Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

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RECOMMENDATIONS FOR DISINFECTION AND STERILIZATION IN HEALTHCARE FACILITIES

A. Rationale

The ultimate goal of the Recommendations for Disinfection and Sterilization in Health-Care Facilities, 2008, is to reduce rates of health-care–associated infections through appropriate use of both disinfection and sterilization. Each recommendation is categorized according to scientific evidence, theoretical rationale, applicability, and federal regulations. Examples are included in some recommendations to aid the reader; however, these examples are not intended to define the only method of implementing the recommendation. The CDC system for categorizing recommendations is defined in the following (Rankings) section.

B. Rankings

Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and by a strong theoretical rationale.

Category IC. Required by state or federal regulations. Because of state differences, readers should not assume that the absence of an *IC* recommendation implies the absence of state regulations.

Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies or by a theoretical rationale.

No recommendation. Unresolved issue. These include practices for which insufficient evidence or no consensus exists regarding efficacy.

C. Recommendations

1. Occupational Health and Exposure

a. Inform each worker of the possible health effects of his or her exposure to infectious agents (e.g., hepatitis B virus [HBV], hepatitis C virus, human immunodeficiency virus [HIV]), and/or chemicals (e.g., EtO, formaldehyde). The information should be consistent with Occupational Safety and Health Administration (OSHA) requirements and identify the areas and tasks in which potential exists for exposure. *Category II, IC*[214, 320, 959, 997, 998]

b. Educate health-care workers in the selection and proper use of personal protective equipment (PPE). *Category II, IC*

c. Ensure that workers wear appropriate PPE to preclude exposure to infectious agents or chemicals through the respiratory system, skin, or mucous membranes of the eyes, nose, or mouth. PPE can include gloves, gowns, masks, and eye protection. The exact type of PPE depends on the infectious or chemical agent and the anticipated duration of exposure. The employer is responsible for making such equipment and training available. *Category II, IC*. [214, 997-999]

d. Establish a program for monitoring occupational exposure to regulated chemicals (e.g., formaldehyde, EtO) that adheres to state and federal regulations. *Category II, IC*. [997, 1000, 1001]

e. Exclude healthcare workers with weeping dermatitis of hands from direct contact with patient-care equipment. *Category IB*. [1002, 1003]

2. Cleaning of Patient-Care Devices

a. In hospitals, perform most cleaning, disinfection, and sterilization of patient-care devices in a central processing department in order to more easily control quality. *Category II*. [454, 836, 959]

b. Meticulously clean patient-care items with water and detergent, or with water and enzymatic cleaners before high-level disinfection or sterilization procedures. *Category IB*. [6, 83, 101, 104-106, 124, 179, 424-426, 436, 465, 471, 911-913, 1004]

i. Remove visible organic residue (e.g., residue of blood and tissue) and inorganic salts with cleaning. Use cleaning agents that are capable of removing visible organic and inorganic residues. *Category IB*. [424-426, 466, 468, 469, 471, 908, 910]

ii. Clean medical devices as soon as practical after use (e.g., at the point of use) because soiled materials become dried onto the instruments. Dried or baked materials on the instrument make the removal process more difficult and the disinfection or sterilization process less effective or ineffective. *Category IB*. [55, 56, 59, 291, 465, 1005, 1006]

c. Perform either manual cleaning (i.e., using friction) or mechanical cleaning (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizers). *Category IB*. [426, 456, 471, 999]

d. If using an automatic washer/disinfector, ensure that the unit is used in accordance with the manufacturer's recommendations. *Category IB*. [7, 133, 155, 725]

e. Ensure that the detergents or enzymatic cleaners selected are compatible with the metals and other materials used in medical instruments. Ensure that the rinse step is adequate for removing cleaning residues to levels that will not interfere with subsequent disinfection/sterilization processes. *Category II*. [836, 1004]

f. Inspect equipment surfaces for breaks in integrity that would impair either cleaning or disinfection/sterilization. Discard or repair equipment that no longer functions as intended or cannot be properly cleaned, and disinfected or sterilized. *Category II*. [888]

g.

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

a. Before use on each patient, sterilize critical medical and surgical devices and instruments that enter normally sterile tissue or the vascular system or through which a sterile body fluid flows (e.g., blood). See recommendation 7g for exceptions. *Category IA*. [179, 497, 821, 822, 907, 911, 912]

b. Provide, at a minimum, high-level disinfection for semicritical patient-care equipment (e.g., gastrointestinal endoscopes, endotracheal tubes, anesthesia breathing circuits, and respiratory therapy equipment) that touches either mucous membranes or nonintact skin. *Category IA*. [6-8, 17, 20, 99, 101, 108, 113-115, 129, 138, 139, 147, 152-154, 471, 1007]

c. Perform low-level disinfection for noncritical patient-care surfaces (e.g., bedrails, over-the-bed table) and equipment (e.g., blood pressure cuff) that touch intact skin (see Recommendation 5g). *Category II*. [17, 46-48, 50-52, 67, 68, 372, 373, 378, 382, 401]

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

a. Process noncritical patient-care devices using a disinfectant and the concentration of germicide listed in Table 1. *Category IB*. [17, 46-48, 50-52, 67, 68, 378, 382, 401]

b. Disinfect noncritical medical devices (e.g., blood pressure cuff) with an EPA-registered hospital disinfectant using the label's safety precautions and use directions. Most EPA-registered hospital disinfectants have a label contact time of 10 minutes. However, multiple scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens with a contact time of at least 1 minute. By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability from any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA. *Category IB*. [17, 47, 48, 50, 51, 53-57, 59, 60, 62-64, 355, 378, 382]

c. Ensure that, at a minimum, noncritical patient-care devices are disinfected when visibly soiled and on a regular basis (such as after use on each patient or once daily or once weekly). *Category II*. [378, 380, 1008]

d. If dedicated, disposable devices are not available, disinfect noncritical patient-care equipment after using it on a patient who is on contact precautions before using this equipment on another patient. *Category IB*. [47, 67, 391, 1009]

5. Cleaning and Disinfecting Environmental Surfaces in Healthcare Facilities

a. Clean housekeeping surfaces (e.g., floors, tabletops) on a regular basis, when spills occur, and when these surfaces are visibly soiled. *Category II*. [23, 378, 380, 382, 1008, 1010]

b. Disinfect (or clean) environmental surfaces on a regular basis (e.g., daily, three times per week) and when surfaces are visibly soiled. *Category II*. [378, 380, 402, 1008]

c. Follow manufacturers' instructions for proper use of disinfecting (or detergent) products --- such as recommended use-dilution, material compatibility, storage, shelf-life, and safe use and

disposal. *Category II*. [327, 365, 404]

d. Clean walls, blinds, and window curtains in patient-care areas when these surfaces are visibly contaminated or soiled. *Category II*. [1011]
e. Prepare disinfecting (or detergent) solutions as needed and replace these with fresh solution frequently (e.g., replace floor mopping solution every three patient rooms, change no less often than at 60-minute intervals), according to the facility's policy. *Category IB*. [68, 379]
f. Decontaminate mop heads and cleaning cloths regularly to prevent contamination (e.g., launder and dry at least daily). *Category II*. [68, 402, 403]
g. Use a one-step process and an EPA-registered hospital disinfectant designed for housekeeping purposes in patient care areas where 1) uncertainty exists about the nature of the soil on the surfaces (e.g., blood or body fluid contamination versus routine dust or dirt); or 2) uncertainty exists about the presence of multidrug resistant organisms on such surfaces. See 5n for recommendations requiring cleaning and disinfecting blood-contaminated surfaces. *Category II*. [23, 47, 48, 51, 214, 378, 379, 382, 416, 1012]

h. Detergent and water are adequate for cleaning surfaces in nonpatient-care areas (e.g., administrative offices). *Category II.* [23]

