the Food and Drug Administration (FDA) and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met (Table 1). When a disinfectant is selected for use with certain patient-care items, the chemical compatibility after extended use with the items to be disinfected also must be considered.
The complete elimination of all microorganisms in or on an instrument with the exception of small numbers of bacterial spores is the traditional definition of high-level disinfection. FDA’s definition of high-level disinfection is a chemical sterilant used for a shorter contact time to achieve a 6-log₁₀ kill of an appropriate mycobacterium species. Cleaning followed by high-level disinfection should eliminate sufficient pathogens to prevent transmission of infection.₁⁷,₁⁸

Laparoscopes and arthroscopes entering sterile tissue ideally should be sterilized between patients. However, they sometimes undergo only high-level disinfection between patients in the United States.₁⁹-₂¹ As with flexible endoscopes, these devices may be difficult to clean and high-level disinfect/sterilize due to intricate device design (e.g., long narrow lumens, hinges). Meticulous cleaning must precede any high-level disinfection/sterilization process. Although sterilization is preferred, there are no published outbreaks resulting following high-level disinfection of these scopes when properly cleaned and high-level disinfected. Newer models of these instruments can withstand steam sterilization that for critical items would be preferable to high-level disinfection.

Semicritical items should be rinsed with sterile water after high-level disinfection to prevent their contamination with organisms that may be present in tapwater, such as nontuberculous mycobacteria,₈,₂² Legionella,₂³,₂⁴ or gram-negative bacilli such as Pseudomonas.₁³,₁⁵,₂⁶-₂⁷ In circumstances where rinsing with sterile water rinse is not feasible, a tapwater or filtered water (0.₂µ filter) rinse should be followed by an alcohol rinse and forced air drying.₁⁹,₂⁷,₂⁸ Forced-air drying markedly reduces bacterial contamination of stored endoscopes, most likely by removing the wet environment favorable for bacterial growth.₂⁸ After rinsing, items should be dried and stored (e.g., packaged) in a manner that protects them from recontamination.

Noncritical Items

Noncritical items are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is "not critical." Examples of noncritical items are bedpans, blood pressure cuffs, crutches, bed rails, linens, some food utensils, bedside tables, patient furniture, and floors. In contrast to critical and some semicritical items, most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. There is virtually no documented risk of transmitting infectious agents to patients via noncritical items when they are used as noncritical items and do not contact non-intact skin and/or mucous membranes. However, these items (e.g., bedside tables, bed rails) could potentially contribute to secondary transmission by contaminating hands of healthcare workers or by contact with medical equipment that will subsequently come in contact with patients.₉,₂⁹-₃² Table 1 lists several low-level disinfectants that may be used for noncritical items. The exposure time listed in Table 1 is less than or equal to 10 minutes. Most Environmental Protection Agency (EPA)-registered disinfectants have a 10-minute label claim. However, multiple investigators have demonstrated the effectiveness of these disinfectants against vegetative bacteria (e.g., Listeria, Escherichia coli, Salmonella, vancomycin-resistant Enterococci [VRE], methicillin-resistant Staphylococcus aureus [MRSA]), yeasts (e.g., Candida), mycobacteria (e.g., M. tuberculosis), and viruses (e.g. poliovirus) at exposure times of 30 to 60 seconds.₃₀-₃⁹ Disinfect noncritical medical equipment (e.g., blood pressure cuff) and noncritical surfaces (e.g., bedside table) with a EPA-registered disinfect or disinfectant/detergent at the proper use-dilution and a contact time of at least 30 to 60 seconds.₄⁰

Mops and reusable cleaning cloths are regularly used to achieve low-level disinfection. However, they are commonly not kept adequately cleaned and disinfected, and if the water-disinfectant mixture is not changed regularly (e.g., after every three to four rooms, no longer than 60 minute intervals), the mopping procedure may actually spread heavy microbial contamination throughout the healthcare facility.₄¹ In one study, standard laundering provided acceptable decontamination of heavily contaminated mopheads but chemical disinfection with a phenolic was less effective.₄¹ The frequent laundering of mops (e.g., daily) is, therefore, recommended.
DISINFECTION

A great number of 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. With some exceptions (e.g., ethanol or bleach), commercial formulations based on these chemicals are considered unique products and must be registered with the EPA or cleared by the FDA. In most instances, a given product is designed for a specific purpose and is to be used in a certain manner. Therefore, the label should be read carefully to ensure that the right product is selected for the intended use and applied in an efficient manner.

Disinfectants are not interchangeable and an overview of the performance characteristics of each is provided below so the user has sufficient information to select an appropriate disinfectant for any item and use it in the most efficient way. It should be recognized that excessive costs may be attributed to incorrect concentrations and inappropriate disinfectants. Finally, occupational diseases among cleaning personnel have been associated with the use of several disinfectants such as formaldehyde, glutaraldehyde, chlorine and others, and precautions (e.g., gloves, proper ventilation) should be used to minimize exposure. \textsuperscript{42} \textsuperscript{43} Asthma and reactive airway disease may occur in sensitized individuals exposed to any airborne chemical including germicides. Clinically important asthma may occur at levels below ceiling levels regulated by Occupational Safety and Health Administration (OSHA). The preferred method of control is to eliminate the chemical (via engineering controls, or substitution) or relocate the worker.

Chemical Disinfectants

Alcohol

In the healthcare setting, "alcohol" refers to two water-soluble chemical compounds whose germicidal characteristics are generally underrated: ethyl alcohol and isopropyl alcohol. \textsuperscript{44} These alcohols are rapidly bactericidal rather than bacteriostatic against vegetative forms of bacteria; they also are tuberculocidal, fungicidal, and virucidal but do not destroy bacterial spores. Their cidal activity drops sharply when diluted below 50% concentration and the optimum bactericidal concentration is in the range of 60-90% solutions in water (volume/volume). \textsuperscript{45} \textsuperscript{46}

Alcohols are not recommended for sterilizing medical and surgical materials principally because of their lack of sporicidal action and their inability to penetrate protein-rich materials. Fatal post-operative wound infections with \textit{Clostridium} have occurred when alcohols were used to sterilize surgical instruments contaminated with bacterial spores. \textsuperscript{47} Alcohols have been used effectively to disinfect oral and rectal thermometers, hospital pagers, scissors, stethoscopes, and fiberoptic endoscopes. \textsuperscript{48} Alcohol towelettes have been used for years to disinfect small surfaces such as rubber stoppers of multiple-dose medication vials or vaccine bottles. \textsuperscript{48} Beck-Sague and Jarvis described three bloodstream infection outbreaks when alcohol was used to disinfect transducer heads in an intensive care setting. \textsuperscript{49}

Alcohols are flammable and consequently must be stored in a cool, well-ventilated area. They also evaporate rapidly and this makes extended exposure time difficult to achieve unless the items are immersed.

Chlorine and Chlorine Compounds

Hypochlorites are the most widely used of the chlorine disinfectants and are available in a liquid (e.g., sodium hypochlorite) or solid (e.g., calcium hypochlorite) form. The most prevalent chlorine products in the United States are aqueous solutions of 5.25% to 6.15% sodium hypochlorite, which usually are called household bleach. They have a broad spectrum of antimicrobial activity (i.e., bactericidal, virucidal, fungicidal, mycobactericidal, sporicidal), do not leave toxic residues, are unaffected by water hardness, are inexpensive and fast acting, \textsuperscript{50} remove dried or fixed organisms and biofilms from surfaces, \textsuperscript{51} and a low incidence of serious toxicity. \textsuperscript{52} Sodium hypochlorite at the concentration used in domestic bleach (5.25-6.15%) may produce ocular irritation or oropharyngeal, esophageal, and gastric burns. \textsuperscript{43} \textsuperscript{53} \textsuperscript{54} Other disadvantages of hypochlorites include corrosiveness to metals in high concentrations (>500 ppm), inactivation by organic matter, discoloring or "bleaching" of
fabrics, release of toxic chlorine gas when mixed with ammonia or acid (e.g., household cleaning agents) and relative stability.  

Reports have examined the microbicidal activity of a new disinfectant, “superoxidized water”. The concept of electrolyzing saline to create a disinfectant or antiseptics is appealing as the basic materials of saline and electricity are cheap and the end product (i.e., water) is not damaging to the environment. The main products of this water are hypochlorous acid (e.g., at a concentration of about 144 mg/l) and chlorine. As with any germicide, the antimicrobial activity of superoxidized water is strongly affected by the concentration of the active ingredient (available free chlorine) \( \text{mg} / \text{l} \). Data have shown that freshly generated superoxidized water is rapidly effective (<2 minutes) in achieving a 5-log \( \log_{10} \) reduction of pathogenic microorganisms (i.e., \( M. \) tuberculosis, \( M. \) chelonae, poliovirus, HIV, MRSA, \( E. \) coli, \( C. \) albicans, \( E. \) faecalis, \( P. \) aeruginosa) in the absence of organic loading. However, the biocidal activity of this disinfectant was substantially reduced in the presence of organic material (5% horse serum) \(^{58, 59} \).

Hypochlorites are widely used in healthcare facilities in a variety of settings. \(^{50} \) Inorganic chlorine solution is used for disinfecting tonometer heads and for spot disinfection of counter tops and floors. A 1:10 to 1:100 dilution of 5.25-6.15% sodium hypochlorite (i.e., household bleach) \(^{61-64} \) or an EPA-registered tuberculocidal disinfectant \(^{13} \) has been recommended for decontaminating blood spills. For small spills of blood (i.e., drops of blood) on noncritical surfaces, the area can be disinfected with a 1:100 dilution of 5.25-6.15% sodium hypochlorite or an EPA-registered tuberculocidal disinfectant. Since hypochlorites and other germicides are substantially inactivated in the presence of blood, \(^{39, 65} \) large spills of blood require that the surface be cleaned before an EPA-registered disinfectant or a 1:10 (final concentration) solution of household bleach is applied. If there is a possibility of a sharps injury, there should be an initial decontamination, \(^{43, 66} \) followed by cleaning and terminal disinfection (1:10 final concentration) \(^{39} \). Extreme care should always be employed to prevent percutaneous injury. At least 500 ppm available chlorine for 10 minutes is recommended for decontamination of cardiopulmonary resuscitation training manikins. Other uses in healthcare include as an irrigating agent in endodontic treatment and for disinfecting manikins, laundry, dental appliances, hydrotherapy tanks, and regulated medical waste before disposal, \(^{50} \) and the water distribution system in hemodialysis centers and hemodialysis machines. \(^{48} \) Hyperchlorination of a Legionella-contaminated hospital water system \(^{67} \) resulted in a dramatic decrease (30% to 1.5%) in the isolation of \( L. \) pneumophila from water outlets and a cessation of healthcare-associated Legionnaires’ disease in the affected unit. \(^{68} \) Chloramine T and hypochlorites have been used in disinfecting hydrotherapy equipment. \(^{48} \) Hypochlorite solutions in tapwater at a pH>8 stored at room temperature (23\(^\circ\)C) in closed, opaque plastic containers may lose up to 40-50% of their free available chlorine level over a period of one month. Thus, if a user wished to have a solution containing 500 ppm of available chlorine at day 30, a solution containing 1000 ppm of chlorine should be prepared at time 0. There is no decomposition of sodium hypochlorite solution after 30 days when stored in a closed brown bottle. \(^{56} \)

Glutaraldehyde

Glutaraldehyde is a saturated dialdehyde that has gained wide acceptance as a high-level disinfectant and chemical sterilant. \(^{69} \) Aqueous solutions of glutaraldehyde are acidic and generally in this state are not sporicidal. Only when the solution is “activated” (made alkaline) by use of alkalinating agents to pH 7.5 to 8.5 does the solution become sporicidal. Once “activated” these solutions have a shelf-life of minimally 14 days because of the polymerization of the glutaraldehyde molecules at alkaline pH levels. This polymerization blocks the active sites (aldehyde groups) of the glutaraldehyde molecules that are responsible for its biocidal activity. \(^{48, 70, 71} \) Novel glutaraldehyde formulations (e.g., glutaraldehyde-phenol-sodium phenate, potentiated acid glutaraldehyde, stabilized alkaline glutaraldehyde) produced in the past 30 years have overcome the problem of rapid loss of activity (e.g., use-life 28 to 30 days) while generally maintaining excellent microbicidal activity. \(^{48, 70, 71} \) However, it should be recognized that antimicrobial activity is dependent not only on age but also on use conditions such as dilution and organic stress. The use of glutaraldehyde-based solutions in healthcare facilities is widespread because of their advantages that
include: excellent biocidal properties; activity in the presence of organic matter (20% bovine serum); and noncorrosive action to endoscopic equipment, thermometers, rubber, or plastic equipment. The advantages, disadvantages, and characteristics of glutaraldehyde are listed in Table 2.

