All invasive procedures involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. The level of disinfection or sterilization is dependent on the intended use of the object: critical (items that contact sterile tissue such as surgical instruments), semicritical (items that contact mucous membrane such as endoscopes), and noncritical (devices that contact only intact skin such as stethoscopes) items require sterilization, high-level disinfection, and low-level disinfection, respectively. Cleaning must always precede high-level disinfection and sterilization.

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High-level disinfection (HLD)  
Destroys all micro-organisms except high numbers of bacterial spores  
Heat automated  
Liquid immersion  
Pasteurization (65°C–77°C, 30 min)  
Chemical sterilants/HLDs: >2% glut (20–45 min); 0.55% OPA (12 min); 1.12% glut with 1.93% phenol (20 min); 7.35% HP with 0.23% PA (15 min); 7.5% HP (30 min); 1.0% HP with 0.08% PA (25 min); 400–450 ppm chlorine (10 min); 2.0% HP (8 min); 3.4% glut with 26% isopropanol (10 min)

Intermediate-level disinfection  
Destroys vegetative bacteria, mycobacteria, most viruses, most fungi but not bacterial spores  
Liquid contact  
EPA-registered hospital disinfectant with label claim regarding tuberculocidal activity (eg, chlorine-based products, phenolics, improved hydrogen peroxide exposure times at least 1 min)

Low-level disinfection  
Destroys vegetative bacteria, some fungi and viruses but not mycobacteria or spores  
Liquid contact  
EPA-registered hospital disinfectant with no tuberculocidal claim (eg, chlorine-based products, phenolics, improved hydrogen peroxide, quaternary ammonium compounds-exposure times at least 1 min) or 70%–90% alcohol

Table 1  
Methods for disinfection and sterilization of patient care items and environmental surfaces*

<table>
<thead>
<tr>
<th>Process</th>
<th>Level of microbial inactivation</th>
<th>Method</th>
<th>Examples (with processing times)</th>
<th>Health care application (examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization</td>
<td>Destroys all microorganisms, including bacterial spores</td>
<td>High temperature Low temperature Liquid immersion</td>
<td>Steam (~40 min), dry heat (1–6 hr depending on temperature) Ethylene oxide gas (~15 hr), hydrogen peroxide gas plasma (28–52 min), ozone (~4 hr), hydrogen peroxide vapor (55 min) Chemical sterilants: &gt;2% glut (~10 hr); 1.12% glut with 1.93% phenol (12 hr); 7.35% HP with 0.23% PA (3 hr); 8.3% HP with 7.0% PA (5 hr); 7.5% HP (6 hr); 1.0% HP with 0.08% PA (8 hr); &gt;0.2% PA (12 min at 50°C–56°C)</td>
<td>Heat-tolerant critical (surgical instruments) and semicritical patient care items Heat-sensitive critical and semicritical patient care items Heat-sensitive critical and semicritical patient care items that can be immersed</td>
</tr>
<tr>
<td>High-level disinfection</td>
<td>Destroys all micro-organisms except high numbers of bacterial spores</td>
<td>Heat automated Liquid immersion</td>
<td>Pasteurization (65°C–77°C, 30 min) Chemical sterilants/HLDs: &gt;2% glut (20–45 min); 0.55% OPA (12 min); 1.12% glut with 1.93% phenol (20 min); 7.35% HP with 0.23% PA (15 min); 7.5% HP (30 min); 1.0% HP with 0.08% PA (25 min); 400–450 ppm chlorine (10 min); 2.0% HP (8 min); 3.4% glut with 26% isopropanol (10 min)</td>
<td>Heat-sensitive semicritical items (eg, respiratory therapy equipment) Heat-sensitive semicritical items (eg, GI endoscopes, bronchoscopes, endovacutary probes)</td>
</tr>
<tr>
<td>Intermediate-level disinfection</td>
<td>Destroys vegetative bacteria, mycobacteria, most viruses, most fungi but not bacterial spores</td>
<td>Liquid contact</td>
<td>EPA-registered hospital disinfectant with label claim regarding tuberculocidal activity (eg, chlorine-based products, phenolics, improved hydrogen peroxide exposure times at least 1 min)</td>
<td>Noncritical patient care item (blood pressure cuff) or surface with visible blood</td>
</tr>
<tr>
<td>Low-level disinfection</td>
<td>Destroys vegetative bacteria, some fungi and viruses but not mycobacteria or spores</td>
<td>Liquid contact</td>
<td>EPA-registered hospital disinfectant with no tuberculocidal claim (eg, chlorine-based products, phenolics, improved hydrogen peroxide, quaternary ammonium compounds-exposure times at least 1 min) or 70%–90% alcohol</td>
<td>Noncritical patient care item (blood pressure cuff) or surface (bedside table) with no visible blood</td>
</tr>
</tbody>
</table>

