

# Reprocessing the Bronchoscope: The Challenges

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## ABSTRACT

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Spread of infection through the flexible bronchoscope is underrecognized and underreported. Prevention of bronchoscopy-induced infection requires increased vigilance by the physician, assiduous implementation of reprocessing protocols, and closer collaboration between bronchoscopy personnel, infection control practitioners, and instrument manufacturers. Patient safety depends on adequate disinfection of bronchoscopes and accessories used, as well as proper training of bronchoscopists, nurses, and ancillary staff. It is important to recognize that microbial transmission may occur via any part of instruments or anything in contact with the instruments including cleaning solutions, automated washers, and rinsing water. Numerous surveys have suggested poor adherence to published preventive guidelines. To address the challenges of reprocessing bronchoscopes, all users must comply with guidelines for cleaning and disinfection and each procedure should be performed with a clean, disinfected bronchoscope.

**KEYWORDS:** Flexible bronchoscope, disinfection, reprocessing, cleaning

**Objectives:** Upon completion of this article, the reader should be able to: (1) List common causes of contamination of bronchoscope; (2) understand necessary steps in reprocessing the bronchoscope; and (3) understand current guidelines for contamination prevention.

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Numerous articles documenting infection after improper processing of flexible bronchoscopes have emphasized the need for appropriate disinfection or sterilization.<sup>1,2</sup> In recent reports a manufacturing defect was blamed for the contamination of the bronchoscopes.<sup>3-5</sup> An emerging theme is that most recent epidemics have occurred when preexisting infection control guidelines were not adhered to carefully. Bronchoscopes

are designed with narrow working channels, ports with obtuse angles, and linings vulnerable to damage and subsequent biofilm formation, posing obstacles to proper cleaning and disinfection or sterilization. To address the challenges of reprocessing bronchoscopes, all users (staff, fellows, ancillary staff) must comply with guidelines for cleaning and disinfection. Each procedure should be performed with a clean, disinfected bronchoscope. The

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following article is a concise overview of current recommendations on reprocessing of flexible bronchoscopes.

According to the Spaulding<sup>6</sup> classification of medical and surgical instruments the flexible bronchoscope is a semicritical item. Semicritical items are those objects that come in contact with mucous membranes or skin that is not intact. That is, they must be free of all microorganisms, with the exception of low numbers of bacterial spores. Semicritical items require high-level disinfection. Because bronchoscopes are classified as semicritical instruments, the minimum recommended practice for bronchoscopes is high-level disinfection with a liquid sterilant/disinfectant approved by the Food and Drug Administration (FDA) (Table 1). One problem associated with the Spaulding scheme is oversimplification. For example, should bronchoscopes still be considered semicritical when used in patients with endobronchial ulcerations or pulmonary hemorrhage syndromes or for biopsying friable lesions? Items assigned to the critical category present a high risk of infection if contaminated with any microorganism, including bacterial spores. These are instruments used to penetrate skin; for example, operating instruments, needles, syringes, biopsy forceps, and implants. Most of the items in this category should be purchased as sterile or should be sterilized by steam under pressure if possible. Noncritical items come in contact with skin but not with mucous membranes. Examples include blood pressure cuffs and bedpans. A disinfectant of low effectiveness that destroys most gram-negative and gram-positive bacteria is sufficient.

*Sterilization* is defined as the destruction of all living organisms, including spores. It is accomplished by either physical or chemical means. *Disinfection* is defined as a process that eliminates many or all pathogenic organisms with the exception of bacterial spores. A disinfectant is usually a chemical agent used to reprocess

instruments and other inanimate objects. Spaulding and Groschel<sup>7</sup> classified disinfectants into three groups according to their effectiveness. High-level disinfection can be expected to destroy all microorganisms, with the exception of high numbers of bacterial spores. The characteristics of an ideal high-level disinfectant should include broad antimicrobial spectrum, rapid activity, material compatibility, lack of human or environmental toxicity, odorlessness, nonstaining, prolonged reuse and shelf life, ease of use, and cost effectiveness. Intermediate-level disinfection inactivates most viruses, most fungi, *Mycobacterium tuberculosis*, and vegetative bacteria but it does not necessarily kill bacterial spores. Low-level disinfection can kill most bacteria, some viruses, and some fungi, but it cannot be relied on to kill resistant microorganisms such as tubercle bacilli and bacterial spores.