i. Do not use high-level disinfectants/liquid chemical sterilants for disinfection of non-critical surfaces. *Category IB*. [23, 69, 318]
j. Wet-dust horizontal surfaces regularly (e.g., daily, three times per week) using clean cloths moistened with an EPA-registered hospital disinfectant (or detergent). Prepare the disinfectant (or detergent) as recommended by the manufacturer. *Category II*. [68, 378, 380, 402, 403, 1008]
k. Disinfect noncritical surfaces with an EPA-registered hospital disinfectant according to the label's safety precautions and use directions. Most EPA-registered hospital disinfectants have a label contact time of 10 minutes. However, many scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens with a contact time of at least 1 minute. By law, the user must follow all applicable label instructions on EPA-registered products. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA. *Category II, IC*. [17, 47, 48, 50, 51, 53-57, 59, 60, 62-64, 355, 378, 382]
l. Do not use disinfectants to clean infant bassinets and incubators while these items are occupied. If disinfectants (e.g., phenolics) are used for the terminal cleaning of infant bassinets and incubators, thoroughly rinse the surfaces of these items with water and dry them before these items are reused. *Category IB*. [17, 739, 740]
m. Promptly clean and decontaminate spills of blood and other potentially infectious materials. Discard blood-contaminated items in compliance with federal regulations. *Category IB, IC*. [214]
n. For site decontamination of spills of blood or other potentially infectious materials (OPIM), implement the following procedures. Use protective gloves and other PPE (e.g., when sharps are involved use forceps to pick up sharps, and discard these items in a puncture-resistant container) appropriate for this task. Disinfect areas contaminated with blood spills using an EPA-registered tuberculocidal agent, a registered germicide on the EPA Lists D and E (i.e., products with specific label claims for HIV or HBV or freshly diluted hypochlorite solution. *Category II, IC*. [214, 215, 557, 1013] If sodium hypochlorite solutions are selected use a 1:100 dilution (e.g., 1:100 dilution of a 5.25-6.15% sodium hypochlorite provides 525-615 ppm available chlorine) to decontaminate nonporous surfaces after a small spill (e.g., <10 mL) of either blood or OPIM. If a spill involves large amounts (e.g., >10 mL) of blood or OPIM, or involves a culture spill in the laboratory, use a 1:10 dilution for the first application of hypochlorite solution before cleaning in order to reduce the risk of infection during the cleaning process in the event of a sharp injury. Follow this decontamination process with a terminal disinfection, using a 1:100 dilution of sodium hypochlorite. *Category IB, IC*. [63, 215, 557]
o. If the spill contains large amounts of blood or body fluids, clean the visible matter with disposable absorbent material, and discard the contaminated materials in appropriate, labeled containment. *Category II, IC.* [44, 214]
p. Use protective gloves and other PPE appropriate for this task. *Category II, IC*. [44, 214]

q. In units with high rates of endemic *Clostridium difficile* infection or in an outbreak setting, use dilute solutions of 5.25%–6.15% sodium hypochlorite (e.g., 1:10 dilution of household bleach) for routine environmental disinfection. Currently, no products are EPA-registered specifically for inactivating *C. difficile* spores. *Category II*. [257-259]

r. If chlorine solution is not prepared fresh daily, it can be stored at room temperature for up to 30 days in a capped, opaque plastic bottle with a 50% reduction in chlorine concentration after 30 days of storage (e.g., 1000 ppm chlorine [approximately a 1:50 dilution] at day 0 decreases to 500 ppm chlorine by day 30). *Category IB*. [327, 1014]

s. An EPA-registered sodium hypochlorite product is preferred, but if such products are not available, generic versions of sodium hypochlorite solutions (e.g., household chlorine bleach) can be used. *Category II.* [44]

6. Disinfectant Fogging

a. Do not perform disinfectant fogging for routine purposes in patient-care areas. C*ategory II*. [23, 228]

7. High-Level Disinfection of Endoscopes

a. To detect damaged endoscopes, test each flexible endoscope for leaks as part of each reprocessing cycle. Remove from clinical use any instrument that fails the leak test, and repair this instrument. *Category II*. [113, 115, 116]

b. Immediately after use, meticulously clean the endoscope with an enzymatic cleaner that is compatible with the endoscope. Cleaning is necessary before both automated and manual disinfection. *Category IA*. [83, 101, 104-106, 113, 115, 116, 124, 126, 456, 465, 466, 471, 1015]

c. Disconnect and disassemble endoscopic components (e.g., suction valves) as completely as possible and completely immerse all components in the enzymatic cleaner. Steam sterilize these components if they are heat stable. *Category IB*. [115, 116, 139, 465, 466]

d. Flush and brush all accessible channels to remove all organic (e.g., blood, tissue) and other residue. Clean the external surfaces and accessories of the devices by using a soft cloth or sponge or brushes. Continue brushing until no debris appears on the brush. *Category IA* [6, 17, 108, 113, 115, 116, 137, 145, 147, 725, 856, 903].

e. Use cleaning brushes appropriate for the size of the endoscope channel or port (e.g., bristles should contact surfaces). Cleaning items (e.g., brushes, cloth) should be disposable or, if they are not disposable, they should be thoroughly cleaned and either high-level disinfected or sterilized after each use. *Category II*. [113, 115, 116, 1016]

f. Discard enzymatic cleaners (or detergents) after each use because they are not microbicidal and, therefore, will not retard microbial growth. *Category IB*. [38, 113, 115, 116, 466]

g. Process endoscopes (e.g., arthroscopes, cystoscope, laparoscopes) that pass through normally sterile tissues using a sterilization procedure before each use; if this is not feasible, provide at least high-level disinfection. High-level disinfection of arthroscopes, laparoscopes, and cytoscopes should be followed by a sterile water rinse. *Category IB*. [1, 17, 31, 32, 35, 89, 90, 113, 554]

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

i. Mechanically clean reusable accessories inserted into endoscopes (e.g., biopsy forceps or other cutting instruments) that break the mucosal barrier (e.g., ultrasonically clean biopsy forceps) and then sterilize these items between each patient. *Category IA*. [1, 6, 8, 17, 108, 113, 115, 116, 138, 145, 147, 153, 278]

j. Use ultrasonic cleaning of reusable endoscopic accessories to remove soil and organic material from hard-to-clean areas. *Category II*. [116, 145, 148]

k. Process endoscopes and accessories that contact mucous membranes as semicritical items, and use at least high-level disinfection after use on each patient. *Category IA*. [1, 6, 8, 17, 108, 113, 115, 116, 129, 138, 145-148, 152-154, 278]

l. Use an FDA-cleared sterilant or high-level disinfectant for sterilization or high-level disinfection (Table 1). *Category IA*. [1, 6-8, 17, 85, 108, 113, 115, 116, 147]

m. After cleaning, use formulations containing glutaraldehyde, glutaraldehyde with phenol/phenate,

ortho-phthalaldehyde, hydrogen peroxide, and both hydrogen peroxide and peracetic acid to achieve high-level disinfection followed by rinsing and drying (see Table 1 for recommended concentrations). *Category IB*. [1, 6-8, 17, 38, 85, 108, 113, 145-148]

n. Extend exposure times beyond the minimum effective time for disinfecting semicritical patient-care equipment cautiously and conservatively because extended exposure to a high-level disinfectant is more likely to damage delicate and intricate instruments such as flexible endoscopes. The exposure times vary among the Food and Drug Administration (FDA)-cleared high-level disinfectants (Table 2). *Category IB*. [17, 69, 73, 76, 78, 83]

o. Federal regulations are to follow the FDA-cleared label claim for high-level disinfectants. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 25°C range from 20-90 minutes, depending upon the product based on three tier testing which includes AOAC sporicidal tests, simulated use testing with mycobacterial and in-use testing. *Category IC*.

