Reprocessing endoscopes: United States perspective

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KEYWORDS
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Summary Endoscopes are used frequently for the diagnosis and therapy of medical disorders. For example, greater than 10,000,000 gastrointestinal endoscopic procedures are performed each year in the United States. Failure to employ appropriate cleaning and disinfection/sterilization of endoscopes has been responsible for multiple nosocomial outbreaks and serious, sometimes life-threatening, infections. Flexible endoscopes, by virtue of the site of use, have a high bioburden of microorganisms after use. The bioburden found on flexible gastrointestinal endoscopes following use has ranged from $10^5$ to $10^{10}$ CFU/ml, with the highest levels being found in the suction channels. Cleaning dramatically reduces the bioburden on endoscopes. Several investigators have shown a mean log\textsubscript{10} reduction factor of 4 (99.99%) in the microbial contaminants with cleaning alone. Cleaning should be done promptly following each use of an endoscope to prevent drying of secretions, allow removal of organic material, and decrease the number of microbial pathogens. Because the endoscope comes into intimate contact with mucous membranes, high-level disinfection is the reprocessing standard after each patient use. High-level disinfection refers to the use of a disinfectant (e.g., FDA-cleared chemical sterilant or high-level disinfectant) that inactivates all microorganisms (i.e., bacteria, viruses, fungi, mycobacteria) but not high levels of bacterial spores. The disinfection process requires immersion of the endoscope in the high-level disinfectant and ensuring all channels are perfused for the approved contact time (e.g., for orthophthaldehyde this is 12 min in the US). Following disinfection, the endoscope and channels are rinsed with sterile water, filtered water, or tapwater. The channels are then flushed with alcohol and dried using forced air. The endoscope should be stored in a manner that prevents recontamination. A protocol that describes the meticulous manual cleaning process, the appropriate training and evaluation of the reprocessing personnel, and a quality assurance program for endoscopes should be adopted and enforced by each unit performing endoscopic reprocessing.

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Introduction

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 to be 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.

Bioburden on endoscopes and efficacy of cleaning

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 $6.4 \times 10^4$ CFU/ml. Cleaning has shown to reduce the level of microbial contamination by a log$_{10}$ factor of 4 to 6 (Table I) unless the level of contamination was initially low (e.g., less than $10^5$ CFU/device). Thus, studies have shown that the post-cleaning bioburden was less than $10^5$ CFU/endo scope. Some data demonstrate that enzymatic cleaners are more effective cleaners than neutral detergents in removing microorganisms from surfaces. Using HIV contaminated endoscopes, several investigators have shown that cleaning completely eliminates the microbial contamination on the scopes. Similarly, other investigators found that ethylene oxide (ETO) sterilization or high-level disinfection (soaking in 2% glutaraldehyde for 20 min) was effective only when the device was first properly cleaned.

High-level disinfectants for use on endoscopes

The Food and Drug Administration (FDA) maintains a list of cleared liquid chemical sterilants/high-level disinfectants that can be used to reprocess heat-sensitive medical devices in the United States, such as flexible endoscopes. Users can access and view the list at http://www.fda.gov/cdrh/ode/germlab.html. At this time, the FDA-cleared formulations include; $\leq 2.4\%$ glutaraldehyde, $0.55\%$ orthophthal aldehyde (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 [Food and Drug administration. Sterilants and high level disinfectants cleared by FDA in a 510 (k) as of January 30, 2002 with general claims for processing reusable medical and dental devices, http://www.fda.gov/cdrh/ode/germlab.html, 2001]. 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 [the latter product is no longer marketed]) have been reported to cause cosmetic and functional damage to endoscopes.