## REPROCESSING FLEXIBLE BRONCHOSCOPES AND ACCESSORIES

In general, the process of bronchoscope disinfection involves four steps: inspection, cleaning, disinfection (manual or automated), and treatment after disinfection.

### Inspection

The external surface of the bronchoscope is examined for any damage and the instrument is "leak tested" after each procedure and before mechanical cleaning. A leak test involves submerging the bronchoscope in water and forcing air at low pressure through the bronchoscope interstitium, looking for air bubbles to identify leaks either in the covering or internally through the channels. The presence of a leak indicates a breach in the integrity of the luminal surfaces. If damage is detected, the bronchoscope should not be reused. A bronchoscope sent for repair should be considered a contaminated medical device and labeled as such for shipping. An outbreak of bronchoscopy-related *Mycobacterium tuberculosis* infections due to lack of bronchoscope leak testing has been reported.<sup>8</sup> A hole in the sheath provided access to a space that was difficult to mechanically clean and chemically disinfect.

### Cleaning

Meticulous physical cleaning must precede high-level disinfection. Studies have shown that manual and mechanical cleaning of endoscopes achieves approximately a 4-log reduction of contaminating organisms.<sup>9</sup> All suction ports and biopsy attachments should be detached prior to cleaning. Cleaning should be performed immediately after use to remove blood, tissue, and secretions before they dry. Proteins present a physical barrier to disinfectants and compete with

**Table 1 FDA-Approved Agents for High-Level Disinfection**

Agents	Maximum Reuse (Days)
Glutaraldehyde preparations	
2.4%	14 or 28
2.5%	28 or 30
2.6%	14
3%	28
3.2%	28
3.3%	
1.12% glutaraldehyde/1.93% phenol-phenate	14
7.5% hydrogen peroxide	21
7.53% hydrogen peroxide/0.23% peracetic acid	14
1.0% hydrogen peroxide/0.08% peracetic acid	14
0.55% ortho-phthalaldehyde	14

For details refer to [www.fda.gov/cdrh/ode/germlab.html](http://www.fda.gov/cdrh/ode/germlab.html).

microorganisms for active sites. They can also chemically neutralize disinfectants. The bronchoscope should be immersed in warm water and detergent or enzymatic detergent and washed on the outside with disposable sponges or swabs. The biopsy-suction channel should be thoroughly cleaned with a brush appropriate for the instrument and channel size. Attention should be given to the crevices, which are likely to harbor contaminated debris. The tip of the bronchoscope must be gently wiped/brushed to dislodge blood or tissue in and around the inner channel. Detergent solutions or water should not be reused. The cleaning brushes should be disposable or thoroughly cleaned and receive high-level disinfection or sterilization after each use.

### Disinfection

Disinfection can be performed manually or with an automated endoscope reprocessor (AER). The two products most commonly used for reprocessing endoscopes in the United States are glutaraldehyde and peracetic acid.

#### MANUAL DISINFECTION

Manual disinfection involves soaking the bronchoscope and all internal channels for at least 20 minutes in 2% alkaline glutaraldehyde solution at 20°C. Glutaraldehyde is noncorrosive to metals and does not affect rubber or plastics. Multiple other agents are approved for this purpose, including ortho-phthaldehyde, perace-

tic acid, and hydrogen peroxide. Contact of all internal and external surfaces with disinfectant is crucial. Outbreaks have resulted from failure to immerse the bronchoscope fully, failure to disassemble valves, or unrecognized rips or tears in internal channels. After the glutaraldehyde soak, the channel should be rinsed with sterile water or 70% alcohol but not with tap water.

Depending on the formulation, disinfectant solutions may be reused for 14 to 28 days.<sup>10</sup> Use dilution may occur. For this reason, solution concentration as well as pH should be periodically tested with commercially available test kits. Monitoring must be done regularly to ensure that minimum effective concentration is exceeded; however, the test kits should not be used to extend the use life beyond the expiration date. Glutaraldehyde solution should not be used if the concentration is < 2%.