p. Several scientific studies and professional organizations support the efficacy of >2% glutaraldehyde for 20 minutes at 20ºC; that efficacy assumes adequate cleaning prior to disinfection, whereas the FDA-cleared label claim incorporates an added margin of safety to accommodate possible lapses in cleaning practices. Facilities that have chosen to apply the 20 minute duration at 20ºC have done so based on the IA recommendation in the July 2003 SHEA position paper, "Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes [12, 17, 19, 26, 27, 49, 55, 57, 58, 60, 73, 76, 79-81, 83-85, 93, 94, 104-106, 110, 111, 115-121, 124, 125, 233, 235, 236, 243, 265, 266, 609]

q. When using FDA-cleared high-level disinfectants, use manufacturers' recommended exposure conditions. Certain products may require a shorter exposure time (e.g., 0.55% ortho-phthalaldehyde for 12 minutes at 20°C, 7.35% hydrogen peroxide plus 0.23% peracetic acid for 15 minutes at 20°C) than glutaraldehyde at room temperature because of their rapid inactivation of mycobacteria or reduced exposure time because of increased mycobactericidal activity at elevated temperature (e.g., 2.5% glutaraldehyde at 5 minutes at 35°C). *Category IB*. [83, 100, 689, 693, 694, 700]

r. Select a disinfectant or chemical sterilant that is compatible with the device that is being reprocessed. Avoid using reprocessing chemicals on an endoscope if the endoscope manufacturer warns against using these chemicals because of functional damage (with or without cosmetic damage). *Category IB*. [69, 113, 116]

s. Completely immerse the endoscope in the high-level disinfectant, and ensure all channels are perfused. As soon as is feasible, phase out nonimmersible endoscopes. *Category IB*. [108, 113-116, 137, 725, 856, 882]

t. After high-level disinfection, rinse endoscopes and flush channels with sterile water, filtered water, or tapwater to prevent adverse effects on patients associated with disinfectant retained in the endoscope (e.g., disinfectant induced colitis). Follow this water rinse with a rinse with 70% - 90% ethyl or isopropyl alcohol. *Category IB*. [17, 31-35, 38, 39, 108, 113, 115, 116, 134, 145-148, 620-622, 624-630, 1017]

u. After flushing all channels with alcohol, purge the channels using forced air to reduce the likelihood of contamination of the endoscope by waterborne pathogens and to facilitate drying. *Category IB*. [39, 113, 115, 116, 145, 147]

v. Hang endoscopes in a vertical position to facilitate drying. *Category II*. [17, 108, 113, 115, 116, 145, 815]

w. Store endoscopes in a manner that will protect them from damage or contamination. *Category II*. [17, 108, 113, 115, 116, 145]

x. Sterilize or high-level disinfect both the water bottle used to provide intraprocedural flush solution and its connecting tube at least once daily. After sterilizing or high-level disinfecting the water bottle, fill it with sterile water. *Category IB*. [10, 31-35, 113, 116, 1017]

y. Maintain a log for each procedure and record the following: patient's name and medical record number (if available), procedure, date, endoscopist, system used to reprocess the endoscope (if more than one system could be used in the reprocessing area), and serial number or other identifier of the endoscope used. *Category II*. [108, 113, 115, 116]

z. Design facilities where endoscopes are used and disinfected to provide a safe environment for healthcare workers and patients. Use air-exchange equipment (e.g., the ventilation system, out-exhaust ducts) to minimize exposure of all persons to potentially toxic vapors (e.g.,

glutaraldehyde vapor). Do not exceed the allowable limits of the vapor concentration of the chemical sterilant or high-level disinfectant (e.g., those of ACGIH and OSHA). *Category IB, IC*. [116, 145, 318, 322, 577, 652]

aa. Routinely test the liquid sterilant/high-level disinfectant to ensure minimal effective concentration of the active ingredient. Check the solution each day of use (or more frequently) using the appropriate chemical indicator (e.g., glutaraldehyde chemical indicator to test minimal effective concentration of glutaraldehyde) and document the results of this testing. Discard the solution if the chemical indicator shows the concentration is less than the minimum effective concentration. Do not use the liquid sterilant/high-level disinfectant beyond the reuse-life recommended by the manufacturer (e.g., 14 days for *ortho*-phthalaldehyde). *Category IA*. [76, 108, 113, 115, 116, 608, 609]

bb. Provide personnel assigned to reprocess endoscopes with device-specific reprocessing instructions to ensure proper cleaning and high-level disinfection or sterilization. Require competency testing on a regular basis (e.g., beginning of employment, annually) of all personnel who reprocess endoscopes. *Category IA*. [6-8, 108, 113, 115, 116, 145, 148, 155]

cc. Educate all personnel who use chemicals about the possible biologic, chemical, and environmental hazards of performing procedures that require disinfectants. C*ategory IB, IC*. [116, 997, 998, 1018, 1019]

dd. Make PPE(e.g., gloves, gowns, eyewear, face mask or shields, respiratory protection devices) available and use these items appropriately to protect workers from exposure to both chemicals and microorganisms (e.g., HBV). *Category IB, IC*. [115, 116, 214, 961, 997, 998, 1020, 1021]

ee. If using an automated endoscope reprocessor (AER), place the endoscope in the reprocessor and attach all channel connectors according to the AER manufacturer's instructions to ensure exposure of all internal surfaces to the high-level disinfectant/chemical sterilant. *Category IB*. [7, 8, 115, 116, 155, 725, 903]

ff. If using an AER, ensure the endoscope can be effectively reprocessed in the AER. Also, ensure any required manual cleaning/disinfecting steps are performed (e.g., elevator wire channel of duodenoscopes might not be effectively disinfected by most AERs). *Category IB*. [7, 8, 115, 116, 155, 725]

gg. Review the FDA advisories and the scientific literature for reports of deficiencies that can lead to infection because design flaws and improper operation and practices have compromised the effectiveness of AERs. *Category II*. [7, 98, 133, 134, 155, 725]

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

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

jj. No recommendation is made about routinely performing microbiologic testing of either endoscopes or rinse water for quality assurance purposes. *Unresolved Issue.* [116, 164]

kk. If environmental microbiologic testing is conducted, use standard microbiologic techniques*. Category II.* [23, 116, 157, 161, 167]

ll. If a cluster of endoscopy-related infections occurs, investigate potential routes of transmission (e.g., person-to-person, common source) and reservoirs. *Category IA*. [8, 1022]

mm. Report outbreaks of endoscope-related infections to persons responsible for institutional infection control and risk management and to FDA. *Category IB*. [6, 7, 113, 116, 1023] Notify the local and the state health departments, CDC, and the manufacturer(s). C*ategory II*.

nn. No recommendation is made regarding the reprocessing of an endoscope again immediately before use if that endoscope has been processed after use according to the recommendations in this guideline. *Unresolved issue*. [157]

oo. Compare the reprocessing instructions provided by both the endoscope's and the AER's manufacturer's instructions and resolve any conflicting recommendations. *Category IB*. [116, 155]

8. *Management of Equipment and Surfaces in Dentistry*

a. Dental instruments that penetrate soft tissue or bone (e.g., extraction forceps, scalpel blades, bone chisels, periodontal scalers, and surgical burs) are classified as critical and should be

sterilized after each use or discarded. In addition, after each use, sterilize dental instruments that are not intended to penetrate oral soft tissue or bone (e.g., amalgam condensers, air-water syringes) but that might contact oral tissues and are heat-tolerant, although classified as semicritical. Clean and, at a minimum, high-level disinfect heat-sensitive semicritical items. *Category IA*. [43, 209-211]

b. Noncritical clinical contact surfaces, such as uncovered operatory surfaces (e.g., countertops, switches, light handles), should be barrier-protected or disinfected between patients with an intermediate-disinfectant (i.e., EPA-registered hospital disinfectant with a tuberculocidal claim) or low-level disinfectant (i.e., EPA-registered hospital disinfectant with HIV and HBV claim). *Category IB*. [43, 209-211]

c. Barrier protective coverings can be used for noncritical clinical contact surfaces that are touched frequently with gloved hands during the delivery of patient care, that are likely to become contaminated with blood or body substances, or that are difficult to clean. Change these coverings when they are visibly soiled, when they become damaged, and on a routine basis (e.g., between patients). Disinfect protected surfaces at the end of the day or if visibly soiled. *Category II*. [43, 210]