Users should check with endoscope 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 h) 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. OPA has begun to replace glutaraldehyde in many healthcare facilities in the United States as it possesses several potential advantages compared to glutaraldehyde: no know irritation to the eyes and nasal passages, does not require activation or exposure monitoring, and has a 12-minute high-level disinfection claim (at $20^\circ$C) in the United States (5 min in Europe, Asia and Latin America; 10 min in Canada, Australia). Disinfectants that are not FDA cleared and should not be used for reprocessing endoscopes include iodophors, chloride 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
<table>
<thead>
<tr>
<th>Investigator</th>
<th>Endoscope type</th>
<th>Pathogen</th>
<th>Initial contamination (log_{10} CFU/ml for bacteria)</th>
<th>Post-cleaning contamination(^a) (log_{10} CFU/ml for bacteria)</th>
<th>Mean log_{10} reduction factor</th>
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<tr>
<td>Hanson, 1989(^15)</td>
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<td>Mixed bacteria</td>
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<td></td>
<td></td>
<td>HBV, HIV</td>
<td>ND (1/20, 7/20)</td>
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<td>Hanson, 1991(^16)</td>
<td>Gastrointestinal(^b)</td>
<td>HIV</td>
<td>4.7–6.5 pg/mL</td>
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<td>Mixed bacteria</td>
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<td></td>
<td>P. carinii</td>
<td>1.2 cysts/mL</td>
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<tr>
<td></td>
<td></td>
<td>HBV, HCV</td>
<td>ND (1/10, 7/7)</td>
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<td>Gastrointestinal(^b)</td>
<td>Bacillus subtilis</td>
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<td>ND</td>
<td>4.2</td>
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<td>M. tuberculosis</td>
<td>3.1–4.6</td>
<td>0.11–0.7</td>
<td>3.5</td>
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<td>Urayama, 1996(^10)</td>
<td>Gastrointestinal(^b)</td>
<td>M. chelonei</td>
<td>8.34–8.75</td>
<td>3.30–4.38</td>
<td>4.7</td>
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<td>Chu, 1998(^8)</td>
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<td>Mixed bacteria</td>
<td>9.85 (per device)(^c)</td>
<td>5.11 (per device)(^c)</td>
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<td>P. carinii</td>
<td>5.71 (per device)(^d)</td>
<td>4.34 (per device)(^d)</td>
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<td>Alfa, 1999(^11)</td>
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<td>7.95 (per device)</td>
<td></td>
<td>3.89 (per device)</td>
<td>4.1</td>
</tr>
</tbody>
</table>

CFU, colony forming units; HBV, hepatitis B virus; HIV, human immunodeficiency virus; ND, not determined (numbers in parentheses are number of dirty endoscopes contaminated with HBsAg and HIV per number of endoscopes sampled).

\(^a\) A value of zero for bacteria represents the absolute, not logarithmic, count after cleaning.

\(^b\) Experimentally contaminated endoscope.

\(^c\) Bioburden in suction channels.

\(^d\) Bioburden on device surfaces.
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 and hard water to simulate organic and inorganic contamination. The soil is used to represent the type of worse-case 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 provide complete elimination of the test mycobacteria (e.g., 10⁵ to 10⁶ Mycobacterium 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 [Food and Drug Administration. Content and format of premarket notification [510 (k)] submissions for liquid chemical sterilants/high level disinfectants. www.fda.gov/cdrh/ode/397, 2000]. 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. It is important to note that data suggest that M. tuberculosis levels can be reduced by a log₁₀ factor of at least 8. A log₁₀ reduction factor of 4 is achieved by cleaning⁵-¹⁰ and by a further 4–6 if followed by chemical disinfection for 20 min at 20°C.²¹,²²

Based on these data the Association of Professionals in Infection Control (APIC),²³ the Society of Gastroenterology Nurses and Associates (SGNA),²⁴,²⁵ the American Society Gastrointestinal Endoscopy (ASGE),²⁰ and a multi-society guideline²⁶ recommended alternative contact conditions with 2% glutaraldehyde to achieve high-level disinfection based on published literature (e.g., that equipment be immersed in 2% glutaraldehyde at 20°C for at least 20 min for high-level disinfection.⁹,²⁰,²¹,²⁷-³⁴ In the absence of several well-designed experimental scientific studies supporting 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.

Lessons learned from outbreak investigations

Flexible endoscopes are particularly difficult to disinfect³⁵ and easy to damage because of their intricate design, including narrow long lumens, and delicate materials.³⁶ 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,¹⁷,³⁷ HIV³⁸ and Helicobacter pylori.³⁹

Examining healthcare-associated infections related only to endoscopes up to 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,²,³,⁴⁰ and flaws in endoscope design⁴¹,⁴² or automated endoscope reprocessors.⁴ Failure to follow established guidelines has continued to lead to infections associated with gastrointestinal endoscopes³ and bronchoscopes.⁴ Potential device-associated problems in the United States 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], was not FDA-cleared as a high-level disinfectant [an iodophor] or were not using a disinfecting agent) and before use on the next patient.⁴³ 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,⁴⁴-⁴⁶ reduce the
likelihood that an essential reprocessing step will be skipped, and reduce personnel exposure to high-
level disinfectants or chemical sterilizers. Failure of
AERs has been linked to outbreaks of infections or
colonization, and the AER water filtration system may not reliably provide bacteria-free rinse water. It is critical that correct connec-
tors between the AER and the device are used to
ensure complete flow of disinfectants and rinse water. In addition, some endoscopes such as the
duodenoscopes (e.g., endoscopic retrograde cho-
liangiopancreatography [ERCP]) contain features
to ensure the 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 eleva-
tor-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 disinfec-
tion or sterilization. Some types of valves are now available as single use, disposable products (e.g., bronchoscope 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) are being evaluated as an alternative to conventional liquid chemical high-level disinfec-
tion/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 cannot replace colonoscopies.