Levels of glutaraldehyde vapor may exceed allowable limits, especially when the equipment is processed in poorly ventilated rooms. Epistaxis, allergic contact dermatitis, asthma, and rhinitis have been reported in health care workers exposed to glutaraldehyde.<sup>11-13</sup> Air-exchange equipment (ventilation system, exhaust hoods) should be used to minimize exposure of all persons to potentially toxic vapors. Personal protective equipment (gloves, eyewear, respiratory protective devices) should be available and should be used to protect workers from exposure to toxic chemicals. Table 2 summarizes the

**Table 2 Summary of Advantages and Disadvantages for Chemical Sterilants Used Primarily as High-Level Disinfectants**

Sterilization Method	Advantages	Disadvantages
Glutaraldehyde	Relatively inexpensive Excellent materials compatibility Numerous use studies published	Respiratory irritation Pungent and irritating odor Coagulates blood and fixes tissue to surface
Peracetic acid (Steris System 1)	Rapid sterilization cycle Fully automated No adverse effects to operator Rapidly sporicidal Provides procedure standardization	Biological indicator may not be suitable for monitoring Expensive Point-of-use system, no long-term sterile storage
Hydrogen peroxide	No activation required May enhance removal of organic matter and organisms No disposal issues Does not coagulate blood or tissues	Serious eye damage if contacted Material compatibility concerns for brass, zinc, copper, nickel, or silver plating
Ortho-phthaldehyde	Fast-acting high-level disinfectant Odor not an issue Excellent material compatibility Does not coagulate blood or fix tissues to surfaces claimed	Stains skin, clothing, and environmental surfaces Limited clinical use
Peracetic acid	No activation required	Materials compatibility concerns
Hydrogen peroxide	Odor or irritation not significant	Limited clinical use

Modified from Rutala WA, Weber DJ. Disinfection of endoscopes: review of new chemical sterilants used for high-level disinfection. *Infect Control Hosp Epidemiol* 1999;20:69-76 with permission.

advantages and disadvantages of different chemical agents used as high-level disinfectants.

Several commonly used disinfectants are not recommended for reprocessing because of failure to meet the definition of a high-level disinfectant, toxic exposure to personnel, or physical damage to the equipment. These agents include hypochlorite, quaternary ammonium compounds, phenolics, and skin antiseptics.

#### **AUTOMATED ENDOSCOPE REPROCESSING**

AERs have replaced manual disinfection in many centers. AERs offer several advantages to manual reprocessing, including automation and standardization of reprocessing steps, which reduces the likelihood that an essential reprocessing step will be skipped, and reduction of personal exposure to high-level disinfectants.<sup>14,15</sup> The effectiveness of these machines depends on the water quality, water delivery system, type of disinfectant, exposure time, temperature, flow rates, and design of the washer.<sup>16</sup> Recent evidence highlights the importance of lumen flow of chemical sterilant.<sup>17,18</sup> Table 3 outlines a few general recommendations for bronchoscope reprocessing using AERs. Failure of AERs has been linked to bronchoscopy-related outbreaks and pseudo-outbreaks, in part because the water filtration system may not reliably provide sterile rinse water.<sup>19</sup>

### **Treatment of Bronchoscopes after Disinfection**

#### **RINSING**

To prevent toxic effects of residual chemicals after disinfection, the equipment must be adequately rinsed. One potential source of organisms is tap water used for rinsing bronchoscopes after disinfection.<sup>19</sup> In several reports contaminated tap water was the suspected source of microorganism transmission to patients through previously disinfected bronchoscopes.<sup>20,21</sup> To avert recontamination, we recommend rinsing with sterile water or with high-quality filtered tap water followed by 70% alcohol.

#### **DRYING**

To prevent growth of microorganisms in moist environments, the bronchoscope should be thoroughly dried by 70% alcohol and compressed air.

#### **STORAGE**

Bronchoscopes should always be stored in an upright (hanging) position to prevent accumulation of moisture. Suction valves and caps should not be reassembled until the time of the next bronchoscopy.<sup>22</sup> There should be ample space to keep the bronchoscopes and other equipment from coming into contact with each other.

### **BRONCHOSCOPIC ACCESSORY REPROCESSING**

In general, all bronchoscopic accessories that enter mucosal surfaces should either be disposable or sterilized between uses. Biopsy forceps are heat stable and should be cleaned with an ultrasonic cleaner and sterilized. Reuse of medical equipment labeled for single use is potentially hazardous, especially if no quality control system is in place to monitor sterility and function after reprocessing.<sup>23</sup>

### **ADEQUACY OF DISINFECTION/STERILIZATION**

Bronchoscopes may be contaminated at any step during reprocessing.<sup>24,25</sup> The choice of disinfectant or duration of disinfectant could be inappropriate, the cleaning of accessories could be flawed, and unfiltered tap water could be used for rinsing. In some cases, flawed AERs have been implicated in numerous contaminations. The ideal chemical sterilant does not exist because all products have limitations. Biological and chemical markers are available to assess disinfectant strength, pH, and efficacy of decontamination. However, the reliability of such kits has not been established. AERs are associated with several potential routes of contamination.<sup>26</sup> Although the insides of the devices are periodically disinfected, water supply tanks, tubing, and pumps are not in contact with disinfectant. These areas may serve as reservoirs for ongoing contamination.