9. Processing Patient-Care Equipment Contaminated with Bloodborne Pathogens (HBV, Hepatitis C Virus, HIV), Antibiotic-Resistant Bacteria (e.g., Vancomycin-Resistant Enterococci, Methicillin-Resistant Staphylococcus aureus, Multidrug Resistant Tuberculosis), or Emerging Pathogens (e.g., Cryptosporidium, Helicobacter pylori, Escherichia coli O157:H7, Clostridium difficile, Mycobacterium tuberculosis, Severe Acute Respiratory Syndrome Coronavirus), or Bioterrorist Agents

a. Use standard sterilization and disinfection procedures for patient-care equipment (as recommended in this guideline), because these procedures are adequate to sterilize or disinfect instruments or devices contaminated with blood or other body fluids from persons infected with bloodborne pathogens or emerging pathogens, with the exception of prions. No changes in these procedures for cleaning, disinfecting, or sterilizing are necessary for removing bloodborne and emerging pathogens other than prions. *Category IA*. [22, 53, 60-62, 73, 79-81, 105, 118-121, 125, 126, 221, 224-234, 236, 244, 265, 266, 271-273, 279, 282, 283, 354-357, 666]

10. Disinfection Strategies for Other Semicritical Devices

a. Even if probe covers have been used, clean and high-level disinfect other semicritical devices such as rectal probes, vaginal probes, and cryosurgical probes with a product that is not toxic to staff, patients, probes, and retrieved germ cells (if applicable). Use a high-level disinfectant at the FDA-cleared exposure time. (See Recommendations 7o and 11e for exceptions.) *Category IB*. [6-8, 17, 69]

b. When probe covers are available, use a probe cover or condom to reduce the level of microbial contamination. *Category II*. [197-201] Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers because these sheaths and condoms can fail. *Category IB* [197-201]

c. After high-level disinfection, rinse all items. Use sterile water, filtered water or tapwater followed by an alcohol rinse for semicritical equipment that will have contact with mucous membranes of the upper respiratory tract (e.g., nose, pharynx, esophagus). *Category II*. [10, 31-35, 1017]

d. There is no recommendation to use sterile or filtered water rather than tapwater for rinsing semicritical equipment that contact the mucous membranes of the rectum (e.g., rectal probes, anoscope) or vagina (e.g., vaginal probes). *Unresolved issue.* [11]

e. Wipe clean tonometer tips and then disinfect them by immersing for 5-10 minutes in either 5000 ppm chlorine or 70% ethyl alcohol. None of these listed disinfectant products are FDA-cleared high-level disinfectants. *Category II*. [49, 95, 185, 188, 293]

11. Disinfection by Healthcare Personnel in Ambulatory Care and Home Care

a. Follow the same classification scheme described above (i.e., that critical devices require sterilization, semicritical devices require high-level disinfection, and noncritical equipment

requires low-level disinfection) in the ambulatory-care (outpatient medical/surgical facilities) setting because risk for infection in this setting is similar to that in the hospital setting (see Table 1). *Category IB*. [6-8, 17, 330]

b. When performing care in the home, clean and disinfect reusable objects that touch mucous membranes (e.g., tracheostomy tubes) by immersing these objects in a 1:50 dilution of 5.25%-6.15% sodium hypochlorite (household bleach) (3 minutes), 70% isopropyl alcohol (5 minutes), or 3% hydrogen peroxide (30 minutes) because the home environment is, in most instances, safer than either hospital or ambulatory care settings because person-to-person transmission is less likely. *Category II*. [327, 328, 330, 331]

c. Clean noncritical items that would not be shared between patients (e.g., crutches, blood pressure cuffs) in the home setting with a detergent or commercial household disinfectant. *Category II*. [53, 330]

12. Microbial Contamination of Disinfectants

a. Institute the following control measures to reduce the occurrence of contaminated disinfectants: 1) prepare the disinfectant correctly to achieve the manufacturer's recommended use-dilution; and 2) prevent common sources of extrinsic contamination of germicides (e.g., container contamination or surface contamination of the healthcare environment where the germicide are prepared and/or used). *Category IB*. [404, 406, 1024]

13. Flash Sterilization

a. Do not flash sterilize implanted surgical devices unless doing so is unavoidable. *Category IB*. [849, 850]

b. Do not use flash sterilization for convenience, as an alternative to purchasing additional instrument sets, or to save time. Category II. [817, 962]

c. When using flash sterilization, make sure the following parameters are met: 1) clean the item before placing it in the sterilizing container (that are FDA cleared for use with flash sterilization) or tray; 2) prevent exogenous contamination of the item during transport from the sterilizer to the patient; and 3) monitor sterilizer function with mechanical, chemical, and biologic monitors. *Category IB*. [812, 819, 846, 847, 962]

d. Do not use packaging materials and containers in flash sterilization cycles unless the sterilizer and the packaging material/container are designed for this use. *Category IB*. [812, 819, 1025]

e. When necessary, use flash sterilization for patient-care items that will be used immediately (e.g., to reprocess an inadvertently dropped instrument). *Category IB*. [812, 817, 819, 845]

f. When necessary, use flash sterilization for processing patient-care items that cannot be packaged, sterilized, and stored before use. *Category IB*. [812, 819]

14. Methods of Sterilization

a. Steam is the preferred method for sterilizing critical medical and surgical instruments that are not damaged by heat, steam, pressure, or moisture. *Category IA*. [181, 271, 425, 426, 827, 841, 1026, 1027]

b. Cool steam- or heat-sterilized items before they are handled or used in the operative setting. *Category IB*. [850]

c. Follow the sterilization times, temperatures, and other operating parameters (e.g., gas concentration, humidity) recommended by the manufacturers of the instruments, the sterilizer, and the container or wrap used, and that are consistent with guidelines published by government agencies and professional organizations. *Category IB*. [811-814, 819, 825, 827, 841, 1026-1028]

d. Use low-temperature sterilization technologies (e.g., EtO, hydrogen peroxide gas plasma) for reprocessing critical patient-care equipment that is heat or moisture sensitive. *Category IA* [469, 721, 825, 856, 858, 878, 879, 881, 882, 890, 891, 1027].

e. Completely aerate surgical and medical items that have been sterilized in the EtO sterilizer (e.g., polyvinylchloride tubing requires 12 hours at 50°C, 8 hours at 60°C) before using these items in patient care. *Category IB*. [814]

f. Sterilization using the peracetic acid immersion system can be used to sterilize heat-sensitive

immersible medical and surgical items. *Category IB*. [90, 717-719, 721-724]

g. Critical items that have been sterilized by the peracetic acid immersion process must be used immediately (i.e., items are not completely protected from contamination, making long-term storage unacceptable). *Category II*. [817, 825]
h. Dry-heat sterilization (e.g., 340°F for 60 minutes) can be used to sterilize items (e.g., powders, oils) that can sustain high temperatures. *Category IB*. [815, 827]
i. Comply with the sterilizer manufacturer's instructions regarding the sterilizer cycle parameters (e.g., time, temperature, concentration). *Category IB*. [155, 725, 811-814, 819]
j. Because narrow-lumen devices provide a challenge to all low-temperature sterilization technologies and direct contact is necessary for the sterilant to be effective, ensure that the sterilant has direct contact with contaminated surfaces (e.g., scopes processed in peracetic acid must be connected to channel irrigators). *Category IB*. [137, 725, 825, 856, 890, 891, 1029]

