MEDICAL DEVICE REPORTING
FDA MEDICINE MANUFACTURERS

User Facility Reporting

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INFECTIONS FROM INADEQUATELY REPROCESSED ENDOSCOPES: FDA and CDC ISSUE PUBLIC HEALTH ADVISORY

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) issued a Public Health Advisory on September 10, 1999, to alert hospitals and medical practitioners about potentially serious infections resulting from inadequately reprocessed endocopes. FDA has learned of several incidents in which patients developed serious infections after being examined with bronchoscopes that apparently were inadequately reprocessed in an automated endoscope reprocessor (AER). Although both FDA and CDC recognize the benefit of endoscopy as a medical procedure, both agencies are concerned that endoscopes be properly prepared for patient contact.

Nature of the Problem

In a recent publication titled "Bronchoscopy-related infections and pseudoinfections – New York, 1996 and 1998", CDC reported apparent patient-to-patient transmission of infections following bronchoscopic procedures that used bronchoscopes 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
- the 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 facilities are using AERs to reprocess certain endoscopes not compatible with automated reprocessing. This practice may have resulted in damaged endoscopes and raises questions about whether such processing results in an endoscope properly prepared for patient contact.

Manufacturer Labeling for Endoscopes and AERs

Users of endoscopes should be aware that FDA requires certain information to be 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 labeling. The level of reprocessing should be based on the devices' 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 an AER include instructions for reprocessing specific models of endoscopes. The instructions should be based on the results of validation studies

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In This Issues:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

October 8, 1999

Complications Related to the Use of Vascular Hemostasis Devices

Dear Colleague:

I am writing to inform you of adverse events related to the use of vascular hemostasis devices. These devices provide an alternative to manual compression in achieving hemostasis following percutaneous femoral arterial punctures in patients undergoing diagnosis and treatment for cardiovascular disease. Reported complications related to these devices include hematoma, retroperitoneal bleed, pseudoaneurysm, late bleeding, and infrequently, death.

Reports

Since 1996, FDA has received reports of adverse events, including deaths, concerning closure devices. In one case, a patient, who had previously been treated with a vascular hemostasis device, suffered an acute myocardial infarction. During the ensuing catheterization, the hemostasis device was dislodged, necessitating surgical intervention. In another case, following closure with a vascular hemostasis device, the patient was discharged only to return days later with bleeding from the groin. This patient then required surgery to repair a ruptured pseudoaneurysm.

Complications can also occur when manual compression is used to achieve hemostasis. Review of the literature does show that the types of complications associated with manual compression and vascular hemostasis devices are similar. After analyzing the specific circumstances that led to the adverse events reported for vascular hemostasis devices, we believe that the following recommendations may be helpful in minimizing adverse events relating to the use of these devices.

Recommendations

Manufacturers' instructions and recommendations may vary for individual vascular hemostasis devices. In general, to avoid complications when using vascular hemostasis devices, we recommend that you carefully follow the device manufacturer's warnings, precautions, and instructions regarding patient selection and device use.

In addition, we offer the following specific recommendations:

- Do not use vascular hemostasis devices to treat patients with suspected double wall punctures, as punctures of the posterior wall are not closed with these devices.

- Carefully weigh the risk of bleeding at the puncture site against the benefits of using a vascular hemostasis device when treating patients with bleeding disorders or patients medicated with platelet glycoprotein IIb/IIIa receptor inhibitors.

- Carefully monitor the groin puncture site to minimize the occurrence of complications with vascular hemostasis devices.

- Special attention should be paid to any post-procedure patient-management instructions or ambulation recommendations for the specific vascular hemostasis device used.

Reporting adverse events to FDA

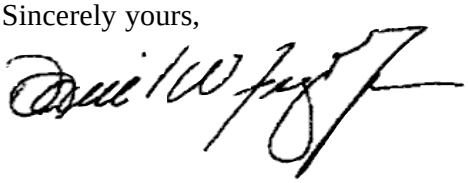
FDA is interested in additional data on adverse events involving the use of hemostasis devices. Healthcare providers employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facility. All other providers may submit their reports to MedWatch, FDA's voluntary reporting program. The reports can be submitted by phone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; via the MedWatch web site at www.fda.gov/medwatch; or by mail to MedWatch, FDA, HF-2, 5600 Fishers Lane, Rockville, Maryland 20852-9787.

Getting more information

If you have questions regarding this letter, please contact Paula Simenauer, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov.