Meticulous microbiological testing is needed if clinical or epidemiological findings suggest transmission of infection through the bronchoscope. Investigation should be performed according to the standard methods of outbreak investigation. Cultures should include AERs, tap water used for rinsing, and all internal bronchoscope surfaces by using sterile brushes. A plan should follow these cultures, and specific action should

**Table 3 General Recommendations Regarding the Use of Automated Endoscope Reprocessors**

1. Comply strictly with bronchoscope manufacturer's instructions for disinfection.
2. Intensively educate staff in proper disinfection techniques and the potential danger in deviating from them.
3. Check compatibility of bronchoscopes with automated endoscope reprocessors (AERs) and determine if specific steps are required prior to reprocessing.
4. Compare reprocessing instructions by the bronchoscope and AER manufacturers and resolve conflicting recommendations.
5. Initiate a comprehensive quality control program.

be taken on the basis of the results. Observing the infection control practices of the endoscopy unit staff may provide epidemiological insights by showing where institutional recommendations are not strictly followed. A log should be maintained for each procedure indicating the patient's name and medical record number, the procedure, the bronchoscopist, and the serial number of the bronchoscope.

Routine surveillance cultures are controversial, although they may allow earlier discovery of disinfection breaches. However, there are no clear criteria specifying what to do with positive culture results, what are clinically significant number of organisms, and how frequently to perform such surveillance cultures. For these reasons we do not recommend them.

### THE CHALLENGES

Patient safety depends on adequate disinfection of instruments and accessories used, as well as proper training of bronchoscopists, nurses, and ancillary staff. Outbreaks of infections associated with bronchoscopy have led patients and physicians to question the safety of bronchoscopy—a concern that is receiving heightened attention with the increased focus on patient safety.<sup>27</sup> Numerous surveys have suggested poor adherence to published recommendations.<sup>28,29</sup> A 1997 survey of 218 bronchoscopic units in the United Kingdom revealed that many departments did not apply or follow national guidelines and had inadequate or inappropriate facilities for chemical disinfection.<sup>29</sup> However, there was evidence that dedicated endoscopy units were more likely to follow national guidelines and had better facilities for chemical disinfection. Another investigation revealed that actual disinfection/sterilization procedures for endoscopes were not always optimal.<sup>28</sup> The reasons for poor compliance are unclear, but in one survey, gastroenterology nurses suggested that poor compliance results from lack of administrative support (59%), an insufficient number of endoscopes (32%), an absence of clear-cut standards for infection control procedures (19%), a lack of involvement of infection control staff (18%), the pressure to shorten the down-time of endoscopes between patients (14%), and the complexity of the equipment, which makes cleaning and disinfection difficult (11%).<sup>30</sup> Table 4 outlines most common factors leading to outbreaks of infections through bronchoscopes.

#### Disinfection of Bronchoscopes Contaminated with Hepatitis B, Hepatitis C, and Human Immunodeficiency Virus

Contaminated bronchoscopes can serve as vehicles of transmission. To date, there have been no reported instances of bronchoscopic virus transmission because most viruses, including hepatitis and human immuno-

**Table 4 Factors Leading to Outbreaks of Bronchoscopic Transmission of Infection**

I. FAILURE TO LEAK TEST THE BRONCHOSCOPE
II. IMPROPER MANUAL CLEANING PRIOR TO DISINFECTION
Inability or neglect to clean the suction channel
Contaminated water supply
Contaminated brushes
Contaminated biopsy ports/suction valves
III. FAILURE TO DISINFECT THE BRONCHOSCOPE
Contaminated or expired disinfectant agent
Dilution of disinfected agents to ineffective levels
Insufficient disinfection time
Inadequate training of personnel
Inadequate activity (e.g., iodides)
IV. INEFFECTIVENESS OF AUTOMATED ENDOSCOPE REPROCESSOR (AER)
Improper use of automated washer
Biofilms inside automated washer
Mechanical malfunction of automatic washer
Dilution of disinfectant
AER-incompatible bronchoscope

deficiency virus (HIV), are readily destroyed with high-level disinfectants. Although some authors have suggested intensified disinfection regimens (or sterilization) after bronchoscopy of patients with known viral infections, there is no evidence to support this recommendation. This may lead to a “double standard” of patient care and is inconsistent with the principle of universal precautions. Moreover, because clinical variables and risk factor assessment are not reliable predictors of which patients are infected with hepatitis or HIV, the practice of using intensified reprocessing after high-risk procedures should be abandoned.

