MEDICAL DEVICE REPORTING
FDA MEDICINE MANUFACTURERS

User Facility Reporting

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RETINAL REPAIR RISKS*

By Eileen Woo, RN, BSN

A male patient underwent surgery to repair a retinal tear. His eye was filled with a perfluoropropane gas bubble, and the retina was reattached. Four weeks after the retinal surgery, the patient had prostate surgery under general anesthesia. On awakening, he complained that he was unable to see light. He suffered central retinal artery occlusion that the ophthalmic surgeon thinks may have been caused by an expansion of the perfluoropropane gas bubble and increased intraocular pressure from the nitrous oxide used in general anesthesia during the prostate surgery.

Perfluoropropane and sulfur hexafluoride gases are surgical aids for treatment of retinal detachment. It takes several weeks for either type of gas bubble to diffuse from the eye. If nitrous oxide is administered while the gas bubble remains in the eye, it can diffuse rapidly into the gas bubble and raise intraocular pressure.

The U.S. Food and Drug Administration has received medical device adverse event reports of vision loss in patients who were injected with perfluoropropane for eye surgery and who, within a matter of weeks, received nitrous oxide as anesthesia during vascular, prostatic, and kidney transplant surgery. To help patients avoid potential health risks, ophthalmic operative staff can:

- read the perfluoropropane and sulfur hexafluoride gas product labeling and note the warnings and contraindications;
- tell your patients and give them in writing any precautions to take after administration of the perfluoropropane or sulfur hexafluoride gas bubble;
- make sure to place medical alert bracelets, which are provided by the manufacturer, on patients' wrists postoperatively;
- instruct patients to tell subsequent healthcare providers that they've had retinal detachment surgery and that the gas bubbles may remain in the eye for six to eight weeks; and
- remind patients to avoid any type of travel at high altitudes until the surgeon gives them permission to travel; otherwise, the gas bubbles may expand with reduced atmospheric pressure.

General surgeons, anesthesiologists, and general preoperative staff can remember to:

- ask patients if they have had recent retinal surgery using perfluoropropane or sulfur hexafluoride gas before administration of nitrous oxide; and
- inform anesthesia providers of any patients who are at risk of a perfluoropropane or sulfur hexafluoride nitrous oxide reaction.

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** Adapted from Nursing Spectrum, October 27, 2002*

In This Issue:

REPORTING NEEDLESTICKS

Editor's Note: The following questions about reporting incidents of needlesticks are excerpted from the Food and Drug Administration's guidance document entitled Needlesticks - Medical Device Reporting Guidance, November 12, 2002, available at http://www.fda.gov/cdrh/osb/guidance/250.pdf.

Q. What are the mandatory requirements, under 21 CFR Part 803, for device user facilities, importers, and manufacturers to report needlestick-related adverse events to the FDA?

A. The Medical Device Reporting (MDR) regulation, 21 CFR Part 803, requires that **user facilities** must submit medical device adverse event reports, on FDA Form 3500A, to the FDA and the device manufacturer whenever the facility become aware that a device used at the facility may have caused or contributed to a patient death. User facilities must also report adverse events to the device manufacturer or to FDA (if the manufacturer is unknown) whenever they become aware that a device may have caused or contributed to a serious injury to a patient of the facility.

In addition, user facilities are required to submit an annual report on FDA Form 3419 summarizing the reports submitted by the user facility during the reporting period. 21 CFR Part 803.3

The MDR regulation requires that device **importers** must submit medical device adverse event reports, on FDA Form 3500A, to the FDA and the device manufacturer whenever they become aware that one of their imported devices may have caused or contributed to a death or serious injury. Device importers must also submit adverse event reports to the device manufacturer whenever they become aware that one of their imported devices has malfunctioned, and such a malfunction would be likely to cause or contribute to a death or serious injury if it were to recur.

The MDR regulation requires that device **manufacturers** must submit medical device adverse event reports to the FDA, on FDA Form 3500A, whenever the manufacturer becomes aware that one of their manufactured devices may have caused or contributed to a death or serious injury. Device manufacturers must also submit adverse event reports to FDA whenever they become aware that one of their manufactured devices has malfunctioned, and such a malfunction would be likely to cause or contribute to a death or serious injury if it were to recur.