The in vitro inactivation of microorganisms by glutaraldehydes has been extensively investigated and reviewed. Several investigators showed that >2% aqueous solutions of glutaraldehyde, buffered to pH 7.5 to 8.5 with sodium bicarbonate, were effective in killing vegetative bacteria in <2 minutes; M. tuberculosis, fungi, and viruses in <10 minutes; and spores of Bacillus and Clostridium species in 3 hours. Spores of Clostridium difficile are more rapidly killed by 2% glutaraldehyde than are spores of other species of Clostridium and Bacillus. There have been reports of microorganisms with significant resistance to glutaraldehyde, including some mycobacteria (Mycobacterium chelonae, M. avium-intracellulare, M. xenopi), Methylobacterium mesophilicum, Trichosporon, fungal ascospores (e.g., Microascus cinereus, Cheatomium globosum), and Cryptosporidium. M. chelonae persisted in a 0.2% glutaraldehyde solution used to store porcine prosthetic heart valves.

Dilution of glutaraldehyde during use commonly occurs and studies show a glutaraldehyde concentration decline after a few days of use in an automatic endoscope washer. This occurs because instruments are not thoroughly dried and water is carried in with the instrument, which increases the solution’s volume and dilutes its effective concentration. This emphasizes the need to ensure that semicritical equipment is disinfected with an acceptable concentration of glutaraldehyde. Data suggest that 1.0% to 1.5% glutaraldehyde is the minimum effective concentration for >2% glutaraldehyde solutions when used as a high-level disinfectant. Chemical test strips or liquid chemical monitors are available for determining whether an effective concentration of glutaraldehyde is present despite repeated use and dilution. The frequency of testing should be based on how frequently the solutions are used (e.g., used daily, test daily; used weekly, test before use; used 30 times per day, test each tenth use) but the strips should not be used to extend the use life beyond the expiration date. Data suggest the chemicals in the test strip deteriorate with time and a manufacturer’s expiration date should be placed on the bottles. The bottle of test strips should be dated when opened and used for the period of time indicated on the bottle (e.g., 120 days). The results of test strip monitoring should be documented. The glutaraldehyde test kits have been preliminarily evaluated for accuracy and range but the reliability has been questioned. The concentration should be considered unacceptable or unsafe when the test indicates a dilution below the product’s minimum effective concentration or MEC (generally to 1.0 to 1.5% glutaraldehyde or lower) by the indicator not changing color.

Glutaraldehyde is used most commonly as a high-level disinfectant for medical equipment such as endoscopes, spirometry tubing, dialyzers, transducers, anesthesia and respiratory therapy equipment, hemodialysis proportioning and dialysate delivery systems, and reuse of laparoscopic disposable plastic trocars. Glutaraldehyde is noncorrosive to metal and does not damage lensed instruments, rubber or plastics. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 25°C range from 20-90 minutes depending upon the product. However, multiple scientific studies and professional organizations support the efficacy of >2% glutaraldehyde for 20 minutes at 20°C. Minimally, follow this latter recommendation. Glutaraldehyde should not be used for cleaning noncritical surfaces as it is too toxic and expensive.

Colitis believed due to glutaraldehyde exposure from residual disinfecting solution in the endoscope solution channels has been reported and is preventable by careful endoscope rinsing. One study found that residual glutaraldehyde levels were higher and more variable after manual disinfection (<0.2-159.5 mg/l) than after automatic disinfection (0.2-6.3 mg/l). Similarly, keratopathy and corneal decompensation were caused by ophthalmic instruments that were inadequately rinsed after soaking in 2% glutaraldehyde. Glutaraldehyde exposure should be monitored to ensure a safe work environment. In the absence of an OSHA PEL, if the glutaraldehyde level is higher than the ACGIH ceiling limit of 0.05 ppm, it would be prudent to take corrective action and repeat monitoring.

Hydrogen Peroxide

The literature contains several accounts of the properties, germicidal effectiveness, and potential uses for stabilized hydrogen peroxide in the healthcare setting. Published reports ascribe good
germicidal activity to hydrogen peroxide have been published and attest to its bactericidal, virucidal, sporicidal, and fungicidal properties. The advantages, disadvantages, and characteristics of hydrogen peroxide are listed in Table 2. As with other chemical sterilants, dilution of the hydrogen peroxide must be monitored by regularly testing the minimum effective concentration (i.e., 7.5 to 6.0%). Follow the FDA-cleared label claim for high-level disinfection (i.e., 30 minutes at 20°C for 7.5% hydrogen peroxide).

Commercially available 3% hydrogen peroxide is a stable and effective disinfectant when used on inanimate surfaces. It has been used in concentrations from 3 to 6% for the disinfection of soft contact lenses (e.g., 3% for 2-3 hrs), tonometer biprisms, ventilators, fabrics and endoscopes. Hydrogen peroxide was effective in spot-disinfecting fabrics in patients’ rooms. Corneal damage from a hydrogen peroxide-soaked tonometer tip that was not properly rinsed has been reported. Hydrogen peroxide also has been instilled into urinary drainage bags in an attempt to eliminate the bag as a source of bladder bacteriuria and environmental contamination. While the instillation of hydrogen peroxide into the bag reduced microbial contamination of the bag, this procedure did not reduce the incidence of catheter-associated bacteriuria.

Iodophors

Iodine solutions or tinctures have long been used by health professionals, primarily as antiseptics on skin or tissue. FDA has not cleared any liquid chemical sterilant/high level disinfectants with iodophors as the main active ingredient. Iodophors, on the other hand, have been used both as antiseptics and disinfectants. An iodophor is a combination of iodine and a solubilizing agent or carrier; the resulting complex provides a sustained-release reservoir of iodine and releases small amounts of free iodine in aqueous solution. The best known and most widely used iodophor is povidone-iodine, a compound of polyvinylpyrrolidone with iodine. This product and other iodophors retain the germicidal efficacy of iodine but unlike iodine are generally nonstaining and are relatively free of toxicity and irritancy.

There are several reports that documented intrinsic microbial contamination of antiseptic formulations of povidone-iodine and poloxamer-iodine. It was found that “free” iodine (I₂) contributes to the bactericidal activity of iodophors and dilutions of iodophors demonstrate more rapid bactericidal action than does a full-strength povidone-iodine solution. Therefore, iodophors must be diluted according to the manufacturers’ directions to achieve antimicrobial activity.

Published reports on the in vitro antimicrobial efficacy of iodophors demonstrate that iodophors are bactericidal, mycobactericidal, and virucidal but may require prolonged contact times to kill certain fungi and bacterial spores. Besides their use as an antiseptic, iodophors have been used for the disinfection of blood culture bottles and medical equipment such as hydrotherapy tanks, thermometers, and in the past, endoscopes. Antiseptic iodophors are not suitable for use as hard-surface disinfectants because of concentration differences. Iodophors formulated as antiseptics contain less free iodine than those formulated as disinfectants. Iodine or iodine-based antiseptics should not be used on silicone catheters as the silicone tubing may be adversely affected.

Ortho-phthalaldehyde (OPA)

Ortho-phthalaldehyde is a high-level disinfectant that received FDA clearance in October 1999. It contains 0.55% 1,2-benzenedicarboxaldehyde or OPA. OPA solution is a clear, pale-blue liquid with a pH of 7.5. The advantages, disadvantages, and characteristics of OPA are listed in Table 2.

Studies have demonstrated excellent microbicidal activity in in vitro studies including superior mycobactericidal activity (5-log₁₀ reduction in 5 minutes) compared to glutaraldehyde. Walsh and colleagues also found OPA effective (>5-log₁₀ reduction) against a wide range of microorganisms, including glutaraldehyde-resistant mycobacteria and Bacillus atrophaeus spores.

OPA has several potential advantages compared to glutaraldehyde. It has excellent stability over a wide pH range (pH 3-9), is not a known irritant to the eyes and nasal passages, does not require exposure monitoring, has a barely perceptible odor, and requires no activation. Repeated exposure to OPA, following manual reprocessing of urological instruments, may have resulted in hypersensitivity in
some patients with a history of bladder cancer undergoing repeated cystoscopy. The manufacturer has taken the preventive measure of contraindicating the use of OPA for the reprocessing of urological instrumentation used to treat patients with a history of bladder cancer (Written communication, June 2004). OPA, like glutaraldehyde, has excellent material compatibility. A potential disadvantage of OPA is that it stains proteins gray (including unprotected skin) and thus must be handled with caution. However, skin staining would indicate improper handling that requires additional training and/or personal protective equipment (PPE) (gloves, eye and mouth protection, fluid-resistant gowns). OPA residues remaining on inadequately water-rinsed transesophageal echo probes may leave stains of the patient’s mouth. Meticulous cleaning, using the correct OPA exposure time (e.g., 12 minutes), and copious rinsing of the probe with water should eliminate this problem. PPE should be worn when handling contaminated instruments, equipment, and chemicals.

Peracetic Acid

Peracetic, or peroxyacetic, acid is characterized by a very rapid action against all microorganisms. Special advantages of peracetic acid is its lack of harmful decomposition products (i.e., acetic acid, water, oxygen, hydrogen peroxide), it enhances removal of organic material and leaves no residue. It remains effective in the presence of organic matter and is sporicidal even at low temperatures. Peracetic acid can corrode copper, brass, bronze, plain steel, and galvanized iron but these effects can be reduced by additives and pH modifications. The advantages, disadvantages, and characteristics of peracetic acid are listed in Tables 2 and 3.

Peracetic acid will inactivate gram-positive and gram-negative bacteria, fungi, and yeasts in ≤5 minutes at <100 ppm. In the presence of organic matter, 200-500 ppm is required. For viruses the dosage range is wide (12-2250 ppm), with poliovirus inactivated in yeast extract in 15 minutes with 1500 to 2250 ppm. An automated machine using peracetic acid to chemically sterilize medical (e.g., endoscopes, arthroscopes), surgical instruments is used in the United States. The sterilant, 35% peracetic acid, is diluted to 0.2% with filtered water at a temperature of 50°C. Simulated-use trials have demonstrated excellent microbicidal activity and three clinical trials have demonstrated both excellent microbial killing and no clinical failures leading to infection. Three clusters of infection using the peracetic acid automated endoscope reprocessor were linked to inadequately processed bronchoscopes when inappropriate channel connectors were used with the system. These clusters highlight the importance of training, proper model-specific endoscope connector systems, and quality control procedures to ensure compliance with endoscope manufacturer’s recommendations and professional organization guidelines. An alternative high-level disinfectant available in the United Kingdom contains 0.35% peracetic acid. Although this product is rapidly effective against a broad range of microorganisms, it tarnishes the metal of endoscopes and is unstable, resulting in only a 24-hour use life.