Recommendations for the cleaning, disinfection and sterilization of endoscopes: United States perspective

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 competen-
ty 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—immers the 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 h; 90% after 7 days [1 CFU of coagulase-
negative Staphylococcus in one channel]) for bacterial growth when stored by handing 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 followed by 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 μ). 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 and 2001 and reported 8.7% of samples collected between 1996 and 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 min 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 endoscopes 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 endoscopes 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 staphylococci Bacillus species, diphtheroids). It has also been suggested that the final rinse water used during endoscopes reprocessing should be micro-biologically 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. If culturing of 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 has been described.

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., 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. 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). The highlights the importance of rigorous infection control.

Recommendations

These recommendations closely follow recommendations from a recent consensus guideline of professional organizations and the draft CDC guideline on disinfection and sterilization [Rutala W, Weber DJ, Healthcare Infection Control Practices Advisory Committee. Draft CDC Guideline for Disinfection and Sterilization in Healthcare Facilities. www.cdc.gov/ncidod/hip/dsguide.htm, April 2002]. These guidelines have evolved from both the scientific literature and previous guidelines from professional and governmental organizations. These guidelines were designed for use in the United States and may require adaptation for use in other countries. Recommendations are categorized based on the support of scientific evidence as: strongly recommended (supported by epidemiologic, experimental, and clinical studies, and strong theoretic rationale); suggested (supported by suggestive epidemiologic or clinical studies or theoretic rationale); and unresolved issue (insufficient evidence or no consensus regarding efficacy).

1. Test each flexible endoscope for leaks as part of each reprocessing cycle. Remove any instrument that fails the leak test from clinical use and have it repaired. This recommendation is intended to detect damaged endoscopes. Suggested.

2. Perform meticulous cleaning of the endoscope with an enzymatic cleaner, compatible with the endoscope, immediately after use. Cleaning is essential prior to automated or manual disinfection. Strongly recommended.

3. Disconnect and disassemble endoscopic components (e.g., suction valves) as far as possible and completely immerse components in the enzymatic cleaner. Ideally if heat-stable, steam sterilize these components. Strongly recommended.

4. 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, sponge, or brushes. Continue brushing until there is no debris on the brush. Strongly recommended.
5. Use cleaning brushes appropriate to the size of the endoscope channel or port (e.g., bristles should contact surfaces). Cleaning items (e.g., brushes, cloth) should be disposable or thoroughly cleaned and receive high-level disinfection or sterilization after each use. Suggested.23,25,26

6. Discard enzymatic cleaners (or detergents) after each use, as these products are not microbicidal and will not retard microbial growth. Strongly recommended.14,23,25,26

7. Process endoscopes (e.g., arthroscopes, cystoscopes, 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 cystoscopes should be followed by a sterile water rinse. Strongly recommended.23,25,83,89–95

8. Endoscopes that are critical items (e.g., arthroscopes, cystoscopes, laparoscopes) that cannot be steam sterilized should be phased out and replaced with steam sterilizable instruments when feasible. Suggested.

9. Mechanically clean reusable accessories inserted into endoscopes (e.g., biopsy forceps or other cutting instruments) that break the mucosal barrier as described above (e.g., ultrasonically clean biopsy forceps) and then sterilize between each patient. Strongly recommended.2,3,20,23,25,26,52,58,60,66,83,89,96

10. Use ultrasonic cleaning of reusable endoscopic accessories to remove soil and organic material from hard to clean areas. Suggested.26,58,61

11. Endoscopes and accessories that come in contact with mucous membranes are classified as semicritical items and should receive at least high-level disinfection after each patient use. Strongly recommended.2,3,20,23,25,26,43,52,58–61,65–67,83,89,96


13. Formulations containing glutaraldehyde, glutaraldehyde with phenol/phenate, orthophthalaldehyde, hydrogen peroxide, peracetic acid, and both hydrogen peroxide and peracetic acid can achieve high-level disinfection if the objects are properly cleaned, disinfected, rinsed and dried. (http://www.fda.gov/cdrh/ode/germlab.html). Strongly recommended.2–4,20,23,25,58–61,83,89