*Modified from Rutala and Weber,7 Rutala and Weber,7 and Kohn et al.15 Consult the FDA cleared package insert for information about the cleared contact time and temperature, and see reference Rutala and Weber1 for discussion of why one product is used at a reduced exposure time (2% glutaraldehyde at 20 min, 20°C). Increasing the temperature using an automated endoscope reprocess (AER) will reduce the contact time (eg, OPA 12 min at 20°C but 5 min at 25°C in AER). Exposure temperatures for some high-level disinfectants above varies from 20°C to 25°C; check FDA-cleared temperature conditions. Tubing must be completely filled for high-level disinfection and liquid chemical sterilization. Material compatibility should be investigated when appropriate (eg, HP and HP with PA will cause functional damage to endoscopes).

peracetic acid (12 minutes at 50°C–56°C), the indicated exposure times for liquid chemical sterilants range from 3 to 12 hours.10 Liquid chemical sterilants can be relied on to produce sterility only if cleaning, which eliminates organic and inorganic material, precedes treatment and if proper guidelines as to concentration, contact time, temperature, and pH are met. Another limitation to sterilization of devices with liquid chemical sterilants is that the devices cannot be wrapped during processing in a liquid chemical sterilant; thus, it is impossible to maintain sterility following processing and during storage. Furthermore, devices may require rinsing following exposure to the liquid chemical sterilant with water that generally is not sterile. Therefore, because of the inherent limitations of using liquid chemical sterilants in a nonautomated reprocessor, their use should be restricted to reprocessing critical devices that are heat sensitive and incompatible with other sterilization methods.

**Semicritical items**

Semicritical items are those that come in contact with mucous membranes or nonintact skin. Respiratory therapy and anesthesia equipment, gastrointestinal endoscopes, bronchoscopes, laryngoscopes, esophageal manometry probes, anorectal manometry catheters, endocavitary probes, prostate biopsy probes, infrared coagulation devices, and diaphragm fitting rings are included in this category. These medical devices should be free of all microorganisms (ie, mycobacteria, fungi, viruses, bacteria), 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. Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, peracetic acid with hydrogen peroxide, and chlorine are cleared by the Food and Drug Administration and are dependable high-level disinfectants provided that the factors influencing germicidal procedures are met (Tables 1 and 2). The exposure time for most high-level disinfectants varies from 8 to 45 minutes at 20°C to 25°C. The reprocessing of semicritical items, such as endoscopes, laryngoscopes, and nasopharyngoscopes are discussed in detail in another paper in this Special Issue (Rutala/Weber).

Because semicritical equipment has been associated with reprocessing errors that result in patient lookback and patient notifications, it is essential that control measures be instituted to prevent patient exposures.11 Before new equipment (especially noncritical equipment as the margin of safety is less than that for sterilization)12 is used for patient care on more than 1 patient, reprocessing procedures for that equipment should be developed. Staff should receive training on the safe use and reprocessing of the equipment and be competency tested. Infection control rounds or audits should be conducted annually in all clinical areas that reprocess critical and semicritical devices to ensure adherence to the reprocessing standards and policies. Results of
infection control rounds should be provided to the unit managers, and deficiencies in reprocessing should be corrected and the corrective measures documented to infection control within 2 weeks.