15. Packaging

a. Ensure that packaging materials are compatible with the sterilization process and have received FDA 510[k] clearance. *Category IB*. [811-814, 819, 966]
b. Ensure that packaging is sufficiently strong to resist punctures and tears to provide a barrier to microorganisms and moisture. *Category IB*. [454, 811-814, 819, 966]

16. Monitoring of Sterilizers

a. Use mechanical, chemical, and biologic monitors to ensure the effectiveness of the sterilization process. *Category IB*. [811-815, 819, 846, 847, 975-977]
b. Monitor each load with mechanical (e.g., time, temperature, pressure) and chemical (internal and external) indicators. If the internal chemical indicator is visible, an external indicator is not needed. *Category II*. [811-815, 819, 846, 847, 975-977, 980]
c. Do not use processed items if the mechanical (e.g., time, temperature, pressure) or chemical (internal and/or external) indicators suggest inadequate processing. *Category IB* [811-814, 819].
d. Use biologic indicators to monitor the effectiveness of sterilizers at least weekly with an FDA-cleared commercial preparation of spores (e.g., *Geobacillus stearothermophilus* for steam) intended specifically for the type and cycle parameters of the sterilizer. *Category IB*. [1, 811, 813-815, 819, 846, 847, 976, 977]
e. After a single positive biologic indicator used with a method other than steam sterilization, treat as nonsterile all items that have been processed in that sterilizer, dating from the sterilization cycle having the last negative biologic indicator to the next cycle showing satisfactory biologic indicator results. These nonsterile items should be retrieved if possible and reprocessed. *Category II*. [1]
f. After a positive biologic indicator with steam sterilization, objects other than implantable objects do not need to be recalled because of a single positive spore test unless the sterilizer or the sterilization procedure is defective as determined by maintenance personnel or inappropriate cycle settings. If additional spore tests remain positive, consider the items nonsterile and recall and reprocess the items from the implicated load(s). *Category II*. [1]
g. Use biologic indicators for every load containing implantable items and quarantine items, whenever possible, until the biologic indicator is negative. *Category IB*. [811-814, 819]

17. Load Configuration.

a. Place items correctly and loosely into the basket, shelf, or cart of the sterilizer so as not to impede the penetration of the sterilant. *Category IB*. [445, 454, 811, 813, 819, 836]

18. Storage of Sterile Items

a. Ensure the sterile storage area is a well-ventilated area that provides protection against dust, moisture, insects, and temperature and humidity extremes. *Category II*. [454, 819, 836, 969]
b. Store sterile items so the packaging is not compromised (e.g., punctured, bent). *Category II*. [454, 816, 819, 968, 969, 1030]

c. Label sterilized items with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and, if applicable, the expiration date. *Category IB*. [811, 812, 814, 816, 819]

d. The shelf life of a packaged sterile item depends on the quality of the wrapper, the storage conditions, the conditions during transport, the amount of handling, and other events (moisture) that compromise the integrity of the package. If event-related storage of sterile items is used, then packaged sterile items can be used indefinitely unless the packaging is compromised (see f and g below). *Category IB*. [816, 819, 836, 968, 973, 1030, 1031]

e. Evaluate packages before use for loss of integrity (e.g., torn, wet, punctured). The pack can be used unless the integrity of the packaging is compromised. *Category II*. [819, 968]

f. If the integrity of the packaging is compromised (e.g., torn, wet, or punctured), repack and reprocess the pack before use. *Category II*. [819, 1032]

g. If time-related storage of sterile items is used, label the pack at the time of sterilization with an expiration date. Once this date expires, reprocess the pack. *Category II*. [819, 968]

19. Quality Control

a. Provide comprehensive and intensive training for all staff assigned to reprocess semicritical and critical medical/surgical instruments to ensure they understand the importance of reprocessing these instruments. To achieve and maintain competency, train each member of the staff that reprocesses semicritical and/or critical instruments as follows: 1) provide hands-on training according to the institutional policy for reprocessing critical and semicritical devices; 2) supervise all work until competency is documented for each reprocessing task; 3) conduct competency testing at beginning of employment and regularly thereafter (e.g., annually); and 4) review the written reprocessing instructions regularly to ensure they comply with the scientific literature and the manufacturers' instructions. *Category IB*. [6-8, 108, 114, 129, 155, 725, 813, 819]

b. Compare the reprocessing instructions (e.g., for the appropriate use of endoscope connectors, the capping/noncapping of specific lumens) provided by the instrument manufacturer and the sterilizer manufacturer and resolve any conflicting recommendations by communicating with both manufacturers. *Category IB*. [155, 725]

c. Conduct infection control rounds periodically (e.g., annually) in high-risk reprocessing areas (e.g., the Gastroenterology Clinic, Central Processing); ensure reprocessing instructions are current and accurate and are correctly implemented. Document all deviations from policy. All stakeholders should identify what corrective actions will be implemented. *Category IB*. [6-8, 129]

d. Include the following in a quality control program for sterilized items: a sterilizer maintenance contract with records of service; a system of process monitoring; air-removal testing for prevacuum steam sterilizers; visual inspection of packaging materials; and traceability of load contents. *Category II* [811-814, 819].

e. For each sterilization cycle, record the type of sterilizer and cycle used; the load identification number; the load contents; the exposure parameters (e.g., time and temperature); the operator's name or initials; and the results of mechanical, chemical, and biological monitoring. *Category II* [811-814, 819].

f. Retain sterilization records (mechanical, chemical, and biological) for a time period that complies with standards (e.g., 3 years), statutes of limitations, and state and federal regulations. *Category II, IC*. [1033]

g. Prepare and package items to be sterilized so that sterility can be achieved and maintained to the point of use. Consult the Association for the Advancement of Medical Instrumentation or the manufacturers of surgical instruments, sterilizers, and container systems for guidelines for the density of wrapped packages. *Category II*. [811-814, 819]

h. Periodically review policies and procedures for sterilization. *Category II*. [1033]

i. Perform preventive maintenance on sterilizers by qualified personnel who are guided by the manufacturer's instruction. *Category II*. [811-814, 819]

20. Reuse of Single-Use Medical Devices

a. Adhere to the FDA enforcement document for single-use devices reprocessed by hospitals. FDA considers the hospital that reprocesses a single-use device as the manufacturer of the device and regulates the hospital using the same standards by which it regulates the original equipment manufacturer. *Category II, IC*. [995]

Table 1. Methods of sterilization and disinfection.