14. The exposure time for disinfecting semicritical patent-care equipment varies for the Food and Drug Administration (FDA)-cleared high-level disinfectants (http://www.fda.gov/cdrh/ode/germlab.html). Extend exposure times beyond the minimum effective time (see below and text) cautiously and conservatively because with extended exposure to a high-level disinfectant it is more likely to damage delicate and intricate instruments such as flexible endoscopes. Strongly recommended.9,18,83,97–99

15. Follow the FDA-cleared label claim for high-level disinfection unless several well-designed experimental scientific studies, endorsed by professional societies, demonstrate an alternative exposure time is effective for disinfecting semicritical items. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 25 °C range from 20 to 90 min depending upon the product. However, multiple scientific studies and professional organizations support the efficacy of >2% glutaraldehyde for 20 min at 20 °C Strongly recommended.9,10,12,15–17,21,22,26–34,37,38,83,89,98,100–114

16. When using other FDA-cleared high-level disinfectants, use the manufacturer’s recommended exposure conditions. These products may have a reduce exposure time (e.g., 0.55% orthophthalaldehyde for 12 min of 20 °C, 7.35% hydrogen peroxide plus 0.23% peracetic acid for 15 min at 20 °C) compared to glutaraldehyde at room temperature because of their rapid inactivation of mycobacteria or reduced exposure time due to increased mycobactericidal activity at elevated temperature (2.5% glutaraldehyde for 5 min at 35 °C). Strongly recommended.6,9,115–118

17. Select a disinfectant or chemical sterilant that is compatible with the device being reprocessed. Avoid the use of reprocessing chemicals on an endoscope if the endoscope manufacturer warns against use because of functional damage (with or without cosmetic damage). Strongly recommended.18,23,26

18. Completely immerse the endoscope in the high-level disinfectant and ensure all channels are perfused. Phase out nonimmersible endoscopes. Strongly recommended.20,23,24,26,51,81,86,119

19. After high-level disinfection, rinse endoscopes and the flush channels with sterile water, filtered water, or tap water, followed by a
28. Educate all personnel using chemicals about the biological, chemical, and environmental hazards present while performing procedures that use disinfectants. **Strongly recommended**.2,4,20,23,25,26,58,61,68

30. The selection and use of disinfectants in the healthcare field is dynamic, and products may become available that were not in existence when this guideline was written. As newer disinfectants become available, persons or committees responsible for selecting disinfectants should be guided by products cleared by the FDA, pertinent information from the disinfectant and instrument manufacturers, and information in the scientific literature. **Suggested**.26,83

31. If an automated endoscope reprocessor (AER) is used, 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 with the high-level disinfectant/chemical sterilant. **Strongly recommended**.3,4,26,68,81,87

32. If an AER is used, ensure that the endoscope can be effectively reprocessed in the automated endoscope reprocessor. Also ensure that any required manual steps are performed (e.g., elevator wire channel of duodenoscopes may not be effectively disinfected by most AERs). **Strongly recommended**.3,4,25,26,68,81

33. Since design flaws and improper operation and practices have compromised the effectiveness of AERs, the infection control staff routinely should review the FDA advisories and the scientific literature for reports of deficiencies that may lead to infection. **Suggested**.4,26,47,48,68,81

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

35. Do not use the carrying case used to transport clean and reprocessed endoscopes outside of the healthcare environment, to store an endoscope or to transport the instrument within the healthcare environment. **Suggested**.

36. No recommendation to routinely perform microbiologic testing of endoscopes or rinse
water for quality assurance purposes. Unresolved issue. 26
37. If environmental microbiologic testing is conducted, use standard microbiological techniques. Suggested. 26,69,72,76,77
38. Initiate an investigation to determine potential routes of transmission (e.g., person-to-person, common source) and reservoirs, if a cluster of endoscopy-related infections occurs. Strongly recommended. 2,148
39. Report outbreaks of endoscope-related infections to persons responsible for institutional infection control, risk management and FDA. Strongly recommended. 2,4,23,26,149 Notify local and state health department, CDC, and the manufacturer(s). Suggested.
40. After reprocessing an endoscope according to this guideline, there is no recommendation for a reprocessing just prior to use. Unresolved issue. 69
41. Compare the reprocessing instructions provided by the endoscope and AER manufacturer’s instructions and resolve any conflicting recommendations. Strongly recommended. 2,68

References

62. Jackson FW, Ball MD. Correction of deficiencies in flexible fiberoptic sigmoidoscope cleaning and disinfection technique in family practice and internal medicine offices. Arch Fam Med 1997;6:578–582.
68. Food and Drug Administration, Centers for Disease Control and Prevention, FDA and CDC public health advisory: infections from endoscopes inadequately reprocessed by an automated endoscope reprocessing system. Rockville, MD: Food and Drug Administration; 1999.
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