In addition, the manufacturer is required to submit a baseline report, on FDA Form 3417, for a device when the device model is first reported as required by Parts 803.50 and 803.52. 21 CFR Part 803.55

Q. Where can I find more information about the mandatory reporting requirements for device user facilities, importers and manufacturers?

A. The mandatory MDR requirements, forms, instructions for filling out the forms, guidance documents and Federal Register notices can be found on the Reporting Problems with Medical Devices homepage at: **http://www.fda.gov/cdrh/mdr/**.

You may also submit questions to the Reporting Systems Monitoring Branch, Division of Surveillance Systems, Office of Surveillance and Biometrics e-mail account at: rsmb@cdrh.fda.gov or by contacting them directly at (301) 594-2735.

Q. When do I have to report a needlestick-related event reportable under 21 CFR Part 803?

A. A needlestick-related event is reportable as a death, serious injury or malfunction as detailed below:

1. A death report should be submitted by a user facility, importer and manufacturer if the device may have caused or contributed to the death of the individual.
2. A serious injury report should be submitted by a user facility, importer and manufacturer if the device resulted in an injury to an individual and the injury was life-threatening, resulted in permanent impairment of a body function or permanent damage to a body structure, or necessitated medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
3. A device malfunction report should be submitted by an importer and manufacturer if the device failed to perform as intended and would be likely to cause or contribute to a death or serious injury if the needlestick event recurred.

If a person who is exposed to infectious materials via a needlestick that resulted from a device failure is subsequently treated medically or surgically to prevent permanent impairment, then the event becomes reportable by the user facility, importer, and manufacturer as a serious injury report.

We do not consider first aid to constitute medical intervention, and this type of intervention will not require

NEEDLESTICKS - *Continued*

an MDR report. Examples of first aid are the application of a bandage or simple cleaning of the site of a needlestick. In addition, we do not consider an in-vitro diagnostic test for blood-borne diseases to constitute medical intervention. However, administration of a tetanus shot, a gamma globulin shot or stitches is considered medical intervention. This type of intervention triggers the submission of a mandatory serious injury adverse event report by a device user facility, importer, or manufacturer.

Q. What is a medical device malfunction?

A. A malfunction is the failure of a device to meet its performance specifications or to perform as intended. If you are an importer or manufacturer of a device, you must report a malfunction when it is likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Once a malfunction has caused or contributed to a death or serious injury, a presumption that the malfunction is likely to cause or contribute to a death or serious injury has been established. This presumption will continue until the malfunction has caused or contributed to no further deaths or serious injuries for a period of two years, or valid data shows that the likelihood of another death or serious injury because of the malfunction is remote.

A malfunction that is or can be corrected during routine service or device maintenance should be reported if the malfunction is likely to cause or contribute to a death or serious injury if it were to recur.

You do not need to report a malfunction if it is not likely to result in a death or serious injury.

If you are a user facility, you are not required to report any device malfunctions. However, we encourage you to report device malfunctions to the device manufacturer and/or to the FDA through the voluntary MedWatch program.

Q. Do I have to report a needlestick-related event that involves blood spillage or splattering?

A. You do not need to report a device-related blood spillage or splattering event unless the incident is the result of a device malfunction. If you are a manufacturer or an importer, you should report any spillage or splattering malfunction event if a recurrence is likely to cause or contribute to a death or serious injury.

Q. Do I have to report a needlestick-related event due solely to use error?

A. It depends on the severity of the event. Events involving a death or a serious injury where user error may have caused or contributed to a needlestick-related event are reportable by a user facility, importer, and manufacturer.

Q. How can I submit voluntary MedWatch reports concerning needlestick-related events to FDA when those events are not required to be reported by 21 CFR Part 803?

A. User facilities are not required to submit mandatory malfunction adverse event reports involving needlesticks to the FDA. However, we encourage healthcare workers to report malfunctions involving needlestick-related events to the device manufacturer or to the FDA through the FDA MedWatch Voluntary Reporting Program on FDA Form 3500. Information about the FDA MedWatch Voluntary Reporting program and the Form FDA 3500 Voluntary Reporting Form can be found on the FDA MedWatch home page at: http://www.fda.gov/medwatch/. A voluntary report can be filled out on line by accessing the MedWatch homepage and clicking on "Submit Reports" or by direct access at: http://www.accessdata.fda.gov/scripts/medwatch/. In lieu of submitting a voluntary report via the internet, you may report to us by dialing 1-800-FDA-1088 or 1-301-827-0361.