	Sterilization		Disinfection		
	Critical items (will enter tissue or vascular system or blood will flow through them)		High-level (semicritical items; [except dental] will come in contact with mucous membrane or nonintact skin)	Intermediate-level (some semicritical items[1] and noncritical items)	Low-level (noncritical items; will come in contact with intact skin)
Object	Procedure	Exposure time	Procedure (exposure time 12-30 min at ≥20°C)[2,3]	Procedure (exposure time ≥ 1 m)[9]	Procedure (exposure time ≥ 1 m)[9]
Smooth, hard Surface[1,4]	A	MR	D	K	K
	B	MR	E	L[5]	L
	C	MR	F	M	M
	D	10 h at 20-25°C	H	N	N
	F	6 h	I[6]		O
	G	12 m at 50-56°C	J		
	H	3-8 h			
Rubber tubing and catheters[3,4]	A	MR	D		
	B	MR	E		
	C	MR	F		
	D	10 h at 20-25°C	H		
	F	6 h	I[6]		
	G	12 m at 50-56°C	J		
	H	3-8 h			
Polyethylene tubing and catheters[3,4,7]	A	MR	D		
	B	MR	E		
	C	MR	F		
	D	10 h at 20-25°C	H		
	F	6 h	I[6]		
	G	12 m at 50-56°C	J		
	H	3-8 h			
Lensed instruments[4]	A	MR	D		
	B	MR	E		
	C	MR	F		
	D	10 h at 20-25°C	H		
	F	6 h	J		
	G	12 m at 50-56°C			
	H	3-8 h			
Thermometers (oral and rectal)[8]					K[8]
Hinged instruments[4]	A	MR	D		
	B	MR	E		
	C	MR	F		
	D	10 h at 20-25°C	H		
	F	6 h	I[6]		
	G	12 m at 50-56°C	J		
	H	3-8 h			

Modified from Rutala and Simmons. [15, 17, 18, 421] 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 internal diameter and length restrictions, 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 (1.12%) and 1.93% phenol/phenate. One glutaraldehyde-based product has a high-level disinfection claim of 5 minutes at 35°C.
E, Ortho-phthalaldehyde (OPA) 0.55%
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, single use chlorine generated on-site by electrolyzing saline containing >650-675 active free chlorine; (will 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. Follow the FDA-cleared high-level disinfection claim. 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. 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 25°C in automated endoscope reprocessor).
[3] Tubing must be completely filled for high-level 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] A concentration of 1000 ppm available chlorine should be considered where cultures or concentrated preparations of microorganisms have spilled (5.25% to 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.
[9] By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered products label, the user assumes liability from any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA.

Table 2. Properties of an ideal disinfectant.

Broad spectrum: should have a wide antimicrobial spectrum
Fast acting: should produce a rapid kill
Not affected by environmental factors: should be active in the presence of organic matter (e.g., blood, sputum, feces) and compatible with soaps, detergents, and other chemicals encountered in use
Nontoxic: should not be harmful to the user or patient
Surface compatibility: should not corrode instruments and metallic surfaces and should not cause the deterioration of cloth, rubber, plastics, and other materials
Residual effect on treated surfaces: should leave an antimicrobial film on the treated surface
Easy to use with clear label directions
Odorless: should have a pleasant odor or no odor to facilitate its routine use
Economical: should not be prohibitively high in cost
Solubility: should be soluble in water
Stability: should be stable in concentrate and use-dilution
Cleaner: should have good cleaning properties
Environmentally friendly: should not damage the environment on disposal

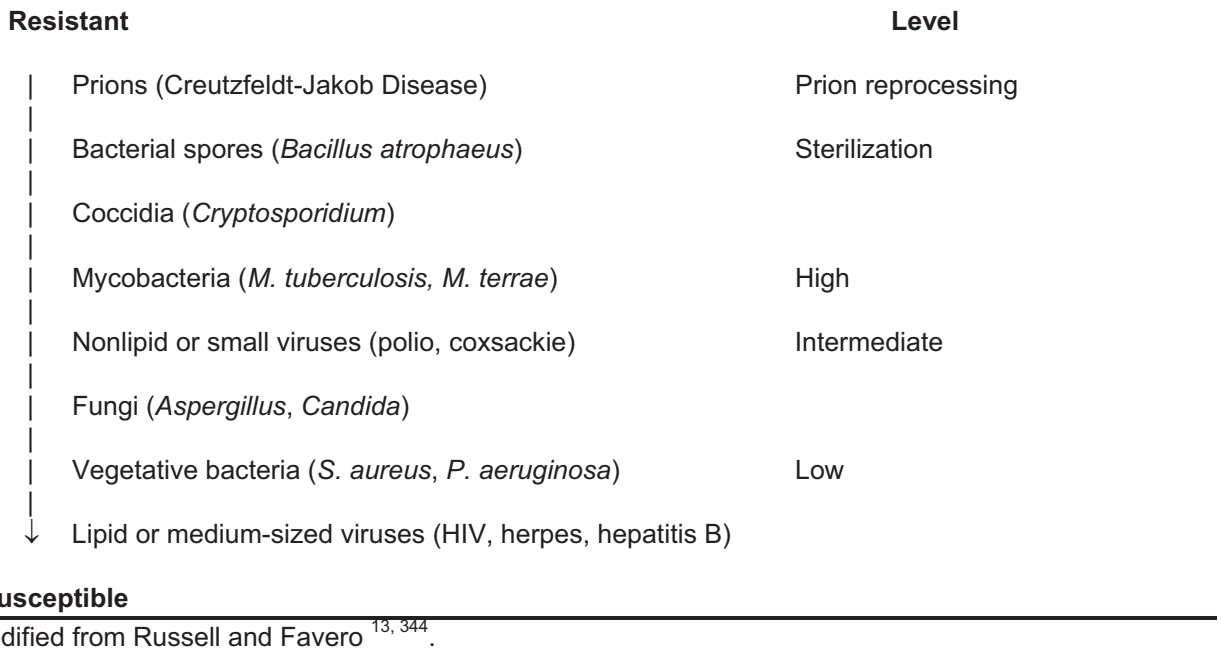
Modified from Molinari[1035].

Table 3. Epidemiologic evidence associated with the use of surface disinfectants or detergents on noncritical environmental surfaces.

Justification for Use of Disinfectants for Noncritical Environmental Surfaces
Surfaces may contribute to transmission of epidemiologically important microbes (e.g., vancomycin-resistant Enterococci, methicillin-resistant *S. aureus*, viruses)
Disinfectants are needed for surfaces contaminated by blood and other potentially infective material
Disinfectants are more effective than detergents in reducing microbial load on floors
Detergents become contaminated and result in seeding the patient's environment with bacteria
Disinfection of noncritical equipment and surfaces is recommended for patients on isolation precautions by the Centers for Disease Control and Prevention.
Advantage of using a single product for decontamination of noncritical surfaces, both floors and equipment
Some newer disinfectants have persistent antimicrobial activity
Justification for Using a Detergent on Noncritical Environmental Surfaces
Noncritical surfaces contribute minimally to endemic healthcare-associated infections
No difference in healthcare-associated infection rates when floors are cleaned with detergent versus disinfectant
No environmental impact (aquatic or terrestrial) issues with disposal
No occupational health exposure issues
Lower costs
Use of antiseptics/disinfectants selects for antibiotic-resistant bacteria (?)
More aesthetically pleasing floor

Modified from Rutala[378].

Figure 1. Decreasing order of resistance of microorganisms to disinfection and sterilization and the level of disinfection or sterilization.



Modified from Russell and Favero [13, 344].

Table 4. Comparison of the characteristics of selected chemicals used as high-level disinfectants or chemical sterilants.

	HP (7.5%)	PA (0.2%)	Glut (≥2.0%)	OPA (0.55%)	HP/PA (7.35%/0.23%)
HLD Claim	30 m @ 20°C	NA	20-90 m @ 20°-25°C	12 m @ 20°C, 5 m @ 25°C in AER	15m @ 20°C
Sterilization Claim	6 h @ 20°	12m @ 50-56°C	10 h @ 20°-25°C	None	3 h @ 20°C
Activation	No	No	Yes (alkaline glut)	No	No
Reuse Life[1]	21d	Single use	14-30 d	14d	14d
Shelf Life Stability[2]	2 y	6 mo	2 y	2 y	2 y
Disposal Restrictions	None	None	Local[3]	Local[3]	None
Materials Compatibility	Good	Good	Excellent	Excellent	No data
Monitor MEC[4]	Yes (6%)	No	Yes (1.5% or higher)	Yes (0.3% OPA)	No
Safety	Serious eye damage (safety glasses)	Serious eye and skin damage (conc soln)[5]	Respiratory	Eye irritant, stains skin	Eye damage
Processing	Manual or automated	Automated	Manual or automated	Manual or automated	Manual
Organic material resistance	Yes	Yes	Yes	Yes	Yes
OSHA exposure limit	1 ppm TWA	None	None[6]	None	HP-1 ppm TWA
Cost profile (per cycle)[7]	+ (manual), ++ (automated)	+++++ (automated)	+ (manual), ++ (automated)	++ (manual)	++ (manual)

Modified from Rutala [69].