**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, 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 nonintact skin and/or mucous membranes. However, these items (e.g., bedside tables, bed rails) could potentially contribute to secondary transmission by contaminating hands of health care workers or by contact with medical equipment that will subsequently come in contact with patients. Table 1 lists several low-level disinfectants that may be used for noncritical items. The exposure time for low-level disinfection of noncritical items is at least 1 minute.

<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peracetic acid/hydrogen peroxide</td>
<td>No activation required</td>
<td>Material compatibility concerns because of limited clinical experience</td>
</tr>
<tr>
<td></td>
<td>Odor or irritation not significant</td>
<td>Antimicrobial claims not independently verified</td>
</tr>
<tr>
<td></td>
<td>No disposal issues</td>
<td>Organic material resistance concerns because of limited data</td>
</tr>
<tr>
<td></td>
<td>No odor or irritation issues</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Does not coagulate blood or fix tissues to surfaces</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glutaraldehyde</td>
<td>Numerous use studies published</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Relatively inexpensive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Excellent material compatibility</td>
<td></td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
<td>No activation required</td>
<td></td>
</tr>
<tr>
<td></td>
<td>May enhance removal of organic matter and organisms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No disposal issues</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No odor or irritation issues</td>
<td></td>
</tr>
<tr>
<td>Ortho-phthalaldehyde</td>
<td>Fast acting high-level disinfectant</td>
<td>Stains protein gray (e.g., skin, mucous membranes, clothing, and environmental surfaces)</td>
</tr>
<tr>
<td></td>
<td>No activation required</td>
<td>Limited clinical experience</td>
</tr>
<tr>
<td></td>
<td>No odor not significant</td>
<td>More expensive than glutaraldehyde</td>
</tr>
<tr>
<td></td>
<td>Excellent materials compatibility claimed</td>
<td>Eye irritation with contact</td>
</tr>
<tr>
<td></td>
<td>Does not coagulate blood or fix tissues to surfaces claimed</td>
<td>Slow sporicidal activity</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>Rapid sterilization cycle time (30-45 min)</td>
<td>Potential material incompatibility (e.g., aluminum anodized coating becomes dull)</td>
</tr>
<tr>
<td></td>
<td>Low temperature (50°C-55°C) liquid immersion sterilization</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Environmental friendly by-products (acetic acid, O₃, H₂O)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fully automated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Single-use system eliminates need for concentration testing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standardized cycle</td>
<td></td>
</tr>
<tr>
<td></td>
<td>May enhance removal of organic material and endotoxin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No adverse health effects to operators under normal operating conditions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Compatible with many materials and instruments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Does not coagulate blood or fix tissues to surfaces</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sterilant flows through scope facilitating salt, protein, and microbe removal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rapidly sporicidal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Provides procedure standardization (constant dilution, perfusion of channel, temperatures, exposure)</td>
<td></td>
</tr>
<tr>
<td>Improved hydrogen peroxide (2.0%); high-level disinfectant</td>
<td>No activation required</td>
<td>Material compatibility concerns because of limited clinical experience</td>
</tr>
<tr>
<td></td>
<td>No odor</td>
<td>Antimicrobial claims not independently verified</td>
</tr>
<tr>
<td></td>
<td>Nonstaining</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No special venting requirements</td>
<td>Organic material resistance concerns because of limited data</td>
</tr>
<tr>
<td></td>
<td>Manual or automated applications</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12-month shelf life, 14-day reuse</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 min at 20°C high-level disinfectant claim</td>
<td></td>
</tr>
</tbody>
</table>
**Table 3**
Summary of advantages and disadvantages of commonly used sterilization technologies