All of FDA's medical devices 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 e-mail on the day they are released by subscribing to our list server. To subscribe, send a message to fdalists@archie.fda.gov. In the body of the text, type subscribe dev-alert.

Sincerely yours,



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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

FDA and CDC 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 staff flush all endoscopes immediately following a 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 whether or not the facility manually reprocesses endoscopes or uses an AER.

2. Check with the endoscope manufacturer to determine if the endoscope can be reprocessed in an AER and if specific steps should 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, ask the AER manufacturer if the endoscope has been tested with its system.

3. Compare the reprocessing instructions provided by the endoscope manufacturer and the AER manufacturer and resolve any conflicting recommendations. Any conflicting recommendations between the manufacturers must be resolved, particularly if they involve the use of channel connections or capping/non-capping of specific lumens or channels. Work with the AER manufacturer's technical staff to clarify conflicting information.

4. In the absence of specific technical instructions about automated reprocessing for each model of endoscope, follow the endoscope manufacturer's manual reprocessing instructions as well as the recommendations of the manufacturers of the chemical germicides used at your facility.

5. Regardless of the processing system used, consider incorporating a final drying step in your facility's reprocessing protocol. Studies 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 into its ASTM Standard F1518-94. Reprocessed endoscopes should also be stored in a manner that will minimize the likelihood of contamination or collection/retention of moisture.

6. Determine if your facility's instructions for preparing endoscopes for patient contact are appropriate and that staff is adhering to these instructions. This includes:

a. Having the correct version of instructions applicable to your AER for the specific endoscope models used at the facility.
b. Making available to all staff responsible for reprocessing copies of written device-specific instructions for every endoscope model and reprocessing system used.
c. Reviewing the written endoscope-specific reprocessing instructions from AER manufacturers to ensure correct implementation at your facility.

7. Provide comprehensive 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:

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MAMMOGRAPHY MATTERS TO BE AVAILABLE ONLY ON INTERNET

FDA will stop printing and mailing free copies of *Mammography Matters* starting with the Spring 2000 issue. The newsletter is intended to help facilities implement the Mammography Quality Standards Act (MQSA). It will still be available on the Internet (http://www.fda.gov/cdrh/mammography) and by paid subscription from the National Technical Information Service (NTIS) in Springfield, VA. To receive an order form, call NTIS at 1-800-363-2068 and ask for title order number SUB9945.

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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 and 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 maintenance schedules and services recommended by the manufacturer 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 learning of adverse events involving the use of endoscopes and AERs. Healthcare professionals employed by 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 http://www.fda.gov/medwatch; or by mail to MedWatch, FDA, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

Getting Additional Information

Questions regarding the Endoscope Public Health Advisory can be e-mailed to 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, HFZ-510, Rockville, MD 20850.

All of FDA's postmarket safety notifications for medical devices are on the World Wide Web at http://www.fda.gov/cdrh/safety.html. They can also be obtained through e-mail on the day of release by subscribing to FDA's list server. To subscribe, send a message to fdalists@archie.fda.gov. In the body of the text, type subscribe dev-alert.

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. Standard practice for cleaning and disinfection of flexible fiberoptic and video endoscopes used in the examination of the hollow viscera. ASTM Standard F1518-94. Vol. 13.01 Medical Devices. *Annual Book of ASTM Standards 1998*: 834-39 (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. (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; 38:149-57.

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 the number 1 to access DSMA Facts; at the second voice prompt, press number 2 and enter document number 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.

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

PROBLEMS WITH CIRCUMCISION CLAMPS*

By Sonia Swayze, RN, MA

During a routine infant circumcision, the circumcision clamp fell off, resulting in a skin tear to the side of the penis. Sutrues were required. When evaluating the clamp afterward, some components did not appear to fit together well.

What went wrong?

Neonatal circumcision is the most common surgical procedure performed in the United States. Circumcision clamps, specially designed to remove an infant's foreskin, are often used. When facilities sterilize and reassemble the clamps, components from different manufacturers may be interchanged. Some manufacturers place identifying marks on components but others do not. Although components may look similar, subtle differences in size may exist.

Clamps that are poorly serviced, fatigued from long use, or reassembled with mismatched components may break, slip, fall off during use, or fail to make a tight seal. The result can be excessive bleeding, lacerations, or tears of the penis.

What precautions can you take?

- Become familiar with the circumcision clamps used in your facility.
- Check the marks on device components to make sure that they match.
- Before use, inspect clamps to make sure that all components fit properly.
- Inspect the clamps for signs of fatigue such as inadequate closure or corrosion.
- Always check the date of expiration for sterilization.