#### Disinfection of Bronchoscope Contaminated with *Mycobacterium*

Mycobacterial pseudoinfections and pseudoepidemics occur more commonly than bacterial or fungal pseudoinfections because many species of nontuberculous mycobacteria grow in natural water as well as in tap water.<sup>31</sup> Disinfection of the bronchoscope with 2% glutaraldehyde solution for 20 minutes or use of automated bronchoscope disinfection with peracetic acid is sufficient to eradicate all mycobacteria provided adequate mechanical cleaning precedes disinfection.<sup>32–34</sup>

### SUMMARY OF RECOMMENDATIONS FOR BRONCHOSCOPIC REPROCESSING

Recommendations for the cleaning and disinfection of the endoscopes have been provided for over 20 years by professional organizations including the Association for

Professionals in Infectious Control and Epidemiology, the American Public Health Association, the Society for Gastrointestinal Nurses and Associates, the American Society for Testing and Materials and the British Thoracic Society.<sup>35-38</sup> These recommendations should be incorporated into individual institutions' policies.

1. Inspect the external surface of the bronchoscope for visible damage, and leak test after each use.
2. Immediately after use dismantle the suction valve and thoroughly wash and brush all parts of the bronchoscope in a detergent recommended by the bronchoscope manufacturer.
3. Detergent solution should be discarded after each use. Cleaning brushes should be either disposable or thoroughly cleaned with high-level disinfection or sterilization after each use.
4. An FDA-approved sterilant/disinfectant should be used for high-level disinfection or sterilization.
5. If 2% glutaraldehyde is used, all immersible internal and external surfaces should be in contact with disinfectant for not less than 20 minutes to achieve high-level disinfection.
6. Ensure compatibility between the bronchoscope and AERs, including the provision of appropriate connectors to provide luminal flow of disinfectants.
7. Compare reprocessing instructions provided by the bronchoscope and AER manufacturers and resolve conflicting recommendations.
8. Personnel assigned to reprocess bronchoscopes must receive device-specific reprocessing instructions to ensure proper cleaning and disinfection.
9. Routinely test disinfectant concentration for facilities using nonprepackaged kits, if the disinfectant is used repeatedly for more than several days.
10. After chemical disinfection, bronchoscopes must be rinsed with sterile water or with tap water followed by a 70% ethyl or isopropyl alcohol.
11. Allow bronchoscopes to dry thoroughly in a designated area prior to storage.
12. To facilitate drying, hang bronchoscopes in a vertical position.
13. Reusable accessories that penetrate mucosal barriers (e.g., biopsy forceps, cytology brushes) should be mechanically cleaned (i.e., by ultrasonics), and then steam sterilized after each patient use.
14. Use single-use stopcocks because reusable ones may be very difficult to clean.
15. Atomizers should not be reused between patients unless they are resterilized.
16. Maintain a log of bronchoscope use as well as AER maintenance and disinfection.
17. Initiate a comprehensive quality control program.
18. In the setting of an outbreak caused by a suspected infectious etiology, the investigation should be per-

formed according to standardized methods of outbreak investigation.

19. Bronchoscopy-related infections or pseudoinfections should be reported to the institutional infection control officer, the bronchoscope manufacturer, the Centers for Disease Control and Prevention (CDC), the state health department, and the FDA.
20. Personal protective equipment (gloves, eyewear, respiratory protective devices) should be available and should be used to protect workers from exposure to infectious agents and toxic chemicals.
21. All bronchoscopy personnel should be educated about the biological and chemical hazards present while performing or assisting bronchoscopic procedures and reprocessing.

## CONCLUSIONS

Spread of infection during flexible bronchoscope is underrecognized and underreported. Prevention of bronchoscopy-induced infection requires increased vigilance by the physician, assiduous implementation of reprocessing protocols, and closer collaboration between bronchoscopy personnel, infection control practitioners, and instrument manufacturers. The role of routine surveillance cultures of the instrument, its accessories, and the bronchoscopy facility remains to be studied.

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