Peracetic Acid and Hydrogen Peroxide

One chemical sterilant is available that contains peracetic acid plus hydrogen peroxide (0.23% peracetic acid plus 7.35% hydrogen peroxide). The advantages, disadvantages, and characteristics of peracetic acid and hydrogen peroxide are listed in Table 2. The bactricidal properties of peracetic acid and hydrogen peroxide have been demonstrated. Manufacturer’s data demonstrated that this combination of peracetic acid and hydrogen peroxide inactivated all microorganisms with the exception of bacterial spores within 20 minutes. A 0.08% peracetic acid plus 1.0% hydrogen peroxide product (no longer available) was effective in inactivating a glutaraldehyde-resistant mycobacteria.

The combination of peracetic acid and hydrogen peroxide has been used for disinfecting hemodialyzers. The percentage of dialysis centers using a peracetic acid-hydrogen peroxide-based disinfectant for reprocessing dialyzers increased from 5% in 1983 to 56% in 1997.

Phenolics

Phenol has occupied a prominent place in the field of hospital disinfection since its initial use as a germicide by Lister in his pioneering work on antisepic surgery. In the past 30 years, however, work
has been concentrated upon the numerous phenol derivatives or phenolics and their antimicrobial properties. Phenol derivatives originate when a functional group (e.g., alkyl, phenyl, benzyl, halogen) replaces one of the hydrogen atoms on the aromatic ring. Two phenol derivatives commonly found as constituents of hospital disinfectants are ortho-phenylphenol and ortho-benzyl-para-chlorophenol.

Published reports on the antimicrobial efficacy of commonly used phenolics showed that they were bactericidal, fungicidal, virucidal, and tuberculocidal. Many phenolic germicides are EPA-registered as disinfectants for use on environmental surfaces (e.g., bedside tables, bedrails, laboratory surfaces) and noncritical medical devices. Phenolics are not FDA-cleared as high-level disinfectants for use with semicritical items but could be used to preclean or decontaminate critical and semicritical devices prior to terminal sterilization or high-level disinfection.

The use of phenolics in nurseries has been questioned because of the occurrence of hyperbilirubinemia in infants placed in bassinets where phenolic detergents were used. In addition, Doan and co-workers demonstrated bilirubin level increases in phenolic-exposed infants compared to nonphenolic-exposed infants when the phenolic was prepared according to the manufacturers’ recommended dilution. If phenolics are used to clean nursery floors, they must be diluted according to the recommendation on the product label. Phenolics (and other disinfectants) should not be used to clean infant bassinets and incubators while occupied. If phenolics are used to terminally clean infant bassinets and incubators, the surfaces should be rinsed thoroughly with water and dried before the infant bassinets and incubators are reused.

Quaternary Ammonium Compounds

The quaternary ammonium compounds are widely used as surface disinfectants. There have been some reports of healthcare-associated infections associated with contaminated quaternary ammonium compounds used to disinfect patient-care supplies or equipment such as cystoscopes or cardiac catheters. As with several other disinfectants (e.g., phenolics, iodophors) gram-negative bacteria have been found to survive or grow in them. Results from manufacturers’ data sheets and from published scientific literature indicate that the quaternaries sold as hospital disinfectants are generally fungicidal, bactericidal, and virucidal against lipophilic (enveloped) viruses; they are not sporidical and generally not tuberculocidal or virucidal against hydrophilic (nonenveloped) viruses. Best et al. and Rutala et al. demonstrated the poor mycobactericidal activities of quaternary ammonium compounds.

The quaternaries are commonly used in ordinary environmental sanitation of noncritical surfaces such as floors, furniture, and walls. EPA-registered quaternary ammonium compounds are appropriate to use when disinfecting medical equipment that come into contact with intact skin (e.g., blood pressure cuffs).

Pasteurization

Pasteurization is not a sterilization process; its purpose is to destroy all pathogenic microorganisms with the exception of bacterial spores. The time-temperature relation for hot-water pasteurization is generally >70°C (158°F) for 30 minutes. The water temperature and time should be monitored as part of a quality assurance program. Pasteurization of respiratory therapy and anesthesia equipment is a recognized alternative to chemical disinfection.

STERILIZATION

Most medical and surgical devices used in healthcare facilities are made of materials that are heat stable and thus are sterilized by 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) have been developed and are being used to sterilize medical devices. This section reviews sterilization technologies used in healthcare and makes recommendations for their optimum performance in the processing of medical devices.

Sterilization destroys all microorganisms on the surface of an article or in a fluid to prevent disease transmission associated with the use of that item. While the use of inadequately sterilized
critical items represents a high risk of transmitting pathogens, documented transmission of pathogens associated with an inadequately sterilized critical item is exceedingly rare. This is likely due to the wide margin of safety associated with the sterilization processes used in healthcare facilities. The concept of what constitutes "sterile" is measured as a probability of sterility for each item to be sterilized. This probability is commonly referred to as the sterility assurance level (SAL) of the product and is defined as the probability of a single viable microorganism occurring on a product after sterilization. SAL is normally expressed a $10^{-n}$. For example, if the probability of a spore surviving were one in one million, the SAL would be $10^{-6}$. In short, a SAL is an estimate of lethality of the entire sterilization process and is a conservative calculation. Dual SALs (e.g., $10^{-2}$ 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). A summary of the advantages and disadvantages for commonly used sterilization technologies is presented in Table 3.

Steam Sterilization

Of all the methods available for sterilization, moist heat in the form of saturated steam under pressure is the most widely used and the most dependable. Steam sterilization is nontoxic, inexpensive, rapidly microbicidal, sporicidal, and rapidly heats and penetrates fabrics (Table 3). Like all sterilization processes, steam sterilization has some deleterious effects on some materials, including corrosion and combustion of lubricants associated with dental handpieces; reduction in ability to transmit light associated with laryngoscopes; and increased hardening time (5.6 fold) with plaster-cast.

The basic principle of steam sterilization, as accomplished in an autoclave, is to expose each item to direct steam contact at the required temperature and pressure for the specified time. Thus, there are four parameters of steam sterilization: steam, pressure, temperature, and time. The ideal steam for sterilization is dry saturated steam and entrained water (dryness fraction ≥97%). Pressure serves as a means to obtain the high temperatures necessary to quickly kill microorganisms. Specific temperatures must be obtained to ensure the microbicidal activity. The two common steam-sterilizing temperatures are $121^\circ C$ ($250^\circ F$) and $132^\circ C$ ($270^\circ F$). These temperatures (and other high temperatures) must be maintained for a minimal time to kill microorganisms. Recognized minimum exposure periods for sterilization of wrapped healthcare supplies are 30 minutes at $121^\circ C$ ($250^\circ F$) in a gravity displacement sterilizer or 4 minutes at $132^\circ C$ ($270^\circ C$) in a prevacuum sterilizer. At constant temperatures, sterilization times vary depending on the type of item (e.g., metal versus rubber, plastic, items with lumens), whether the item is wrapped or unwrapped, and the sterilizer type.

The two basic types of steam sterilizers (autoclaves) are the gravity displacement autoclave and the high-speed prevacuum sterilizer. In the former, steam is admitted at the top or the sides of the sterilizing chamber and, because the steam is lighter than air, forces air out the bottom of the chamber through the drain vent. The gravity displacement autoclaves are primarily used to process laboratory media, water, pharmaceutical products, regulated medical waste, and nonporous articles whose surfaces have direct steam contact. For gravity displacement sterilizers the penetration time into porous items is prolonged because of incomplete air elimination. The high-speed prevacuum sterilizers are similar to the gravity displacement sterilizers except they are fitted with a vacuum pump (or ejector) to ensure air removal from the sterilizing chamber and load before the steam is admitted. The advantage of using a vacuum pump is that there is nearly instantaneous steam penetration even into porous loads.

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

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

The oldest and most recognized agent for inactivation of microorganisms is heat. D-values (time to reduce the surviving population by 90% or 1 log10) allow a direct comparison of the heat resistance of microorganisms. Because a D-value can be determined at various temperatures, a subscript is used to designate the exposure temperature (i.e., $D_{121^\circ C}$). $D_{121^\circ C}$-values for *Geobacillus stearothermophilus* used to monitor the steam sterilization process range from 1 to 2 minutes. Heat-resistant nonspore-forming bacteria, yeasts, and fungi have such low $D_{121^\circ C}$ values that they cannot be experimentally measured.

Steam sterilization should be used whenever possible on all critical and semicritical items that are heat and moisture resistant (e.g., steam sterilizable respiratory therapy and anesthesia equipment), even when not essential to prevent pathogen transmission. Steam sterilizers also are used in healthcare facilities to decontaminate microbiological waste and sharps containers, but additional exposure time is required in the gravity displacement sterilizer for these items.

**Flash Sterilization**

“Flash” steam sterilization was originally defined by Underwood and Perkins as sterilization of an unwrapped object at 132$^\circ$C for 3 minutes at 27-28 lbs. of pressure in a gravity displacement sterilizer. Currently, the time required for flash sterilization depends on the type of sterilizer and the type of item (i.e., porous vs non-porous items). For example, the minimum flash sterilization cycle time for nonporous items only (i.e., routine metal instruments, no lumens) at 270$^\circ$F in a prevacuum sterilizer is 3 minutes. Although the wrapped method of sterilization is preferred for the reasons listed below, correctly performed flash sterilization is an effective process for the sterilization of critical medical devices. Flash sterilization is a modification of conventional steam sterilization (either gravity or prevacuum) in which the flashed item is placed in an open tray or is placed in a specially designed, covered, rigid container to allow for rapid penetration of steam. Historically, it is not recommended as a routine sterilization method because of the lack of timely biological indicators to monitor performance, absence of protective packaging following sterilization, possibility for contamination of processed items during transportation to the operating rooms, and the sterilization cycle parameters (i.e., time, temperature, pressure) are minimal. To address some of these concerns, many healthcare facilities have done the following: placed equipment for flash sterilization in close proximity to operating rooms to facilitate aseptic delivery to the point of use (usually the sterile field in an ongoing surgical procedure); extended the exposure time to ensure lethality comparable to sterilized wrapped items (e.g., 4 minutes at 132$^\circ$C); used biological indicators that provide results in 1 hour for flash-sterilized items; and used protective packaging that permits steam penetration. Further, some rigid, reusable sterilization container systems have been designed and validated by the container manufacturer for use with flash cycles. When sterile items are open to air, they will eventually become contaminated. Thus, the longer a sterile item is exposed to air, the greater the number of microorganisms that will settle on it.

A few adverse events have been associated with flash sterilization. When evaluating an increased incidence of neurosurgical infections, the investigators noted that surgical instruments were flash sterilized between cases and 2 of 3 craniotomy infections involved plate implants that were flash sterilized. A report of two patients who received burns during surgery from instruments that had been flash sterilized reinforced the need to develop policies and educate staff to prevent the use of instruments hot enough to cause clinical burns. Staff should use precautions to prevent burns with potentially hot instruments (e.g., transport tray using heat-protective gloves). Patient burns may be prevented by either air-cooling the instruments or immersion in sterile liquid (e.g., saline).
Flash sterilization is considered acceptable for processing cleaned patient-care items that cannot be packaged, sterilized, and stored before use. It also is used when there is insufficient time to sterilize an item by the preferred package method. Flash sterilization should not be used for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time. Because of the potential for serious infections, flash sterilization is not recommended for implantable devices (i.e., devices placed into a surgically or naturally formed cavity of the human body); however, flash sterilization may be unavoidable for some devices (e.g., orthopedic screw, plates). If flash sterilization of an implantable device is unavoidable, recordkeeping (e.g., load identification, patient's name/hospital identifier, biological indicator result) is essential for epidemiological tracking (e.g., of surgical site infection, tracing results of biological indicators to patients who received the item to document sterility), and for an assessment of the reliability of the sterilization process (e.g., evaluation of biological monitoring records and sterilization maintenance records noting preventive maintenance and repairs with dates).