Goodbye Nancy!

Nancy Lowe, Editor of the *User Facility Reporting Bulletin* has retired. As the founding editor, Nancy has been intimately involved in every step of the *Bulletin.* She has diligently guided the changes over the past 10 years. The *Bulletin* started as a vehicle to provide basic educational information to hospitals on the Safe Medical Devices Act of 1990. It now provides hospitals with a wider breadth of information including feedback on CDRH actions following adverse event reporting, reprints of FDA public health notifications and specific information important for hospitals on medical devices problems and issues.

RESULTS OF FDA SURVEY OF HOSPITAL REPROCESSORS OF SINGLE-USE DEVICES

As part of its study of the reuse and reprocessing of single-use-devices (SUDs), the U.S. Food and Drug Administration (FDA) sponsored a telephone survey of SUD practices in hospitals. The response rate for the survey was 79.1 percent and included all for-profit, non-profit, and government hospitals, except Veterans Administration (VA) and Department of Defense (DoD) hospitals.

FDA's primary goal was to estimate the extent of hospital reprocessing of SUDs that have been used on patients. Additionally, the survey provided data on the types of SUDs reprocessed and how FDA's SUD enforcement guidance affected hospital activities. The survey was designed to help FDA develop cost-effective hospital inspection protocols and enforcement strategies and was conducted between December 2001 and February 2002. The three major findings of the survey are:

- Twenty four percent (after adjusting for non-responses) of all U.S. hospitals reuse SUDs that previously had been used on patients.
- The most commonly reused SUDs are sequential compression device (SCD) sleeves, which are reused by 15.8 percent of all hospitals.
- Nearly half (45.2 percent) of all hospitals with more than 250 beds reuse SUDs, compared to only 12.3 percent of hospitals with fewer than 50 beds.

For additional information about the survey, see the executive summary on the Center for Devices and Radiological Health (CDRH) website at: http://www.fda.gov/cdrh/reuse/survey-execsum.html.

FDA PATIENT SAFETY NEWS

FDA Patient Safety News is a televised series for health care personnel, carried on satellite broadcast networks aimed at hospitals and other medical facilities across the country. Each edition features information on new medical devices, on FDA safety notifications and product recalls, and on ways to protect patients when using medical devices.

This site (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/psn/index.cfm) contains the text for each broadcast, plus links for more information on each story. You can also search the Patient Safety News Headlines. It also has instructions for purchasing videotapes of previous broadcasts and sending comments to FDA about the broadcast.

Topics from November 2002 Broadcast...

- New Drug for Chronic Hepatitis B
- New Drug for Women with Constipation-Predominant IBS
- New Preservative-free Flu Vaccine Approved
- Drug Name Confusion: Serzone and Seroquel
- Possible Risks Associated With IGIV
- Update on Cochlear Implants and Meningitis
- AED's are Becoming More Visible in Public Places
- LASIK Eye Surgery Website

"FAQS" PERTAINING TO REPROCESSED SINGLE-USE DEVICES MEDICAL DEVICES USER FEE AND MODERNIZATION ACT OF 2002

On October 26, 2002, President Bush signed into law the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), P.L. 107-250, amending the Federal Food, Drug, and Cosmetic Act (the Act). The following frequently-asked-questions (FAQs) pertain to the provisions regarding reprocessed single-use devices.

Q. How will reprocessed single-use devices be regulated under the new law?

A. Before enactment of the new law, the regulatory requirements for manufacturers of reprocessed single-use devices (the persons who are reprocessing the device) basically depended upon the class of the device. Manufacturers of reprocessed class I and II single-use devices were required to have a 510(k), unless the device was exempt from 510(k). Reprocessors of class III devices were required to obtain premarket approval. Under the new law, reprocessors of some exempt devices will no longer be exempt from the 510(k) submission requirements but rather will need to submit 510(k)s that include validation data. Validation data will also be required for many reprocessors of single-use devices that are currently the subject of cleared 510(k)s. Finally, reprocessors of class III devices will need to submit a pre-market report (a new type of premarket application). More detail is provided below.

Q. If my reprocessed single-use device was 510(k) exempt before the new law, is it still exempt?

A. Not necessarily. By April 26, 2003, FDA will review the types of ***critical*** reprocessed single-use devices[1] that are currently ***exempt*** from 510(k), and determine which of these exemptions will be terminated. FDA must publish a Federal Register notice listing these devices. 510(k)s submitted for these devices must include validation data (as described below), and must be submitted within 15 months of publication of the list.