<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| **Steam**            | • Nontoxic to patient, staff, environment  
• Cycle easy to control and monitor  
• Rapidly microbial  
• 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 minutes 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  
• Endoscope or medical device restrictions based on lumen internal diameter and length (see manufacturer’s recommendations)  
• Requires synthetic packaging (polypropylene wraps, polyolefin pouches) and special container tray  
• Hydrogen peroxide may be toxic at levels greater than 1 ppm TWA |
| **100% Ethylene oxide** | • 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  
• Only requires electrical outlet | • Requires aeration time to remove ETO residue  
• ETO is toxic, carcinogenic, and flammable  
• ETO emission regulated by states but catalytic cell removes 99.9% of ETO and converts it to CO2 and H2O  
• ETO cartridges should be stored in flammable liquid storage cabinet  
• Lengthy cycle/aeration time  
• Some states (eg, 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, carcinogenic, and flammable  
• Medical devices restrictions based on lumen internal diameter and length; see manufacturer’s recommendations, eg, stainless steel lumen 1-mm diameter, 125-mm length  
• Not used for liquid, linens, powders, or any cellulose materials  
• Requires synthetic packaging (polypropylene)  
• Limited materials compatibility data  
• Limited clinical use and comparative microbialidal efficacy data  
• Limited clinical use (no published data on material compatibility/penetrability/organic material resistance) and limited microbialidal efficacy data |
| **ETO mixtures** | • Penetrates medical packaging and many plastics  
• Compatible with most medical materials  
• Cycle easy to control and monitor | Lengthy cycle/aeration time  
• Some states (eg, 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, carcinogenic, and flammable  
• Medical devices restrictions based on lumen internal diameter and length; see manufacturer’s recommendations, eg, stainless steel lumen 1-mm diameter, 125-mm length  
• Not used for liquid, linens, powders, or any cellulose materials  
• Requires synthetic packaging (polypropylene)  
• Limited materials compatibility data  
• Limited clinical use and comparative microbialidal efficacy data  
• Limited clinical use (no published data on material compatibility/penetrability/organic material resistance) and limited microbialidal efficacy data |
| **Vaporized hydrogen peroxide** | • Safe for the environment and health care worker  
• It leaves no toxic residue; no aeration necessary  
• Fast cycle time, 55 min  
• Used for heat and moisture sensitive items (metal and nonmetal devices) | • Requires aeration time to remove ETO residue  
• ETO is toxic, carcinogenic, and flammable  
• ETO emission regulated by states but catalytic cell removes 99.9% of ETO and converts it to CO2 and H2O  
• ETO cartridges should be stored in flammable liquid storage cabinet  
• Lengthy cycle/aeration time  
• Some states (eg, 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, carcinogenic, and flammable  
• Medical devices restrictions based on lumen internal diameter and length; see manufacturer’s recommendations, eg, stainless steel lumen 1-mm diameter, 125-mm length  
• Not used for liquid, linens, powders, or any cellulose materials  
• Requires synthetic packaging (polypropylene)  
• Limited materials compatibility data  
• Limited clinical use and comparative microbialidal efficacy data  
• Limited clinical use (no published data on material compatibility/penetrability/organic material resistance) and limited microbialidal efficacy data |
| **Ozone** | • Used for moisture and heat-sensitive items  
• Ozone generated from oxygen and water (nontoxic)  
• No aeration needed because of no toxic by-products  
• FDA cleared for metal and plastic instruments including some instruments with lumens | Lengthy cycle/aeration time  
• Some states (eg, 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, carcinogenic, and flammable  
• Medical devices restrictions based on lumen internal diameter and length; see manufacturer’s recommendations, eg, stainless steel lumen 1-mm diameter, 125-mm length  
• Not used for liquid, linens, powders, or any cellulose materials  
• Requires synthetic packaging (polypropylene)  
• Limited materials compatibility data  
• Limited clinical use and comparative microbialidal efficacy data  
• Limited clinical use (no published data on material compatibility/penetrability/organic material resistance) and limited microbialidal efficacy data |

CFC, Chlorofluorocarbon; ETO, ethylene oxide; FDA, Food and Drug Administration; HCFC, hydrochlorofluorocarbon; TWA, time-weighted average.

NOTE. Modified from Rutala and Weber,7 Rutala and Weber,8 Rutala and Weber,17 and Rutala and Weber.18

**CONCLUSION**

When properly used, disinfection and sterilization can ensure the safe use of invasive and noninvasive medical devices. Cleaning should always precede high-level disinfection and sterilization. Strict adherence to current disinfection and sterilization guidelines is essential to prevent patient infections and exposures to infectious agents.

**References**