Ethylene Oxide "Gas" Sterilization

ETO is a colorless gas that is flammable and explosive. The four essential parameters (operational ranges) are: gas concentration (450 to 1200 mg/l); temperature (37 to 63°C); relative humidity (40 to 80%); water molecules carry ETO to reactive sites; and exposure time (1 to 6 hours). These influence the effectiveness of ETO sterilization. Within certain limitations, an increase in gas concentration and temperature may shorten the time necessary for achieving sterilization.

The main disadvantages associated with ETO are the lengthy cycle time, the cost, and its potential hazards to patients and staff; the main advantage is that it can sterilize heat- or moisture-sensitive medical equipment without deleterious effects on the material used in the medical devices (Table 3). Acute exposure to ETO may result in irritation (e.g., to skin, eyes, gastrointestinal or respiratory tracts) and central nervous system depression. Chronic inhalation has been linked to the formation of cataracts, cognitive impairment, neurologic dysfunction, and disabling polyneuropathies. Occupational exposure in healthcare facilities has been linked to hematologic changes and an increased risk of spontaneous abortions and various cancers. ETO should be considered a known human carcinogen.

The use of ETO evolved when few alternatives existed for sterilizing heat- and moisture-sensitive medical devices; however, favorable properties (Table 3) account for its continued widespread use. Two ETO gas mixtures are available to replace ETO-chlorofluorocarbon (CFC) mixtures for large capacity, tank-supplied sterilizers. The ETO-carbon dioxide (CO₂) mixture consists of 8.5% ETO and 91.5% CO₂. This mixture is less expensive than ETO-hydrochlorofluorocarbons (HCFC), but a disadvantage is the need for pressure vessels rated for steam sterilization, because higher pressures (28-psi gauge) are required. The other mixture, which is a drop-in CFC replacement, is ETO mixed with HCFC. HCFCs are approximately 50-fold less damaging to the earth's ozone layer than are CFCs. The EPA will begin regulation of HCFC in the year 2015 and will terminate production in the year 2030. Two companies provide ETO-HCFC mixtures as drop-in replacement for CFC-12; one mixture consists of 8.6% ETO and 91.4% HCFC, and the other mixture is composed of 10% ETO and 90% HCFC. An alternative to the pressurized mixed gas ETO systems is 100% ETO. The 100% ETO sterilizers using unit-dose cartridges eliminate the need for external tanks.

The excellent microbial activity of ETO has been demonstrated in several studies and summarized in published reports. ETO inactivates all microorganisms although bacterial spores (especially B. atrophaeus) are more resistant than other microorganisms. For this reason B. atrophaeus is the recommended biological indicator. Like all sterilization processes, the effectiveness of ETO sterilization can be altered by lumen length, lumen diameter, inorganic salts, and organic materials. For example, although ETO is not used commonly for reprocessing endoscopes, several studies have shown failure of ETO in inactivating contaminating spores in endoscope channels or lumen test units and residual ETO levels averaging 66.2 ppm even after the standard degassing time. Failure of ETO also has been observed when dental handpieces were contaminated with Streptococcus mutans and exposed to ETO. It is recommended that dental handpieces be steam sterilized.
ETO is used in healthcare facilities to sterilize critical items (and sometimes semicritical items) that are moisture or heat sensitive and cannot be sterilized by steam sterilization.

Hydrogen Peroxide Gas Plasma

New sterilization technology based on plasma was patented in 1987 and marketed in the United States in 1993. Gas plasmas have been referred to as the fourth state of matter (i.e., liquids, solids, gases, and gas plasmas). Gas plasmas are generated in an enclosed chamber under deep vacuum using radio frequency or microwave energy to excite the gas (i.e., hydrogen peroxide) molecules and produce charged particles, many of which are in the form of free radicals (e.g., hydroxyl and hydroperoxy). The biological indicator used with this system is *Geobacillus stearothermophilus* spores.

This process has the ability to inactivate a broad range of microorganisms, including resistant bacterial spores. Studies have been conducted against vegetative bacteria (including mycobacteria), yeasts, fungi, viruses, and bacterial spores. Like all sterilization processes, the effectiveness can be altered by lumen length, lumen diameter, inorganic salts, and organic materials.

Materials and devices that cannot tolerate high temperatures and humidity, such as some plastics, electrical devices, and corrosion-susceptible metal alloys, can be sterilized by hydrogen peroxide gas plasma. This method has been compatible with most (>95%) medical devices and materials tested.

Peracetic Acid Sterilization

Peracetic acid is a highly biocidal oxidizer that maintains its efficacy in the presence of organic soil. Peracetic acid removes surface contaminants (primarily protein) on endoscopic tubing. An automated machine using peracetic acid to sterilize medical, surgical, and dental instruments chemically (e.g., endoscopes, arthroscopes) was introduced in 1988. This microprocessor-controlled, low-temperature sterilization method is commonly used in the United States. Interchangeable trays are available to permit the processing of up to three rigid endoscopes or one flexible endoscope. Connectors are available for most types of flexible endoscopes for the irrigation of all channels by directed flow. Rigid endoscopes are placed within a lidded container, and the sterilant fills the lumens either by immersion in the circulating sterilant or by use of channel connectors to direct flow into the lumen(s) (see below for the importance of channel connectors). As with any sterilization process, the system can only sterilize surfaces that can be contacted by the sterilant. For example, bronchoscopy-related infections occurred when bronchoscopes were processed using the wrong connector. Investigation of these incidents revealed that bronchoscopes were inadequately reprocessed when inappropriate channel connectors were used and when there were inconsistencies between the reprocessing instructions provided by the manufacturer of the bronchoscope and the manufacturer of the automatic endoscope reprocessor. The importance of channel connectors to achieve sterilization was also shown for rigid lumen devices.

The manufacturers suggest the use of biological monitors (*G. stearothermophilus* spore strips) both at the time of installation and routinely to ensure effectiveness of the process. The manufacturer’s clip must be used to hold the strip in the designated spot in the machine as a broader clamp will not allow the sterilant to reach the spores trapped under it. The processor is equipped with a conductivity probe that will automatically abort the cycle if the buffer system is not detected in a fresh container of the peracetic acid solution. A chemical monitoring strip that detects that the active ingredient is >1500 ppm is available for routine use as an additional process control.

Peracetic acid will inactivate gram-positive and gram-negative bacteria, fungi, and yeasts in <5 minutes at <100 ppm. In the presence of organic matter, 200-500 ppm is required. For viruses, the dosage range is wide (12-2250 ppm), with poliovirus inactivated in yeast extract in 15 minutes with 1500 to 2250 ppm. Bacterial spores in suspension are inactivated in 15 seconds to 30 minutes with 500 to 10,000 ppm (0.05 to 1%).
OSHA Bloodborne Pathogen Standard

In December 1991, the Occupational Safety and Health Administration (OSHA) promulgated a standard entitled "Occupational Exposure to Bloodborne Pathogens" to eliminate or minimize occupational exposure to bloodborne pathogens. One component of this requirement is that all equipment and environmental and working surfaces be cleaned and decontaminated with an appropriate disinfectant after contact with blood or other potentially infectious materials. While the OSHA standard does not specify the type of disinfectant or procedure, the OSHA original compliance document suggested that a germicide must be tuberculocidal to kill the HBV (e.g., phenolic, chlorine). However, in February 1997, OSHA amended its policy and stated that EPA-registered disinfectants that are labeled as effective against HIV and HBV would be considered as appropriate disinfectants "...provided such surfaces have not become contaminated with agent(s) or volumes of or concentrations of agent(s) for which higher level disinfection is recommended." When bloodborne pathogens other than HBV or HIV are of concern, OSHA continues to require the use of EPA-registered tuberculocidal disinfectants or hypochlorite solution (diluted 1:10 or 1:100 with water). Recent studies demonstrate that, in the presence of large blood spills, a 1:10 final dilution of EPA-registered hypochlorite solution initially should be used to inactivate bloodborne viruses to minimize risk of disease to the healthcare worker from percutaneous injury during the clean-up process.

Emerging Pathogens (Cryptosporidium, Helicobacter pylori, Escherichia coli O157:H7, Rotavirus, Human Papilloma Virus, Norwalk Virus, Severe Acute Respiratory Syndrome [SARS] Coronavirus, Creutzfeldt-Jakob Prion, antibiotic-resistant bacteria [VRE, MRSA])

Emerging pathogens are of growing concern to the general public and infection control professionals. Relevant pathogens include Cryptosporidium parvum, Helicobacter pylori, E. coli O157:H7, HIV, HCV, rotavirus, multidrug-resistant M. tuberculosis, and nontuberculosis mycobacteria (e.g., M. chelonae). The susceptibility of each of these pathogens to chemical disinfectants/sterilants has been studied. With the exception of prions (see below), standard sterilization and disinfection procedures for patient-care equipment (as recommended in Table 1) are adequate to sterilize or disinfect instruments or devices contaminated with blood or other body fluids from persons infected with bloodborne pathogens and emerging pathogens.

Cryptosporidium is resistant to chlorine at concentrations used in potable water. C. parvum is not completely inactivated by most disinfectants used in healthcare including ethyl alcohol, glutaraldehyde, 5.25% hypochlorite, peracetic acid, ortho-phthalaldehyde, phenol, povidone-iodine, and quaternary ammonium compounds. The only chemical disinfectants/sterilants able to inactivate greater than 3 log10 of C. parvum were 6% and 7.5% hydrogen peroxide. Sterilization methods will fully inactivate C. parvum, including steam, ethylene oxide, and hydrogen peroxide gas plasma. Although most disinfectants are ineffective against C. parvum, current cleaning and disinfection practices appear satisfactory to prevent healthcare-associated transmission. For example, endoscopes are unlikely to represent an important vehicle for the transmission of C. parvum because the results of bacterial studies indicate mechanical cleaning will remove approximately 104 organisms and drying rapidly results in loss of C. parvum viability (e.g., 2.9 log10 decrease in 30 minutes, 3.8 log10 decrease in 60 minutes).

Chlorine at ~1 ppm has been found capable of eliminating approximately 4 log10 of E. coli O157:H7 within 1 minute in a suspension test. Electrolyzed oxidizing water at 23°C was effective in 10 minutes in producing a 5-log10 decrease in E. coli O157:H7 inoculated onto kitchen cutting boards. The following disinfectants eliminated >5 log10 of E. coli O157:H7 within 30 seconds: a quaternary ammonium compound, a phenolic, a hypochlorite (1:10 dilution of 5.25% bleach), and ethanol.

Data are available on the susceptibility of H. pylori to disinfectants. Using a suspension test, Akamatsu and colleagues assessed the effectiveness of a variety of disinfectants against nine strains of H. pylori. Ethanol (80%) and glutaraldehyde (0.5%) killed all strains within 15 seconds; chlorhexidine gluconate (0.05%, 1.0%), benzalkonium chloride (0.025%, 0.1%), alkylidamoylethylglycine hydrochloride (0.1%), povidone-iodine (0.1%), and sodium hypochlorite (150 ppm) killed all strains within 30 seconds. Both ethanol (80%) and glutaraldehyde (0.5%) retained similar bactericidal activity in the presence of organic matter while the other disinfectants showed reduced bactericidal activity. In particular, the...
bactericidal activity of povidone-iodine (0.1%) and sodium hypochlorite (150 ppm) was markedly decreased in the presence of dried yeast solution with killing times increased to 5 to 10 minutes and 5 to 30 minutes, respectively.