By April 26, 2004, FDA is to review the types of ***semi-critical*** reprocessed single-use devices[2] that are currently exempt from 510(k), and determine which of these exemptions will be terminated. FDA must publish a Federal Register notice listing these devices. 510(k)s submitted for these devices must include validation data, and must be submitted within 15 months of publication of the list.

Reprocessed single-use devices not included on either the critical or semi-critical device lists may continue to be marketed without submission of a 510(k).

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1. A "critical reprocessed single-use device" is a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

2. A "semi-critical reprocessed single-use device" is reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

Q. When will FDA require validation data for reprocessed single-use devices that already require 510(k) clearance (i.e., devices that are not 510(k) exempt)?

A. By April 26, 2003, FDA will review the types of reprocessed single-use devices now subject to 510(k) clearance and identify those that FDA will now require to submit "validation data . . . regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent . . . after the maximum number of times the device is reprocessed as intended" by the person who submits the 510(k). FDA must publish a list of these devices in the Federal Register and update the list when necessary. A 510(k) for one these devices, submitted after publication of the list, must include validation data. Validation data must also be submitted for a device that already has a cleared 510(k), or marketing must cease; the validation data must be submitted within nine months of the date FDA includes the device on the list of devices for which validation data is required.

Q. When will FDA require premarket reports for class III reprocessed single-use devices?

A. The requirement for submission of premarket reports for class III reprocessed single-use devices went into effect on the Act's effective date, October 26, 2002. Previously, PMAs were required for these devices.

Q. What labeling changes are required for reprocessed single-use devices and when must the new labeling be used?

A. Any reprocessed single-use device (i.e., devices exempt from 510(k) requirements, subject to 510(k) requirements, or subject to a premarket report) introduced into interstate commerce after January 25, 2004 must "prominently and conspicuously" bear the statement:

Reprocessed device for single use. Reprocessed by [name of manufacturer that reprocessed the device].

This provision will make it easier for patients and health care professionals to know when they are using a reprocessed device.

MDUFMA - ***Continued***

Q. How do I obtain additional information on the requirements of the new law?

A. FDA currently is developing its implementation plans for MDUFMA, so we may not be able to answer all your questions at this time. We do have a variety of materials that will help you gain an understanding of the new law:

The web page at http://www.fda.gov/cdrh/mdufma will be updated and expanded periodically and will provide the latest information and guidance from FDA concerning the new law.

- The full text of the new law is available in pdf (http://www.fda.gov/cdrh/mdufma/MDUFMA2002.pdf) and text (http://www.fda.gov/cdrh/mdufma/MDUFMA2002.html) formats.
- FDA has prepared a brief summary that provides additional information on the key provisions of the new law; this summary is available in pdf (http://www.fda.gov/cdrh/mdufma/MDUFMASummary.pdf) and text (http://www.fda.gov/cdrh/mdufma/MDUFMASummary.html) formats.
- You can review the legislative history of MDUFMA on the Library of Congress THOMAS legislative information web site, (http://thomas.loc.gov). Search for these bills: H.R. 5651 (the bill that was enacted) and H.R. 3580 (a predecessor bill that led to H.R. 5651).
- The Division of Small Manufacturers, International and Consumer Assistance (DSMICA) can answer basic questions concerning the new law and help you find guidance documents and other reference materials. The agency is developing procedures for fee collection and qualification to be treated as a small business. When these procedures are completed, we will post them on the MDUFMA website.

If you have a question that is not answered by DSMICA or the available reference materials, send an e-mail message to MDUFMA@cdrh.fda.gov

TWO QUESTIONS ON REGISTRATION AND LISTING ADDED TO REUSE WEBSITE

The following two questions about registration and listing were added to the Reuse Website (http://www.fda.gov/cdrh/reuse/index.html) on December 11, 2002.

Q. My establishment is registered as a manufacturer of medical devices, some of which are labeled for single use. We also reprocess for reuse some of the single-use devices that we manufacture. Do we have to add the establishment operation type of "Reprocessor of Single-Use Devices" to our existing registration information?

A. Yes, your establishment needs to be registered for all of the operations that are being performed at the same location.