Abbreviations: HLD=high-level disinfectant; HP=hydrogen peroxide; PA=peracetic acid; glut=glutaraldehyde; PA/HP=peracetic acid and hydrogen peroxide; OPA =ortho-phthalaldehyde (FDA cleared as a high-level disinfectant, included for comparison to other chemical agents used for high-level disinfection); m=minutes; h=hours; NA=not applicable; TWA=time-weighted average for a conventional 8-hour workday.

[1]number of days a product can be reused as determined by re-use protocol

[2]time a product can remain in storage (unused)

[3]no U.S. EPA regulations but some states and local authorities have additional restrictions

[4]MEC=minimum effective concentration is the lowest concentration of active ingredients at which the product is still effective

[5]Conc soln=concentrated solution

[6]The ceiling limit recommended by the American Conference of Governmental Industrial Hygienists is 0.05 ppm.

[7]per cycle cost profile considers cost of the processing solution (suggested list price to healthcare facilities in August 2001) and assumes maximum use life (e.g., 21 days for hydrogen peroxide, 14 days for glutaraldehyde), 5 reprocessing cycles per day, 1-gallon basin for manual processing, and 4-gallon tank for automated processing. + = least expensive; +++++ = most expensive

Table 5. Summary of advantages and disadvantages of chemical agents used as chemical sterilants[1] or as high-level disinfectants.		
Sterilization Method	Advantages	Disadvantages
Peracetic Acid/Hydrogen Peroxide	• No activation required • Odor or irritation not significant	• Materials compatibility concerns (lead, brass, copper, zinc) both cosmetic and functional • Limited clinical experience • Potential for eye and skin damage
Glutaraldehyde	• Numerous use studies published • Relatively inexpensive • Excellent materials compatibility	• Respiratory irritation from glutaraldehyde vapor • Pungent and irritating odor • Relatively slow mycobactericidal activity • Coagulates blood and fixes tissue to surfaces • Allergic contact dermatitis • Glutaraldehyde vapor monitoring recommended
Hydrogen Peroxide	• No activation required • May enhance removal of organic matter and organisms • No disposal issues • No odor or irritation issues • Does not coagulate blood or fix tissues to surfaces • Inactivates *Cryptosporidium* • Use studies published	• Material compatibility concerns (brass, zinc, copper, and nickel/silver plating) both cosmetic and functional • Serious eye damage with contact
Ortho-phthalaldehyde	• Fast acting high-level disinfectant • No activation required • Odor not significant • Excellent materials compatibility claimed • Does not coagulate blood or fix tissues to surfaces claimed	• Stains skin, mucous membranes, clothing, and environmental surfaces • Repeated exposure may result in hypersensitivity in some patients with bladder cancer • More expensive than glutaraldehyde • Eye irritation with contact • Slow sporicidal activity
Peracetic Acid	• Rapid sterilization cycle time (30-45 minutes) • Low temperature (50-55°C) liquid immersion sterilization • Environmental friendly by-products (acetic acid, O_2, H_20) • Fully automated • Single-use system eliminates need for concentration testing • Standardized cycle • May enhance removal of organic material and endotoxin • No adverse health effects to operators under normal operating conditions • Compatible with many materials and instruments • Does not coagulate blood or fix tissues to surfaces • Sterilant flows through scope facilitating salt, protein, and microbe removal • Rapidly sporicidal • Provides procedure standardization (constant dilution, perfusion of channel, temperatures, exposure)	• Potential material incompatibility (e.g., aluminum anodized coating becomes dull) • Used for immersible instruments only • Biological indicator may not be suitable for routine monitoring • One scope or a small number of instruments can be processed in a cycle • More expensive (endoscope repairs, operating costs, purchase costs) than high-level disinfection • Serious eye and skin damage (concentrated solution) with contact • Point-of-use system, no sterile storage

Modified from Rutala[69].

[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 6. Summary of advantages and disadvantages of commonly used sterilization technologies.

Sterilization Method	Advantages	Disadvantages
Steam	· Nontoxic to patient, staff, environment · Cycle easy to control and monitor · Rapidly microbicidal · Least affected by organic/inorganic soils among sterilization processes listed · Rapid cycle time · Penetrates medical packing, device lumens	· Deleterious for heat-sensitive instruments · Microsurgical instruments damaged by repeated exposure · May leave instruments wet, causing them to rust • Potential for burns
Hydrogen Peroxide Gas Plasma	· Safe for the environment · Leaves no toxic residuals · Cycle time is 28-75 minutes (varies with model type) and no aeration necessary · Used for heat- and moisture-sensitive items since process temperature <50°C · Simple to operate, install (208 V outlet), and monitor · Compatible with most medical devices . Only requires electrical outlet	· Cellulose (paper), linens and liquids cannot be processed · Sterilization chamber size from 1.8-9.4 ft^3 total volume (varies with model type) · Some endoscopes or medical devices with long or narrow lumens cannot be processed at this time in the United States (see manufacturer's recommendations for internal diameter and length restrictions) · Requires synthetic packaging (polypropylene wraps, polyolefin pouches) and special container tray • Hydrogen peroxide may be toxic at levels greater than 1 ppmTWA
100% Ethylene Oxide (ETO)	· Penetrates packaging materials, device lumens · Single-dose cartridge and negative- pressure chamber minimizes the potential for gas leak and ETO exposure · Simple to operate and monitor · Compatible with most medical materials	· Requires aeration time to remove ETO residue · Sterilization chamber size from 4.0-7.9 ft^3 total volume (varies with model type) · ETO is toxic, a carcinogen, and flammable · ETO emission regulated by states but catalytic cell removes 99.9% of ETO and converts it to CO_2 and H_2O · ETO cartridges should be stored in flammable liquid storage cabinet · Lengthy cycle/aeration time
ETO Mixtures 8.6% ETO/91.4% HCFC 10% ETO/90% HCFC 8.5% ETO/91.5% CO_2	· Penetrates medical packaging and many plastics · Compatible with most medical materials · Cycle easy to control and monitor	· Some states (e.g., CA, NY, MI) require ETO emission reduction of 90-99.9% · CFC (inert gas that eliminates explosion hazard) banned in 1995 · Potential hazards to staff and patients · Lengthy cycle/aeration time . ETO is toxic, a carcinogen, and flammable
Peracetic Acid	· Rapid cycle time (30-45 minutes) Low temperature (50-55°C liquid immersion sterilization · Environmental friendly by-products · Sterilant flows through endoscope which facilitates salt, protein and microbe removal	· Point-of-use system, no sterile storage · Biological indicator may not be suitable for routine monitoring · Used for immersible instruments only · Some material incompatibility (e.g., aluminum anodized coating becomes dull) · One scope or a small number of instruments processed in a cycle • Potential for serious eye and skin damage (concentrated solution) with contact

Modified from Rutala. [825]

Abbreviations: CFC=chlorofluorocarbon, HCFC=hydrochlorofluorocarbon.

Table 7. Minimum cycle times for steam sterilization cycles

Type of sterilizer	Item	Exposure time at 250°F (121°C)	Exposure time at 270°F (132°C)	Drying time
Gravity displacement	Wrapped instruments	30 min	15 min	**15-30** min
	Textile packs	30 min	25 min	**15** min
	Wrapped utensils	30 min	15 min	**15-30** min
Dynamic-air-removal (e.g., prevacuum)	Wrapped instruments		4 min	**20-30** min
	Textile packs		4 min	**5-20** min
	Wrapped utensils		4 min	20 min

Modified from Association for the Advancement of Medical Instrumentation. [813, 819]

Table 8. Examples of flash steam sterilization parameters.