Immersion of biopsy forceps in formalin before obtaining a specimen does not affect the ability to culture *H. pylori* from the biopsy specimen. 202 The following methods have been demonstrated to be ineffective for eliminating *H. pylori* from endoscopes: cleaning with soap and water, immersion in 70% ethanol for 3 minutes, instillation of 70% ethanol, instillation of 30 ml of 83% methanol, and instillation of 0.2% Hyamine solution. 203 The differing results with regard to the efficacy of ethyl alcohol are unexplained. Cleaning followed by use of 2% alkaline glutaraldehyde (or automated peracetic acid) has been demonstrated by culture to be effective in eliminating *H. pylori*. 204, 205 Epidemiologic investigations of patients who had undergone endoscopy with endoscopes mechanically washed and disinfected with 2.0 to 2.3% glutaraldehyde have revealed no evidence of person-to-person transmission of *H. pylori*. 206 Disinfection of experimentally contaminated endoscopes using 2% glutaraldehyde (10 minutes, 20 minutes, 45 minutes exposure times) or the peracetic acid system (with and without active peracetic acid) has been demonstrated to be effective in eliminating *H. pylori*. 205 *H. pylori* DNA has been detected by PCR in fluid flushed from endoscope channels following cleaning and disinfection with 2% glutaraldehyde. 207 The clinical significance of this finding is unclear. *In vitro* experiments have demonstrated a >3.5-log reduction in *H. pylori* after exposure to 0.5 mg/L of free chlorine for 80 seconds. 208

An outbreak of healthcare-associated rotavirus gastroenteritis on a pediatric unit has been reported. 209 Person-to-person via the hands of healthcare workers was proposed as the mechanism of transmission. Prolonged survival of rotavirus on environmental surfaces (90 minutes to more than 10 days at room temperature) and hands (>4 hours) has been demonstrated. Rotavirus suspended in feces can survive for a longer period of time. 210 Vectors for this infection have included air, hands, fomites, water, and food. 210 Products with demonstrated efficacy (>3 log reduction in virus) against rotavirus within 1 minute include: 95% ethanol, 70% isopropanol, some phenolics, 2% glutaraldehyde, 0.35% peracetic acid, and some quaternary ammonium compounds. 38, 211, 212 In a human challenge study, a disinfectant spray (0.1% ortho-phenylphenol and 79% ethanol), sodium hypochlorite (800 ppm free chlorine), and a phenol-based product (14.7% phenol diluted 1:256 in tapwater) when sprayed onto contaminated stainless steel disks, were effective in interrupting the transfer of a human rotavirus from stainless steel disk to fingerpads of volunteers after an exposure time of 3 to 10 minutes. A quaternary ammonium product (7.05% quaternary ammonium compound diluted 1:128 in tapwater) and tapwater allowed transfer of virus. 34

There are no data on the inactivation of human papillomavirus by alcohol or other disinfectants because *in vitro* replication of complete virions has not been achieved. Similarly, little is known about the inactivation of Norwalk virus and Norwalk virus-like particles (members of the family *Caliciviridae* and important causes of gastroenteritis in humans) as they cannot be grown in tissue culture. Inactivation studies with a closely related cultivable virus (i.e., feline calicivirus) have shown the effectiveness of chlorine, glutaraldehyde, and iodine-based products whereas the quaternary ammonium compound, detergent, and ethanol failed to inactivate the virus completely. 141

The CDC announced that a previously unrecognized human virus from the coronavirus family is the leading hypothesis for the cause of a recently described syndrome of SARS or Severe Acute Respiratory Syndrome. 213 Two coronaviruses that are known to infect humans causes one-third of common colds and may cause gastroenteritis. The virucidal efficacy of chemical germicides against coronavirus have been investigated. Sattar and colleagues 214 investigated the activity of several disinfectants against coronavirus 229E and found several disinfectants were effective after a 1 min contact time including sodium hypochlorite (at a free chlorine concentration of 1000 ppm and 5000 ppm), 70% ethyl alcohol, and povidone-iodine (1% iodine). Saknimit and coworkers 215 showed that 70% ethanol, 50% isopropanol, 0.05% benzalkonium chloride, 50 ppm iodine in iodophor, 0.23% sodium chloride, 1% cresol soap and 0.7% formaldehyde inactivated greater than 3 logs of two animal coronaviruses (mouse hepatitis virus, canine coronavirus) after a 10 minute exposure time. Sizun et al demonstrated the activity of povidone-iodine against human coronaviruses 229E and OC43. 216 Since the SARS coronavirus is stable in feces and urine at room temperature for at least 1-2 days (World
Health Organization, 2003; http://www.who.int/csr/sars/survival_2003_05_04/en/index.html), surfaces may be a possible source of contamination and lead to infection with the SARS coronavirus and should be disinfected. Until more precise information is available, assume the environment in which SARS patients are housed is heavily contaminated and thoroughly disinfect the room and equipment daily and after the patient is discharged. Use EPA-registered disinfectants or 1:100 dilution of household bleach and water for surface disinfection and disinfection on non-critical patient care equipment. High-level disinfection and sterilization of semicritical and critical medical devices, respectively, does not need to be altered for patients with known or suspected SARS.

The prions of CJD and other TSEs exhibit an unusual resistance to conventional chemical and physical decontamination methods. Since the CJD agent is not readily inactivated by conventional disinfection and sterilization procedures and because of the invariably fatal outcome of CJD, the procedures for disinfection and sterilization of the CJD prion have been both cautious and controversial for many years. Recommendations for disinfection and sterilization of prion-contaminated medical devices are as follows. Instruments should be kept wet or damp until they are decontaminated and they should be decontaminated as soon as possible after use. Dried films of tissue are more resistant to prion inactivation by steam sterilization compared to tissues that were kept moist. This may relate to the rapid heating that occurs in the film of dried material compared to the bulk of the sample, and the rapid fixation of the prion protein in the dried film. It also appears that prions in the dried portions of the brain macerates are less efficiently inactivated than undisturbed tissue. For high-risk tissues (brain, spinal cord, eyes), high-risk patients, and critical or semicritical medical devices, clean the device and sterilize preferably using a combination of sodium hydroxide and autoclaving as recommended by WHO (e.g., Option 1- immerse in 1N NaOH [1N NaOH is a solution of 40 g NaOH in 1 liter of water] for 1 hour; remove and rinse in water, then transfer to an open pan and autoclave [121°C gravity displacement or 134°C porous or prevacuum sterilizer] for 1 hour; or Option 2 - immerse instruments in 1N NaOH for 1 hour and heat in a gravity displacement sterilizer at 121°C for 30 minutes; clean; and subject to routine sterilization), or Option 3 - by autoclaving at 134°C for 18 minutes in a prevacuum sterilizer, or Option 4 - 132°C for 1 hour in a gravity displacement sterilizer. The temperature should not exceed 134°C since under certain conditions the effectiveness of autoclaving actually declines as the temperature is increased (e.g., 136°C, 138°C). Prion-contaminated medical devices that are impossible or difficult to clean should be discarded. Flash sterilization should not be used for reprocessing. To minimize environmental contamination, noncritical environmental surfaces should be covered with plastic-backed paper and when contaminated with high-risk tissues the paper should be properly discarded. Environmental surfaces (noncritical) contaminated with high-risk tissues should be cleaned and then spot decontaminated with a 1:10 dilution of hypochlorite solutions.

To minimize the possibility of use of neurosurgical instruments that have been potentially contaminated during procedures performed on patients in whom CJD is later diagnosed, healthcare facilities should consider using the sterilization guidelines outlined above for neurosurgical instruments used during brain biopsy done on patients in whom a specific lesion has not been demonstrated (e.g., by magnetic resonance imaging or computerized tomography scans). Alternatively, neurosurgical instruments used in such patients could be disposable or instruments quarantined until the pathology of the brain biopsy is reviewed and CJD excluded.

Currently, there are no data to show that antibiotic-resistant bacteria are less sensitive to the liquid chemical germicides that antibiotic-sensitive bacteria at currently used germicide contact conditions and concentrations. Several studies have found antibiotic-resistant hospital strains of common healthcare-associated pathogens (i.e., Enterococcus, P. aeruginosa, Klebsiella pneumoniae, E. coli, S. aureus, and S. epidermidis) to be equally susceptible to disinfectants as antibiotic-sensitive strains. The susceptibility of glycopeptide-intermediate S. aureus was similar to vancomycin-susceptible, methicillin-resistant S. aureus. Based on these data, routine disinfection and housekeeping protocols do not need to be altered because of antibiotic resistance provided the disinfection method is effective. A recent study that evaluated the efficacy of selected cleaning methods (e.g., QUAT-sprayed cloth, and QUAT-immersed cloth) for eliminating VRE found that currently used disinfection processes are likely highly effective in eliminating VRE. However, surface disinfection must involve contact with all contaminated surfaces.
Inactivation of Bioterrorist Agents

Recent publications have highlighted the concern about the potential for biological terrorism. The CDC has categorized several agents as “high priority” because they can be easily disseminated or transmitted person-to-person, cause high mortality, and are likely to cause public panic and social disruption. These agents include *Bacillus anthracis* (anthrax), *Yersinia pestis* (plague), variola major (smallpox), *Clostridium botulinum* toxin (botulism), *Francisella tularensis* (tularemia), filoviruses (Ebola hemorrhagic fever, Marburg hemorrhagic fever); and arenaviruses (Lassa [Lassa fever], Junin [Argentine hemorrhagic fever]), and related viruses.

A few comments can be made regarding the role of sterilization and disinfection of potential agents of bioterrorism. First, the susceptibility of these agents to germicides in vitro is similar to other related pathogens. For example, variola is similar to vaccinia and *B. anthracis* is similar to *B. atrophaeus* (formerly *B. subtilis*). Thus, one can extrapolate from the larger database available on the susceptibility of genetically similar organisms. Second, many of the potential bioterrorist agents are stable enough in the environment that contaminated environmental surfaces or fomites could lead to transmission of agents such as *B. anthracis*, *F. tularensis*, variola major, *C. botulinum* toxin, and *C. burnetti*. Third, data suggest that current disinfection and sterilization practices are appropriate for the management of patient care equipment and environmental surfaces when potentially contaminated patients are evaluated and/or admitted in a healthcare facility following exposure to a bioterrorist agent. For example, sodium hypochlorite may be used for surface disinfection (see http://www.epa.gov/pesticides/factsheets/bleachfactsheet.htm). In instances where the healthcare facility is the site of a bioterrorist attack, environmental decontamination may require special decontamination procedures (e.g., chlorine dioxide gas for anthrax spores; see http://www.epa.gov/pesticides/factsheets/chlorinedioxidefactsheet.htm). Use of disinfectants for decontamination following a bioterrorist attack requires crises exemption from the EPA (see http://www.epa.gov/opprd001/section18/). Of only theoretical concern is the possibility that a bioterrorist agent could be engineered to be less susceptible to disinfection and sterilization processes.

Inactivation of *Clostridium difficile*

The source of healthcare-associated acquisition of *C. difficile* in nonepidemic settings has not been determined. The environment and carriage on the hands of healthcare personnel have been considered as possible sources of infection. Carpeted rooms occupied by a patient with *C. difficile* are more heavily contaminated with *C. difficile* than noncarpeted rooms. Since *C. difficile* may display increased levels of spore production when exposed to non-chlorine-based cleaning agents and the spores are more resistant than vegetative cells to commonly used surface disinfectants, some investigators have recommended the use of dilute solutions of hypochlorite (1600 ppm available chlorine) for routine environmental disinfection of rooms of patients with *C. difficile*-associated diarrhea or colitis, to reduce the incidence of *C. difficile* diarrhea, or in units with high *C. difficile* rates. Mayfield and co-workers showed a marked reduction in *C. difficile*-associated diarrhea rates in the bone-marrow transplant unit (from 8.6 to 3.3 cases per 1000 patient-days) during the period of bleach disinfection (1:10 dilution) of environmental surfaces compared to cleaning with a quaternary ammonium compound. Thus, use of a diluted hypochlorite should be considered in units with high *C. difficile* rates. However, studies have shown that asymptomatic patients constitute an important reservoir within the healthcare facility and that person-to-person transmission is the principal means of transmission between patients. Thus, handwashing, barrier precautions, and meticulous environmental cleaning with an EPA-registered disinfectant (e.g., germicidal detergent) should be effective in preventing the spread of the organism.

