

September 10, 1999

**FDA and CDC PUBLIC HEALTH ADVISORY:  
Infections from Endoscopes Inadequately Reprocessed by an Automated  
Endoscope Reprocessing System**

(You are encouraged to copy and distribute this information)

To: Director, Hospital Risk Management  
Director, Hospital Administration  
Director, Ambulatory Surgical Centers  
Director, Infection Control  
Director, Surgical Services/Operating Room  
All Practitioners Who Use Bronchoscopes or Other Flexible Endoscopes  
All Practitioners Who Use Automated Endoscope Reprocessors

This is to alert you to several incidents in which patients developed serious infections after being examined with bronchoscopes that apparently were inadequately reprocessed in an automated endoscope reprocessor (AER) and to provide recommendations that may help to reduce future incidents. FDA and CDC recognize the benefit of endoscopy as a medical procedure, but both agencies are concerned that endoscopes be properly prepared for patient contact.

**Nature of Problem**

In a recent publication titled "Bronchoscopy-related infections and pseudoinfections – New York, 1996 and 1998" (MMWR 1999; 48(26); 557-560), CDC reported apparent patient-to-patient transmission of infections following bronchoscopic procedures that used bronchoscopes that were inadequately reprocessed by AERs. Investigation of the reported incidents revealed that:

- there were inconsistencies between the reprocessing instructions provided by the manufacturer of the bronchoscope and the manufacturer of the AER; or
- bronchoscopes were inadequately reprocessed when inappropriate channel connectors were used with the AER.

FDA also is aware from its Medical Device Reporting (MDR) program that some users are using AERs to reprocess endoscopes that should not be processed in AERs. This practice may have resulted in damaged endoscopes and also raises questions about whether such processing results in an endoscope that is properly prepared for patient contact.

## Manufacturer Labeling for Endoscopes and AERs

Endoscope users should be aware that FDA requires certain information in the labeling of these devices. Since 1996, the Agency has requested manufacturers of reusable medical devices to recommend at least one reprocessing method in their device labeling. The level of reprocessing should be based on the device's contact with the patient and the risk for disease transmission. Generally, endoscope manufacturers provide manual reprocessing instructions for each endoscope model. Following these instructions should result in endoscopes that are patient-ready.

FDA has also requested that the labeling of the AER include instructions for reprocessing specific models of endoscopes. The instructions should be based on the results of validation studies with the specific endoscope models. The 1993 FDA guidance for AER manufacturers recommended that the AER labeling:

- list all brands and models of endoscopes that are compatible with the AER;
- identify the AER's limitation to process certain brands and models of endoscopes and accessories, or identify the endoscopes and accessories that cannot be reliably reprocessed in the AER; and
- be compatible with the endoscope manufacturer's cleaning and disinfection instructions.

### Recommendations

We recommend that healthcare facilities responsible for preparing endoscopes for patient contact do the following:

- 1. Be sure that all staff who handle soiled endoscopes comply with the endoscope manufacturer's instructions for cleaning of the endoscope.** It is imperative that your staff flush all endoscopes immediately following the procedure. In addition, they should meticulously remove any debris or residuals collected in or on the endoscope, perform leak tests, and visually inspect the endoscope to ensure that it is in proper working order in accordance with the endoscope manufacturer's recommendations. These steps are critical regardless of whether your facility manually reprocesses endoscopes or uses an AER.
- 2. Check with your endoscope manufacturers to determine whether your endoscopes can be reprocessed in an AER. Also, check with your endoscope manufacturer to determine whether your endoscopes require that specific steps be taken before being reprocessed in an AER.** Not all endoscopes can be reliably reprocessed in an AER. For example, the elevator-wire-channel of most duodenoscopes cannot be accessed by the AER and requires manual reprocessing. If not specifically indicated in the AER labeling, it is advisable to ask the AER manufacturer if the endoscope you are using has been tested with their system.

- 3. Compare the reprocessing instructions provided by the endoscope and AER manufacturers and resolve any conflicting recommendations.** Any conflicting recommendations between the manufacturers must be resolved, particularly when they involve the use of channel connections or capping/non-capping of specific lumens or channels. We encourage you to work with the AER manufacturers' technical staff to clarify conflicting information.
- 4. In the absence of specific technical instructions on automated reprocessing for each model of endoscope used in your facility, be sure to follow the endoscope manufacturer's manual reprocessing instructions as well as the recommendations of the manufacturer of the chemical germicides used at your facility.**
- 5. Regardless of whether you manually reprocess your endoscope or use an AER, consider incorporating a final drying step in your reprocessing protocol.** There are studies that have demonstrated that a final drying step that includes flushing all channels with alcohol followed by purging the channels with air (to remove the alcohol) greatly reduces the possibility of recontamination of the endoscope by water-borne microorganisms. The American Society for Testing and Materials (ASTM) has incorporated this recommendation in its ASTM Standard F1518-94. It also is recommended that reprocessed endoscopes be stored in a manner that will minimize the likelihood of contamination or collection/retention of moisture.
- 6. Check to be sure that your facility's instructions for preparing endoscopes for patient contact are appropriate and your staff is adhering to these instructions.** This includes:
  - a. Confirming that you have the correct version of the instructions applicable to your AER for the specific endoscope models used at your facility.
  - b. Making available to all staff responsible for reprocessing, copies of written, device-specific instructions for every endoscope model and reprocessing system you use.
  - c. Reviewing the written endoscope-specific reprocessing instructions from AER manufacturers to be sure that they are correctly implemented at your facility.
- 7. Provide comprehensive and intensive training for all staff assigned to reprocessing endoscopes to ensure that they understand the importance of proper reprocessing of all endoscopes used in your facility.** To achieve and maintain competency, each member of this staff should periodically receive:
  - a. Hands-on training with each written endoscope-specific reprocessing instruction for every endoscope model and AER used at your facility. Work should be closely supervised until competency is documented for each reprocessing task from cleaning through storage of the endoscope.
  - b. Additional training with documented competency for new models of endoscopes or AERs as they are introduced in your facility.
  - c. Strict warnings with frequent reminders not to deviate from the written instructions for preparing endoscopes for patient contact.