Type of sterilizer	Load configuration	Temperature	Time
Gravity displacement	Nonporous items only (i.e., routine metal instruments, no lumens)	132°C (270°F)	3 minutes
	Nonporous and porous items (e.g., rubber or plastic items, items with lumens) sterilized together	132°C (270°F)	10 minutes
Prevacuum	Nonporous items only (i.e., routine metal instruments, no lumens)	132°C (270°F)	3 minutes
	Nonporous and porous items (e.g., rubber or plastic items, items with lumens) sterilized together	132°C (270°F)	4 minutes
Steam-flush pressure-pulse	Nonporous or mixed nonporous/porous items	132° (270°F) Manufacturers' instruction	**4** minutes

Modified from Association for the Advancement of Medical Instrumentation. [812, 819]

Table 9. Characteristics of an ideal low-temperature sterilization process.

High efficacy: the agent should be virucidal, bactericidal, tuberculocidal, fungicidal and sporicidal
Rapid activity: ability to quickly achieve sterilization
Strong penetrability: ability to penetrate common medical-device packaging materials and penetrate into the interior of device lumens
Material compatibility: produces only negligible changes in the appearance or the function of processed items and packaging materials even after repeated cycling
Nontoxic: presents no toxic health risk to the operator or the patient and poses no hazard to the environment
Organic material resistance: withstands reasonable organic material challenge without loss of efficacy
Adaptability: suitable for large or small (point of use) installations
Monitoring capability: monitored easily and accurately with physical, chemical, and biological process monitors
Cost effectiveness: reasonable cost for installation and for routine operation

Modified from Schneider. [851]

Table 10. Factors affecting the efficacy of sterilization.

Factors	Effect
Cleaning[1]	Failure to adequately clean instrument results in higher bioburden, protein load, and salt concentration. These will decrease sterilization efficacy.
Bioburden[1]	The natural bioburden of used surgical devices is 10^0 to 10^3 organisms (primarily vegetative bacteria), which is substantially below the 10^5-10^6 spores used with biological indicators.
Pathogen type	Spore-forming organisms are most resistant to sterilization and are the test organisms required for FDA clearance. However, the contaminating microflora on used surgical instruments consists mainly of vegetative bacteria.
Protein[1]	Residual protein decreases efficacy of sterilization. However, cleaning appears to rapidly remove protein load.
Salt[1]	Residual salt decreases efficacy of sterilization more than does protein load. However, cleaning appears to rapidly remove salt load.
Biofilm accumulation[1]	Biofilm accumulation reduces efficacy of sterilization by impairing exposure of the sterilant to the microbial cell.
Lumen length	Increasing lumen length impairs sterilant penetration. May require forced flow through lumen to achieve sterilization.
Lumen diameter	Decreasing lumen diameter impairs sterilant penetration. May require forced flow through lumen to achieve sterilization.
Restricted flow	Sterilant must come into contact with microorganisms. Device designs that prevent or inhibit this contact (e.g., sharp bends, blind lumens) will decrease sterilization efficacy.
Device design and construction	Materials used in construction may affect compatibility with different sterilization processes and affect sterilization efficacy. Design issues (e.g., screws, hinges) will also affect sterilization efficacy.

Modified from Alfa and Rutala. [470, 825] [1] Factor only relevant for reused surgical/medical devices

Table 11. Comparative evaluation of the microbicidal activity of low-temperature sterilization technology.

	Carriers Sterilized by Various Low-Temperature Sterilization Technologies						
Challenge	**ETO 12/88**	**100% ETO**	**HCFC-ETO**	**HPGP 100**	**HPGP 100S**	**PA**	**Reference**
No salt or serum[1]	100%	100%	96%	100%	ND	ND	Alfa [721]
10% serum and 0.65% salt[2]	97%	60%	95%	37%	ND	ND	Alfa [721]
Lumen (125 cm long x 3 mm wide) without serum or salt[1]	ND	96%	96%	ND	ND	ND	Alfa [721]
Lumen (125 cm long x 3 mm wide) with 10% serum and 0.65% salt[2]	44%	40%	49%	35%	ND	100%[1]	Alfa [721]
Lumen (40 cm long x 3 mm wide)[3]	ND	ND	100%	95%	100%	8%	Rutala [856]
Lumen (40 cm long x 2 mm wide)[3]	ND	ND	100%	93%	100%	ND	Rutala [856]
Lumen (40 cm long x 1 mm wide)[3]	ND	ND	100%	26%	100%	ND	Rutala [856]
Lumen (40 cm long x 3 mm wide)[4]	ND	ND	100%	100%	100%	ND	Rutala [856]

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Modified from Rutala. [825]
Abbreviations: ETO=ethylene oxide; HCFC=hydrochlorofluorocarbon; ND=no data; HPGP=hydrogen peroxide gas plasma; PA=peracetic acid.

[1]Test organisms included *Enterococcus faecalis*, *Mycobacterium chelonae*, and *Bacillus atrophaeus* spores.
[2]Test organisms included *E. faecalis*, *P. aeruginosa*, *E. coli*, *M. chelonae*, *B. atrophaeus* spores, *G. stearothermophilus* spores, and *B. circulans* spores.
[3]Test organism was *G. stearothermophilus* spores . The lumen test units had a removable 5 cm center piece (1.2 cm diameter) of stainless steel sealed to the narrower steel tubing by hard rubber septums.
[4]Test organism was *G. stearothermophilus* spores. The lumen test unit was a straight stainless steel tube.

Table 12. Suggested protocol for management of positive biological indicator in a steam sterilizer.

1. Take the sterilizer out of service. Notify area supervisor and infection control department.
2. Objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or the sterilization procedure is defective. As soon as possible, repeat biological indicator test in three consecutive sterilizer cycles. If additional spore tests remain positive, the items should be considered nonsterile, and supplies processed since the last acceptable (negative) biological indicator should be recalled. The items from the suspect load(s) should be recalled and reprocessed.
3. Check to ensure the sterilizer was used correctly (e.g., verify correct time and temperature setting). If not, repeat using appropriate settings and recall and reprocess all inadequately processed items.
4. Check with hospital maintenance for irregularities (e.g., electrical) or changes in the hospital steam supply (i.e., from standard $\geq$97% steam, <3% moisture). Any abnormalities should be reported to the person who performs sterilizer maintenance (e.g., medical engineering, sterilizer manufacturer).
5. Check to ensure the correct biological indicator was used and appropriately interpreted. If not, repeat using appropriate settings.

If steps 1 through 5 resolve the problem

6. If all three repeat biological indicators from three consecutive sterilizer cycles (step 2 above) are negative, put the sterilizer back in service.

If one or both biological indicators are positive, do one or more of the following until problem is resolved.

7. A. Request an inspection of the equipment by sterilizer maintenance personnel.
   B. Have hospital maintenance inspect the steam supply lines.
   C. Discuss the abnormalities with the sterilizer manufacturer.
   D. Repeat the biological indicator using a different manufacturer's indicator.

If step 7 does not resolve the problem

Close sterilizer down until the manufacturer can assure that it is operating properly. Retest at that time with biological indicators in three consecutive sterilizer cycles.

Modified from Bryce. [839]

Disclosure of Financial Interests and Relationships (2000- July 2004)

William A. Rutala: Honoraria from Advanced Sterilization Products, Kimberly-Clark; consultation with Advanced Sterilization Products, Aesculap, Clorox, 3M, SC Johnson, Intelligent Biocides, Metrex; and an educational grant from Consumer Specialty Products Association, Kimberly-Clark.

David J. Weber: Honoraria from Consumer Specialty Products Association; consultation with Clorox; and educational grant from Consumer Specialty Products Association.