Contaminated medical devices such as colonoscopes and thermometers could serve as vehicles for the transmission of *C. difficile* spores. For this reason, investigators have studied commonly used disinfectants and exposure times to assess whether current practices may be placing patients at risk. Data demonstrate that 2% glutaraldehyde reliably kills *C. difficile* spores using exposure times of 5 to 20 minutes.
Reprocessing of Endoscopes

Physicians use endoscopes to diagnose and treat numerous medical disorders. While endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine and the incidence of infection associated with use has been reported as very low (about 1 in 1.8 million procedures) more healthcare-associated outbreaks have been linked to contaminated endoscopes than to any other medical device. In order to prevent the spread of healthcare-associated infections, all heat-sensitive endoscopes (e.g., gastrointestinal endoscopes, bronchoscopes, nasopharyngoscopes) must be properly cleaned and at a minimum subjected to high-level disinfection following each use. High-level disinfection can be expected to destroy all microorganisms although when high numbers of bacterial spores are present, a few spores may survive.

Flexible endoscopes, by virtue of the types of body cavities they enter, acquire high levels of microbial contamination (bioburden) during each use. For example, the bioburden found on flexible gastrointestinal endoscopes following use has ranged from 10^5 colony forming units (CFU)/ml to 10^10 CFU/ml, with the highest levels being found in the suction channels. The average load on bronchoscopes before cleaning was 6.4x10^4 CFU/ml. Cleaning reduces the level of microbial contamination by 4 to 6 log_{10}. Using HIV contaminated endoscopes, several investigators have shown that cleaning completely eliminates the microbial contamination on the scopes. Similarly, other investigators found that ETO sterilization or high-level disinfection (soaking in 2% glutaraldehyde for 20 minutes) were effective only when the device was first properly cleaned.

FDA maintains a list of cleared liquid chemical sterilants/high-level disinfectants that can be used to reprocess heat-sensitive medical devices, such as flexible endoscopes. Users can access and view the list at [http://www.fda.gov/cdrh/ode/germlab.html](http://www.fda.gov/cdrh/ode/germlab.html). At this time, the FDA-cleared formulations include: >2.4% glutaraldehyde, 0.55% ortho-phthalaldehyde (OPA), 0.95% glutaraldehyde with 1.64% phenol/phenate, 7.35% hydrogen peroxide with 0.23% peracetic acid, 1.0% hydrogen peroxide with 0.08% peracetic acid, and 7.5% hydrogen peroxide. These products have excellent antimicrobial activity; however, some oxidizing chemicals (e.g., 7.5% hydrogen peroxide and 1.0% hydrogen peroxide with 0.08% peracetic acid [latter product is no longer marketed]) have been reported to cause cosmetic and functional damage to endoscopes. Users should check with device manufacturers for information on germicide compatibility with their device. If the germicide is FDA-cleared then it is safe when used according to the label directions; however, professionals should review the scientific literature as new data may become available regarding human safety or material compatibility. ETO sterilization of flexible endoscopes is infrequent because it requires a lengthy processing and aeration time (e.g., 12 hours) and is a potential hazard to staff and patients. The two products that are most commonly used for reprocessing endoscopes in the United States are glutaraldehyde and an automated, liquid chemical sterilization process that uses peracetic acid. The American Society for Gastrointestinal Endoscopy (ASGE) recommends glutaraldehyde solutions that do not contain surfactants because the soapy residues of surfactants are difficult to remove during rinsing. Ortho-phthalaldehyde has begun to replace glutaraldehyde in many healthcare facilities as it possesses several potential advantages compared to glutaraldehyde: no known irritation to the eyes and nasal passages, does not require activation or exposure monitoring, and has a 12-minute high-level disinfection claim in the United States. Disinfectants that are not FDA cleared and should not be used for reprocessing endoscopes include iodophors, chlorine solutions, alcohols, quaternary ammonium compounds, and phenolics. These solutions may still be in use outside the United States, but their use should be strongly discouraged because of lack of proven efficacy against all microorganisms or materials incompatibility.

The FDA’s clearance of the contact conditions listed on germicide labeling is based on the manufacturer’s test results. They conduct the testing under worst-case conditions for germicide formulation (i.e., minimum recommended concentration of the active ingredient), and include organic soil. Typically, manufacturers use 5% serum as the organic soil and hard water as examples of organic and inorganic challenges. The soil is used to represent the organic loading to which the device is exposed during actual use and that would remain on the device in the absence of cleaning. This method assures that the contact conditions provides complete elimination of the test mycobacteria (e.g., 10^6 to 10^9 Mycobacteria tuberculosis in organic soil and dried on a scope) if inoculated in the most difficult areas for the disinfectant to penetrate and contact in the absence of cleaning and thus, provides a margin of safety. For 2.4% glutaraldehyde that requires a 45-minute immersion at 25°C to achieve
high-level disinfection (i.e., 100% kill of *Mycobacterium tuberculosis*). FDA itself does not conduct testing, but relies solely on the disinfectant manufacturer’s data. Users can find the contact conditions for cleared high-level disinfectants/chemical sterilants at [http://www.fda.gov/cdrh/ode/germlab.html](http://www.fda.gov/cdrh/ode/germlab.html). It is important to note that data suggest that *M. tuberculosis* levels can be reduced by at least 8 log_{10} with cleaning (4 log_{10}) followed by chemical disinfection for 20 minutes at 20 °C. (4 to 6 log_{10}) Based on these data, APIC, the Society of Gastroenterology Nurses and Associates (SGNA), and the ASGE recommend alternative contact conditions with 2% glutaraldehyde to achieve high-level disinfection based on articles in the literature (e.g., that equipment be immersed in 2% glutaraldehyde at 20 °C for at least 20 minutes for high-level disinfection. It is FDA’s position that if the user chooses to use alternative contact conditions, they assume liability. In the absence of several well-designed experimental scientific studies regarding alternative exposure times of high-level disinfectants, the manufacturers’ recommendations to achieve high-level disinfection should be followed. Currently, such data are available only for 2% glutaraldehyde solutions.

Flexible endoscopes are particularly difficult to disinfect and easy to damage because of their intricate design and delicate materials. Meticulous cleaning must precede any sterilization or high-level disinfection of these instruments. Failure to perform good cleaning may result in a sterilization or disinfection failure and outbreaks of infection may occur. Several studies have demonstrated the importance of cleaning in experimental studies with the duck hepatitis B virus, HIV, and *Helicobacter pylori*. Examining healthcare-associated infections related only to endoscopes through July 1992, Spach found that 281 infections were transmitted by gastrointestinal endoscopy and 96 were transmitted by bronchoscopy. The clinical spectrum ranged from asymptomatic colonization to death. *Salmonella* species and *P. aeruginosa* repeatedly were identified as causative agents of infections transmitted by gastrointestinal endoscopy, and *M. tuberculosis* (TB), atypical mycobacteria, and *P. aeruginosa* were the most common causes of infections transmitted by bronchoscopy. Major reasons for transmission were inadequate cleaning, improper selection of a disinfecting agent, failure to follow recommended cleaning and disinfection procedures, and flaws in endoscope design or automated endoscope reprocessors. Failure to follow established guidelines has continued to lead to infections associated with gastrointestinal endoscopes and bronchoscopes. Potential device-associated problems should be reported to the FDA’s Center for Devices and Radiologic Health. One multi-state investigation found that 23.9% of the bacterial cultures from the internal channels of 71 gastrointestinal endoscopes grew ≥100,000 colonies of bacteria after completion of all disinfection/sterilization procedures (9 of 25 facilities were using a product that has been removed from the marketplace [6 facilities using 1:16 glutaraldehyde phenate], is not FDA-cleared as a high-level disinfectant [an idophor] or no disinfecting agent) and before use on the next patient. It should be acknowledged that the incidence of post-endoscopic procedure infections resulting from an improperly processed endoscope has not been rigorously assessed.

Automated endoscope reprocessors (AER) offer several advantages compared to manual reprocessing: they automate and standardize several important reprocessing steps, reduce the likelihood that an essential reprocessing step will be skipped, and reduce personnel exposure to high-level disinfectants or chemical sterilants. Failure of AERs has been linked to outbreaks of infections or colonization, and the AER water filtration system may not be able to reliably provide bacteria-free rinse water. It is critical that correct connectors between the AER and the device are established to ensure complete flow of disinfectants and rinse water. In addition, some endoscopes such as the duodenoscopes (e.g., endoscopic retrograde cholangiopancreatography [ERCP]) contain features (e.g., elevator-wire channel) that require a flushing pressure that is not achieved by most AERs and must be reprocessed manually using a 2- to 5-ml syringe. New duodenoscopes equipped with a wider elevator-channel that AERs can reliably reprocess may be available in the future. Outbreaks involving removable endoscope parts such as suction valves and endoscopic accessories designed to be inserted through flexible endoscopes such as biopsy forceps emphasize the importance of cleaning to remove all foreign matter before high-level disinfection or sterilization. Some types of valves are now available as single use, disposable products (e.g., bronchoscopic valves) or steam sterilizable products (e.g., gastrointestinal endoscope valves).
There is a need for further development and redesign of AERs and endoscopes so that they do not represent a potential source of infectious agents. Endoscopes employing disposable components (e.g., protective barrier devices or sheaths) can provide an alternative to conventional liquid chemical high-level disinfection/sterilization. Another new technology is a swallowable camera-in-a-capsule that travels through the digestive tract and transmits color pictures of the small intestine to a receiver that is worn outside the body. At present, this capsule will not replace colonoscopies.

Recommendations for the cleaning and disinfection of endoscopic equipment have been published and should be strictly followed. Unfortunately, audits have shown that personnel do not adhere to guidelines on reprocessing and outbreaks of infection continue to occur. In order to ensure that reprocessing personnel are properly trained, there should be initial and annual competency testing for each individual who reprocesses endoscopic instruments.

In general, endoscope disinfection or sterilization with a liquid chemical sterilant involves five steps after leak testing: 1) clean - mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion); 2) disinfect - immerse endoscope in high-level disinfectant (or chemical sterilant) and perfuse (eliminates air pockets and ensures contact of the germicide with the internal channels) disinfectant into all accessible channels such as the suction/biopsy channel and air/water channel and expose for a time recommended for specific products; 3) rinse – rinse the endoscope and all channels with sterile water or filtered water (commonly used with AERs); if this is not feasible use tapwater; 4) dry – rinse the insertion tube and inner channels with alcohol and dry with forced air after disinfection and before storage; and 5) store - store the endoscope in a way that prevents recontamination and promotes drying (e.g., hung vertically). One study demonstrated that reprocessed endoscopes (i.e., air/water channel, suction/biopsy channel) were generally negative (100% after 24 hours; 90% after 7 days [1 CFU of coagulase-negative Staphylococcus in one channel]) for bacterial growth when stored by hanging in a vertical position in a ventilated cabinet. Because tapwater may contain low levels of microorganisms some have suggested that only sterile water (which may be prohibitively expensive) or AER filtered water be used. The suggestion to use only sterile water or filtered water is not consistent with published guidelines that allow tapwater with an alcohol rinse and forced air-drying or the scientific literature. In addition, there has been no evidence of disease transmission when tapwater followed by an alcohol rinse and forced air-drying has been used. AERs produce filtered water via passage through a bacterial filter (e.g., 0.2 µm). Filtered rinse water was identified as a source of bacterial contamination in a recent study that cultured the accessory and suction channels of endoscopes and the internal chambers of AERs between 1996-2001 and reported 8.7% of samples collected between 1996-1998 had bacterial growth with 54% being Pseudomonas species. Following the introduction of a system of hot water flushing of the piping (60°C for 60 minutes daily), the frequency of positive cultures fell to approximately 2% with only rare isolation of >10 CFU/ml. In addition to the endoscope reprocessing steps, a protocol should be developed that assures the user knows whether an endoscope has been appropriately cleaned and disinfected (e.g., using a room or cabinet for processed endoscopes only) or has not been reprocessed. Confusion can result when users leave endoscopes on movable carts and it is unclear whether the endoscope has been processed or not. While one guideline has recommended that an endoscope (e.g., a duodenoscope) should be reprocessed immediately before its use, other guidelines do not require this activity and with the exception of the Association of periOperative Registered Nurses (AORN), professional organizations do not recommended that reprocessing be repeated so long as the original processing is done correctly. As part of a quality assurance program, healthcare facility personnel may consider random bacterial surveillance cultures of processed endoscopes to ensure high-level disinfection or sterilization.