**8. Implement a comprehensive quality control program.** Your reprocessing program should include:

- a. Visual inspections of the equipment to identify conditions that may affect the cleaning or disinfecting processes.
- b. Assurance that all manufacturer-recommended maintenance schedules and services are performed for endoscopes and AERs used in your facility.
- c. Use of appropriate process monitors as recommended by your AER and germicide manufacturers.
- d. Records of the use of each endoscope, showing the patient upon whom it was used, the type of procedure involved, and the system used to reprocess the endoscope.
- e. A surveillance system capable of detecting clusters of infections or pseudoinfections associated with endoscopic procedures.

### **Reporting adverse events**

FDA is interested in additional data on adverse events involving the use of endoscopes and AERs. Healthcare professionals employed by healthcare facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. The reports can be submitted by phone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; via the MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch); or by mail to: MedWatch, FDA, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

### **Getting more information**

Questions regarding this advisory can be e-mailed to [phann@cdrh.fda.gov](mailto:phann@cdrh.fda.gov); faxed to Ms. Marian Zellner at 301-594-2968; or submitted in writing to Ms. Zellner at FDA, CDRH, Office of Surveillance and Biometrics at 1350 Piccard Drive, Mail Stop HFZ-510, Rockville, MD 20850.

All of FDA's medical device postmarket safety notifications can be found on the World Wide Web at <http://www.fda.gov/cdrh/safety.html>. Postmarket safety notifications can also be obtained through email on the day they are released by subscribing to our list server. To subscribe, visit: <http://list.nih.gov/cgi-bin/wa?SUBED1=dev-alert&A=1>

Sincerely yours,

David W. Feigal, Jr., MD, MPH  
Director  
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Food and Drug Administration

James M. Hughes, MD  
Director  
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### Suggested Reading and Sources of Additional Information

Agerton T, et al. Transmission of a highly drug-resistant strain (strain W1) of *Mycobacterium tuberculosis*. *JAMA* 1997; 278:1073-77.

American Society for Testing and Materials (ASTM): F1518-94 Standard practice for cleaning and disinfection of flexible fiberoptic and video endoscopes used in the examination of the hollow viscera. Vol. 13.01 Medical Devices. *Annual Book of ASTM Standards 1998*: 834-39 (their website is <http://www.astm.org/>).

Bennett SN, et al. Bronchoscopy-associated *Mycobacterium xenopi* pseudoinfections. *Am J Resp Crit Care Med* 1994; 150:245-50.

Blanc DS, et al. Nosocomial infections and pseudoinfections from contaminated bronchoscopes: two-year follow-up using molecular markers. *Infec Control Hosp Epidemiol* 1997; 18:134-36.

Bronowicki JP, et al. Patient-to-patient transmission of hepatitis C virus during colonoscopy. *New Eng J Med* 1997; 337:237-40.

Centers for Disease Control and Prevention. Bronchoscope-related infections and pseudoinfections-New York, 1996 and 1998. *MMWR* 1999; 48(26); 557-560. (A copy of this article can be downloaded from the CDC Web site at <http://www2.cdc.gov/mmwr/>.)

Deva AK, et al. Detection of persistent vegetative bacteria and amplified viral nucleic acid from in-use testing of gastrointestinal endoscopes. *J Hosp Infec* 1998; 39:149-57.

ECRI: Recommended protocol for reprocessing immersible flexible endoscopes. *Health Devices* 1999; 28(5-6): 178.

FDA, Center for Devices and Radiological Health. FDA Reviewer Guidance: Labeling reusable medical devices for reprocessing in health care facilities. (A copy of this document can be obtained from CDRH's Facts-on-Demand system by calling 1-800-899-0381 from a touch-tone telephone. At the main F-O-D voice prompt, press #1 to access DSMA Facts, at the second voice prompt press #2 and enter document #198.)

Kovacs BJ, et al. High-level disinfection of gastrointestinal endoscopes: are current guidelines adequate? *Am J Gastroenterol* 1999; 94:1546-50.

Maloney S, et al. *Mycobacterium abscessus* pseudoinfection traced to an automated endoscope washer: utility of epidemiological and laboratory investigation. *J Infect Dis* 1994; 169:1166-69.

Martin MA, et al. APIC guideline for infection control in flexible endoscopy. *Am J Infect Control* 1994; 22(1): 19-38.

Rutala WA. Disinfection and sterilization of patient-care items. *Infect Control Hosp Epidemiol* 1996; 17:377-84.

Society of Gastroenterology Nurses and Associates (SGNA). Endoscope cleaning and high level disinfection self study module, SGNA, Inc.