The American Association of Pediatrics recently concluded that routine circumcision of newborn males is not essential for a child's well-being. Together, parents and physicians should discuss the advantages and disadvantages of the procedure.

Sonia Swayze is a nurse-consultant in the Center for Devices and Radiological Health's Office of Surveillance and Biometrics.

*This article was adapted from the September issue of *Nursing '99*.

REPORTING Y2K ADVERSE EVENTS

Despite careful preparation, unexpected date-related problems could occur after January 1, 2000. If your facility becomes aware of a Y2K problem with a medical device that appears to have serious implications for patient safety, please report it immediately to FDA's Emergency Operations Center. The FDA Emergency Operations Center can be reached by calling 301-443-1240 or 1-888-INFO-FDA (1-888-463-6332). FDA requests that facilities **immediately** fulfill their reporting responsibilities upon learning of a reportable adverse event, rather than taking advantage of the longer timeframes provided for in 21 CFR Part 803. The following is a summary of the reporting requirements and procedures.

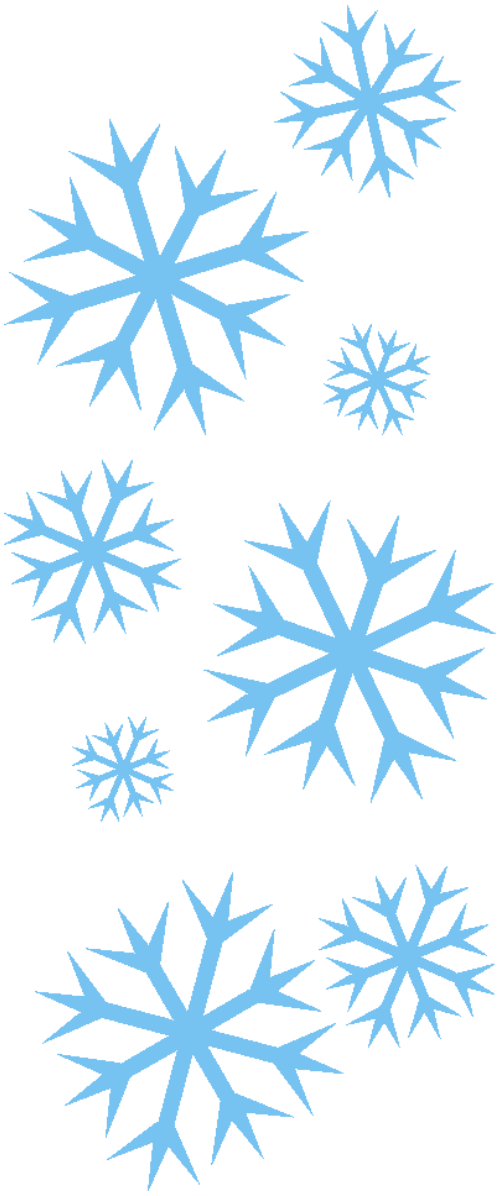
Mandatory Reports

User facilities are required to report deaths to both FDA and the manufacturer; injuries are reported only to the manufacturer. Report these problems through procedures already established by your facility and identify the report as a Y2K problem, using the following special codes on the FDA Form 3500A, in addition to other appropriate codes:

MedWatch Device Problem Codes, Block F10	MedWatch Conclusion Codes, Block H6
2581 - Date-related problem, Y2K	90 - Date-related problem, Y2K
2582 - Date-related problem, not Y2K	91 - Date-related problem, not Y2K

Voluntary Reports

Facilities may report any date-related problem that did not cause death or injury, but may have been related to unexpected performance of the device. This would include device malfunctions that could cause death or serious injury if the problem recurred. Again, be sure to identify the report as a **Y2K problem**. FDA encourages facilities to report any contradiction between their observations of device performance and the performance described by the manufacturer of the device. Voluntary reports can be submitted as follows: by telephone, to 1-800-FDA-1088; by mail (Form 3500), to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857-9787; and electronically, at http://www.fda.gov/medwatch/index.html.



WATCH FOR THE WINTER ISSUE COMING IN 2000!

User Facility Reporting Bulletin

FDA produces the *User Facility Reporting Bulletin* quarterly to assist hospitals, nursing homes and other medical device user facilities in complying with their statutory reporting requirements under the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Administration Modernization Act of 1997. The *Bulletin's* contents may be freely reproduced. Comments should be sent to the Editor.

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