Reprocessed endoscopes should be free of microbial pathogens except for small numbers of relatively avirulent microbes that represent exogenous environmental contamination (e.g., coagulase-negative Staphylococcus, Bacillus species, diphtheroids). It has also been suggested that the final rinse water used during endoscope reprocessing be microbiologically cultured at least monthly. The microbiologic standard that should be met has not been set. However, neither the routine culture of reprocessed endoscopes nor the final rinse water has been validated by correlating viable counts on an endoscope to infection following an endoscopic procedure.
reprocessed endoscopes were done, sampling the endoscope would assess water quality as well as other important steps (e.g., disinfectant effectiveness, exposure time, cleaning) in the reprocessing procedure. A number of methods for sampling endoscopes and water have been described. [Riley R, 2002 #12059; Bond WW, 1992 #12060; Centers for Disease Control, 2001 #11396; Pang, 2002 #12110; Moses, 2003 #12140; Murray, 1999 #12128]

The carrying case used to transport clean and reprocessed endoscopes outside of the healthcare environment, should not be used to store an endoscope or to transport the instrument within the healthcare facility. A contaminated endoscope should never be placed in the carrying case as the case can also become contaminated. When the endoscope is removed from the case and properly reprocessed and put back in the case, the endoscope can become recontaminated by the case. If the carrying case becomes contaminated, it should be discarded (Olympus America, June 2002, written communication).

Infection control professionals should ensure that institutional policies are consistent with national guidelines and conduct infection control rounds periodically (e.g., at least annually) in areas where endoscopes are reprocessed to make certain there is compliance with policy. Breaches in policy should be documented and corrective action instituted. In incidents in which endoscopes were not exposed to a high-level disinfection process, all patients were assessed for possible acquisition of HIV, HBV, and hepatitis C virus (HCV). This highlights the importance of rigorous infection control.

Tonometers, Cervical Diaphragm Fitting Rings, Cryosurgical Instruments, Endocavitary Probes

Disinfection strategies for other semicritical items (e.g., applanation tonometers, rectal/vaginal probes, cryosurgical instruments, and diaphragm fitting rings) are highly variable. Currently, FDA requests that the device manufacturer include at least one validated cleaning and disinfection/sterilization protocol in the labeling for their device. As with all medications and devices, users should be familiar with the label instructions. One study revealed that no uniform technique was in use for disinfection of applanation tonometers, with disinfectant contact times varying from <15 sec to 20 minutes. In view of the potential for transmission of viruses (e.g., herpes simplex virus [HSV], adenovirus 8, or HIV) by tonometer tips, CDC recommends that the tonometer tips be wiped clean and disinfected for 5-10 minutes with either 3% hydrogen peroxide, 5000 ppm chlorine, 70% ethyl alcohol, or 70% isopropyl alcohol. Since viral inactivation studies have shown that 3% hydrogen peroxide and 70% isopropyl alcohol have limited activity against viruses, immersion in 5000 ppm chlorine or 70% ethyl alcohol are recommended. Structural damage to Schiotz tonometers has been observed with a 1:10 sodium hypochlorite (5000 ppm chlorine) and 3% hydrogen peroxide. After disinfection, the tonometer should be thoroughly rinsed in tapwater and air dried before use. The guidelines of the American Academy of Ophthalmology for preventing infections in ophthalmology focus on only one potential pathogen, HIV. Because a short and simple decontamination procedure is desirable in the clinical setting, swabbing the tonometer tip with a 70% isopropyl alcohol wipe is sometimes practiced. Preliminary reports suggest that wiping the tonometer tip with an alcohol swab and then allowing the alcohol to evaporate may be an effective means of eliminating HSV, HIV, and adenovirus. However, since these studies involved only a few replicates and were conducted in a controlled laboratory setting, further studies are needed before this technique can be recommended. In addition, two reports have found that disinfection of pneumotonometer tips between uses with a 70% isopropyl alcohol wipe contributed to outbreaks of epidemic keratoconjunctivitis caused by adenovirus type 8.

There are also limited studies that evaluated disinfection techniques for other items that contact mucous membranes, such as diaphragm fitting rings, cryosurgical probes, transesophageal echocardiography probes, or vaginal/rectal probes used in sonographic scanning. Lettau, Bond, and McDougal of CDC supported the recommendation of a diaphragm fitting ring manufacturer that involved using a soap-and-water wash followed by a 15-minute immersion in 70% alcohol. This disinfection method should be adequate to inactivate HIV, HBV, and HSV even though alcohols are not classified as high-level disinfectants because their activity against picornaviruses is somewhat limited. There are no data on the inactivation of human papillomavirus by alcohol or other disinfectants because in vitro replication of complete virions has not been achieved. Thus, while alcohol for 15 minutes should kill pathogens of relevance in gynecology, there are no clinical studies that provide direct support for this practice.
Vaginal probes are used in sonographic scanning. A vaginal probe and all endocavitary probes without a probe cover are semicritical devices as they have direct contact with mucous membranes (e.g., vagina, rectum, pharynx). While one could argue that the use of the probe cover changes the category, this guideline proposes that a new condom/probe cover should be used to cover the probe for each patient and since condoms/probe covers may fail, high-level disinfection of the probe also should be performed. The relevance of this recommendation is reinforced with the findings that sterile transvaginal ultrasound probe covers have a very high rate of perforations even before use (0%, 25%, and 65% perforations from three suppliers). After oocyte retrieval use, Hignett and Claman found a very high rate of perforations in used endovaginal probe covers from two suppliers (75% and 81%) while Amis and co-workers and Milki and Fisch demonstrated a lower rate of perforations after use of condoms (0.9% and 2.0%, respectively). Rooks and co-workers found that condoms were superior to commercially available probe covers for covering the ultrasound probe (1.7% for condoms versus 8.3% leakage for probe covers).

These studies underscore the need for routine probe disinfection between examinations. Although most ultrasound manufacturers recommend the use of 2% glutaraldehyde for high-level disinfection of contaminated transvaginal transducers, the use of this agent has been questioned because it may shorten the life of the transducer and may have toxic effects on the gametes and embryos. An alternative procedure for disinfecting the vaginal transducer has been offered by Garland and deCrespigny. It involves the mechanical removal of the gel from the transducer, cleaning the transducer in soap and water, wiping the transducer with 70% alcohol or soaking it for 2 minutes in 500 ppm chlorine, and rinsing with tapwater and air drying. The effectiveness of this and other methods has not been validated in either rigorous laboratory experiments or in clinical use. High-level disinfection with a product (e.g., hydrogen peroxide) that is not toxic to staff, patients, probes, and retrieved cells should be used until such time as the effectiveness of alternative procedures against microbes of importance at the cavitory site is demonstrated by well-designed experimental scientific studies. Other probes such as rectal, cryosurgical, and transesophageal probes/devices should also be subjected to high-level disinfection between patients.

Ultrasound probes may also be used during surgical procedures and have contact with sterile body sites. These probes may be covered with a sterile sheath to reduce the level of contamination on the probe and reduce the risk of infection. However, since the sheath does not provide complete protection of the probe, the probes should be sterilized between each patient use as with other critical items.

Some cryosurgical probes are not fully immersible. When reprocessing these probes, the tip of the probe should be immersed in a high-level disinfectant for the appropriate time (e.g., 20 minutes exposure with 2% glutaraldehyde) and any other portion of the probe that could have mucous membrane contact could be disinfected by immersion or wrapping with a cloth soaked in a high-level disinfectant in order to allow the recommended contact time. After disinfection, the probe should be rinsed with tapwater and dried before use. Healthcare facilities that use nonimmersible probes should replace them as soon as possible with fully immersible probes.

As with other high-level disinfection procedures, proper cleaning of probes is necessary to ensure the success of the subsequent disinfection. Muradali and colleagues demonstrated a reduction of vegetative bacteria inoculated on vaginal ultrasound probes when the probes were cleaned with a towel. No information is available on either the level of contamination of such probes by potential viral pathogens such as HBV and human papilloma virus (HPV) or their removal by cleaning (such as with a towel). Because these pathogens may be present in vaginal and rectal secretions and contaminate probes during use, high-level disinfection of the probes after such use is recommended.

**CONCLUSION**

When properly used, disinfection and sterilization can ensure the safe use of invasive and noninvasive medical devices. However, current disinfection and sterilization guidelines must be strictly followed. Hospitals must develop and maintain a written management plan describing the processes it uses to comply with state and federal medical waste regulations.
Table 1. Methods of sterilization and disinfection.

<table>
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<tr>
<th>Sterilization</th>
<th>Disinfection</th>
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<tr>
<td>Critical items (will enter tissue or vascular system or blood will flow through them)</td>
<td>High-level (semicritical items; [except dental] will come in contact with mucous membrane or nonintact skin)</td>
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<tr>
<td>Object</td>
<td>Procedure</td>
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<tr>
<td>Smooth, hard Surface¹,⁴</td>
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Rubber tubing and catheters³,⁴

| Object | Procedure | Exposure time | Procedure (exposure time 12-30 min at ≥20°C) | Procedure (exposure time ≥ 1 min) | Procedure (exposure time ≥ 1 min) |
| Smooth, hard Surface¹,⁴ | A | MR | D | K | K |
| | B | MR | E | L⁵ | L |
| | C | MR | F | M | M |
| | D | 10 h at 20-25°C | H | N | N |
| | E | NA | J⁶ | O | |
| | F | 6 h | J | | |
| | G | 12 m at 50-56°C | | | |
| | H | 3-8 h | | | |

Polyethylene tubing and catheters³,⁴,⁷

<p>| Object | Procedure | Exposure time | Procedure (exposure time 12-30 min at ≥20°C) | Procedure (exposure time ≥ 1 min) | Procedure (exposure time ≥ 1 min) |
| Smooth, hard Surface¹,⁴ | A | MR | D | K | K |
| | B | MR | E | L⁵ | L |
| | C | MR | F | M | M |
| | D | 10 h at 20-25°C | H | N | N |
| | E | NA | J⁶ | O | |
| | F | 6 h | J | | |
| | G | 12 m at 50-56°C | | | |
| | H | 3-8 h | | | |</p>
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<th>Lensed instruments</th>
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<td>A</td>
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<td>3-8 h</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Thermometers (oral and rectal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>MR</td>
</tr>
<tr>
<td>B</td>
<td>MR</td>
</tr>
<tr>
<td>C</td>
<td>MR</td>
</tr>
<tr>
<td>D</td>
<td>10 h at 20-25°C</td>
</tr>
<tr>
<td>E</td>
<td>NA</td>
</tr>
<tr>
<td>F</td>
<td>6 h</td>
</tr>
<tr>
<td>G</td>
<td>12 m at 50-56°C</td>
</tr>
<tr>
<td>H</td>
<td>3-8 h</td>
</tr>
</tbody>
</table>

Modified from. 11, 13, 14, 48. The selection and use of disinfectants in the healthcare field is dynamic, and products may become available that are not in existence when this guideline was written. As newer disinfectants become available, persons or committees responsible for selecting disinfectants and sterilization processes should be guided by products cleared by the FDA and the EPA as well as information in the scientific literature.

- **A**, Heat sterilization, including steam or hot air (see manufacturer's recommendations, steam sterilization processing time from 3-30 minutes)
- **B**, Ethylene oxide gas (see manufacturer's recommendations, generally 1-6 hours processing time plus aeration time of 8-12 hours at 50-60°C)
- **C**, Hydrogen peroxide gas plasma (see manufacturer's recommendations for endoscope or medical device restrictions on internal diameter and length; processing time between 45-72 minutes)
- **D**, Glutaraldehyde-based formulations (>2% glutaraldehyde, caution should be exercised with all glutaraldehyde formulations when further in-use dilution is anticipated); glutaraldehyde (0.95%) and 1.64% phenol/phenate. One glutaraldehyde-based product has a high-level disinfection claim of 5 minute at 35°C.
- **E**, Ortho-phthalaldehyde 0.55% (FDA cleared as high-level disinfectant; passes the Sporicidal Activity Test in 32 hrs at 20°C but not cleared as a chemical sterilant)
- **F**, Hydrogen peroxide 7.5% (will corrode copper, zinc, and brass)
- **G**, Peracetic acid, concentration variable but 0.2% or greater is sporicidal. Peracetic acid immersion system operates at 50-56°C.
- **H**, Hydrogen peroxide (7.35%) and 0.23% peracetic acid; hydrogen peroxide 1% and peracetic acid 0.08% (will corrode metal instruments)
I. Wet pasteurization at 70°C for 30 minutes with detergent cleaning

J. Hypochlorite >650-675 ppm active free chlorine, single use chlorine generated on site by electrolyzing saline (may corrode metal instruments)

K. Ethyl or isopropyl alcohol (70-90%)

L. Sodium hypochlorite (5.25-6.15% household bleach diluted 1:500 provides >100 ppm available chlorine)

M. Phenolic germicidal detergent solution (follow product label for use-dilution)

N. Iodophor germicidal detergent solution (follow product label for use-dilution)

O. Quaternary ammonium germicidal detergent solution (follow product label for use-dilution)

MR. Manufacturer's recommendations.

NA. Not applicable

1 See text for discussion of hydrotherapy.

2 The longer the exposure to a disinfectant, the more likely it is that all microorganisms will be eliminated. Ten-minute exposure is not adequate to disinfect many objects, especially those that are difficult to clean because they have narrow channels or other areas that can harbor organic material and bacteria. Twenty-minute exposure at 20°C is the minimum time needed to reliably kill M. tuberculosis and nontuberculous mycobacteria with a 2% glutaraldehyde. With the exception of >2% glutaraldehydes, follow the FDA-cleared high-level disinfection claim. Some high-level disinfectants have a reduced exposure time (e.g., ortho-phthalaldehyde at 12 minutes at 20°C) because of their rapid activity against mycobacteria or reduced exposure time due to increased mycobactericidal activity at elevated temperature (e.g., 2.5% glutaraldehyde at 5 minutes at 35°C, 0.55% OPA at 5 min at 20°C in automated endoscope reprocessor).

3 Tubing must be completely filled for disinfection and liquid chemical sterilization; care must be taken to avoid entrapment of air bubbles during immersion.

4 Material compatibility should be investigated when appropriate.

5 Used in laboratory where cultures or concentrated preparations or microorganisms have spilled. A concentration of 1000 ppm available chlorine should be considered where cultures of microorganisms or blood has spilled (5.25-6.15% household bleach diluted 1:50 provides >1000 ppm available chlorine). This solution may corrode some surfaces.

6 Pasteurization (washer-disinfector) of respiratory therapy or anesthesia equipment is a recognized alternative to high-level disinfection. Some data challenge the efficacy of some pasteurization units.

7 Thermostability should be investigated when appropriate.

8 Do not mix rectal and oral thermometers at any stage of handling or processing.
<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peracetic Acid/Hydrogen</td>
<td>• No activation required</td>
<td>• Materials compatibility concerns (lead, brass, copper, zinc) both cosmetic and functional</td>
</tr>
<tr>
<td>Peroxide</td>
<td>• Odor or irritation not significant</td>
<td>• Limited clinical experience</td>
</tr>
<tr>
<td></td>
<td>• Numerous use studies published</td>
<td>• Potential for eye and skin damage</td>
</tr>
<tr>
<td></td>
<td>• Relatively inexpensive</td>
<td>• Respiratory irritation from glutaraldehyde vapor</td>
</tr>
<tr>
<td></td>
<td>• Excellent materials compatibility</td>
<td>• Pungent and irritating odor</td>
</tr>
<tr>
<td></td>
<td>• No activation required</td>
<td>• Relatively slow mycobactericidal activity</td>
</tr>
<tr>
<td></td>
<td>• May enhance removal of organic matter and organisms</td>
<td>• Coagulates blood and fixes tissue to surfaces</td>
</tr>
<tr>
<td></td>
<td>• No disposal issues</td>
<td>• Allergic contact dermatitis</td>
</tr>
<tr>
<td></td>
<td>• No odor or irritation issues</td>
<td>• Material compatibility concerns (brass, zinc, copper, and nickel/silver plating) both cosmetic and functional</td>
</tr>
<tr>
<td></td>
<td>• Does not coagulate blood or fix tissues to surfaces</td>
<td>• Serious eye damage with contact</td>
</tr>
<tr>
<td></td>
<td>• Inactivates Cryptosporidium</td>
<td>• Stains skin, mucous membranes, clothing, and environmental surfaces</td>
</tr>
<tr>
<td></td>
<td>• Use studies published</td>
<td>• Limited clinical experience</td>
</tr>
<tr>
<td></td>
<td>• Fast acting high-level disinfectant</td>
<td>• More expensive than glutaraldehyde</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde</td>
<td>• No activation required</td>
<td>• Eye irritation with contact</td>
</tr>
<tr>
<td></td>
<td>• Excellent materials compatibility claimed</td>
<td>• Anaphylaxis-like reactions in bladder cancer patients</td>
</tr>
<tr>
<td></td>
<td>• Does not coagulate blood or fix tissues to surfaces claimed</td>
<td>• Slow sporidial activity</td>
</tr>
<tr>
<td></td>
<td>• Rapid sterilization cycle time (30-45 minutes)</td>
<td>• Potential material incompatibility (e.g., aluminum anodized coating becomes dull)</td>
</tr>
<tr>
<td>Peracetic Acid</td>
<td>• Low temperature (50-55°C) liquid immersion sterilization</td>
<td>• Used for immersible instruments only</td>
</tr>
<tr>
<td></td>
<td>• Environmental friendly by-products (acetic acid, O₂, H₂O)</td>
<td>• Biological indicator may not be suitable for routine monitoring</td>
</tr>
<tr>
<td></td>
<td>• Fully automated</td>
<td>• One scope or a small number of instruments can be processed in a cycle</td>
</tr>
<tr>
<td></td>
<td>• Single-use system eliminates need for concentration testing</td>
<td>• More expensive (endoscope repairs, operating costs, purchase costs) than high-level disinfection</td>
</tr>
<tr>
<td></td>
<td>• Standardized cycle</td>
<td>• Serious eye and skin damage (concentrated solution) with contact</td>
</tr>
<tr>
<td></td>
<td>• May enhance removal of organic material and endotoxin</td>
<td>• Point-of-use system, no sterile storage</td>
</tr>
<tr>
<td></td>
<td>• No adverse health effects to operators under normal operating conditions</td>
<td>• Unstable, particularly when diluted</td>
</tr>
<tr>
<td></td>
<td>• Compatible with many materials and instruments</td>
<td>• Sterilant flows through scope facilitating salt, protein, and microbe removal</td>
</tr>
<tr>
<td></td>
<td>• Does not coagulate blood or fix tissues to surfaces</td>
<td>• Rapidly sporidial</td>
</tr>
<tr>
<td></td>
<td>• Sterilant flows through scope facilitating salt, protein, and microbe removal</td>
<td>Provides procedure standardization (constant dilution, perfusion of channel, temperatures, exposure)</td>
</tr>
</tbody>
</table>

1 All products effective in presence of organic soil, relatively easy to use, and have a broad spectrum of antimicrobial activity (bacteria, fungi, viruses, bacterial spores, and mycobacteria). The above characteristics are documented in the literature, contact the manufacturer of the instrument and sterilant for additional information. All products listed above are FDA-cleared as chemical sterilants except OPA, which is an FDA-cleared high-level disinfectant.
<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>• Nontoxic to patient, staff, environment</td>
<td>• Deleterious for heat-sensitive instruments</td>
</tr>
<tr>
<td></td>
<td>• Cycle easy to control and monitor</td>
<td>• Microsurgical instruments damaged by repeated exposure</td>
</tr>
<tr>
<td></td>
<td>• Rapidly microbicidal</td>
<td>• May leave instruments wet, causing them to rust</td>
</tr>
<tr>
<td></td>
<td>• Least affected by organic/inorganic soils among sterilization processes</td>
<td>• Potential for burns</td>
</tr>
<tr>
<td></td>
<td>listed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Rapid cycle time</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Penetrates medical packing, device lumens</td>
<td></td>
</tr>
<tr>
<td>Hydrogen Peroxide Gas</td>
<td>• Safe for the environment</td>
<td>• Cellulose (paper), linens and liquids cannot be processed</td>
</tr>
<tr>
<td>Plasma</td>
<td>• Leaves no toxic residuals</td>
<td>• Sterilization chamber is small, about 3.5 to 7.3 ft³</td>
</tr>
<tr>
<td></td>
<td>• Cycle time is 45-73 minutes and no aeration necessary</td>
<td>• Endoscopes or medical devices with lumens &gt;12.5 cm or a diameter of &lt; 1 mm cannot be processed at this time in the United States</td>
</tr>
<tr>
<td></td>
<td>• Used for heat- and moisture-sensitive items since process temperature &lt;50°C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Simple to operate, install (206 V outlet), and monitor</td>
<td>• Requires synthetic packaging (polypropylene wraps, polyethylene pouches) and special container tray</td>
</tr>
<tr>
<td></td>
<td>• Compatible with most medical devices</td>
<td>• Hydrogen peroxide may be toxic at levels greater than 1 ppm TWA</td>
</tr>
<tr>
<td></td>
<td>• Only requires electrical outlet</td>
<td></td>
</tr>
<tr>
<td>100% Ethylene Oxide (ETO)</td>
<td>• Penetrates packaging materials, device lumens</td>
<td>• Requires aeration time to remove ETO residue</td>
</tr>
<tr>
<td></td>
<td>• Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and ETO exposure</td>
<td>• Sterilization chamber is small, 4 ft³ to 8.8 ft³</td>
</tr>
<tr>
<td></td>
<td>• Simple to operate and monitor</td>
<td>• ETO is toxic, a carcinogen, and flammable</td>
</tr>
<tr>
<td></td>
<td>• Compatible with most medical materials</td>
<td>• ETO emission regulated by states but catalytic cell removes 99.9% of ETO and converts it to CO₂ and H₂O</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• ETO cartridges should be stored in flammable liquid storage cabinet</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lengthy cycle/aeration time</td>
</tr>
<tr>
<td>ETO Mixtures</td>
<td>• Penetrates medical packaging and many plastics</td>
<td>• Some states (e.g., CA, NY, MI) require ETO emission reduction of 80-99.9%</td>
</tr>
<tr>
<td>8.6% ETO/91.4% HCFC</td>
<td>• Compatible with most medical materials</td>
<td>• CFC (inert gas that eliminates explosion hazard) banned in 1995</td>
</tr>
<tr>
<td>10% ETO/90% HCFC</td>
<td>• Cycle easy to control and monitor</td>
<td>• Potential hazards to staff and patients</td>
</tr>
<tr>
<td>8.5% ETO/91.5% CO₂</td>
<td></td>
<td>• Lengthy cycle/aeration time</td>
</tr>
<tr>
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<td>• ETO is toxic, a carcinogen, and flammable</td>
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</tr>
<tr>
<td></td>
<td>• Standardized cycle</td>
<td></td>
</tr>
</tbody>
</table>

Modified from. 195

Abbreviations: CFC=chlorofluorocarbon, HCFC=hydrochlorofluorocarbon.
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