Q. My establishment is registered as a manufacturer of medical devices, some of which are labeled for single use. We also reprocess for reuse some of the single-use devices that we manufacture. Do we have to update our existing device listing information?

A. Yes, your establishment needs to have all of the operations that are being performed on a particular device listed with FDA.

REUSE CD ROM AVAILABLE

The Center for Devices and Radiological Health developed a CD ROM entitled: **"An Overview of the Regulatory Requirements for Reprocessing of Single-Use Devices by Hospitals."** While supplies last, a free copy of the CD-ROM is available by request at http://www.fda.gov/cdrh/Reuse/reuse-messages.html.

The two-disc set covers the regulatory requirements that a hospital must meet if it reprocesses single-use devices (SUDs). Topics include:

- Introduction about reprocessing SUDs
- Registration and Listing
- Premarket Review
- Labeling
- Corrections and Removals
- Medical Device Tracking
- Problems with Reprocessing
- Medical Device Reporting
- Quality System Regulation
- Useful Information

To see the PowerPoint presentations from the CD ROM, visit the Reuse Web Page at: http://www.fda.gov/cdrh/reuse/reuse-documents.html#10.

FDA Public Health Notification: Diathermy Interactions with Implanted Leads and Implanted Systems with Leads

(You are encouraged to copy and distribute this Advisory)

December 19, 2002

Dear Colleague:

This is to alert you to the risk of serious injury or death if patients with implanted electrical leads are exposed to diathermy treatments.

Background

Adverse events

FDA has received reports in which patients with implanted deep brain stimulators (DBS) died after receiving diathermy therapy. One patient received diathermy following oral surgery, the other for treatment of chronic scoliosis. In both cases, the interaction of the diathermy with the implanted device caused severe brain damage in the area where the lead electrodes were implanted.

Types of diathermy affected

There are three types of diathermy equipment used by physicians, dentists, physical therapists, chiropractors, sports therapists, and others: radio frequency (shortwave) diathermy, microwave diathermy and ultrasound diathermy. Shortwave and microwave diathermy, in both heating and non-heating modes, can result in serious injury or death to patients with implanted devices with leads. This kind of interaction is not expected with ultrasound diathermy. Electrocautery devices are not included in this notification.

Medical devices affected

Laboratory testing has shown that patients with **any** implanted metallic lead are at risk of serious injury when exposed to shortwave or microwave diathermy therapy. **This is true even if the implanted device is not turned on, and even if the lead is no longer connected to an implanted system.** Interaction of the diathermy energy with the implanted lead causes excessive heating in the tissue surrounding the lead electrodes. Insufficient testing has been done to determine whether there is a safe distance between the diathermy applicator and the implant system that might allow patients to be treated with diathermy without risk of injury.

Recommendations

Shortwave or microwave diathermy SHOULD NOT BE USED on patients who have ANY implanted metallic lead, or any implanted system that may contain a lead. Both the heating and non-heating modes of operation pose a risk of tissue destruction.

If you are a physician who implants or monitors patients with leads or implanted systems with leads:

- Explain to the patient what diathermy is, and stress that they should NOT receive shortwave or microwave diathermy therapy.

If you are a health care professional who uses diathermy (shortwave or microwave) in your practice:

- **Be sure to ask the patient about possible implants** before deciding to administer shortwave or microwave diathermy therapy. If the patient has an implanted lead or an implant containing a lead, diathermy therapy should not be used, **even if the implant has been turned off**. Examples of implanted systems that may contain a lead include cardiac pacemakers and defibrillators, cochlear implants, bone growth stimulators, deep brain stimulators, spinal cord stimulators, and other nerve stimulators.

PUBLIC HEALTH NOTIFICATION - *Continued*

- **Do not administer shortwave or microwave diathermy therapy to a patient who has had an implant in the past** unless you are absolutely certain that the implant and all leads in their entirety have been removed. Note that leads are often left implanted after the implant is removed.

Reporting adverse events to FDA

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. This means that if a patient death or serious injury can possibly be attributable to a diathermy device, or attributable to interactions of diathermy devices with any implanted device, you should follow the procedures established by your facility for mandatory reporting.

If you have experienced problems with diathermy devices, or adverse events involving interactions of diathermy devices with any implanted device, you can report this directly to the manufacturer. Alternatively, you can report directly to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch four ways: online to http://www.accessdata.fda.gov/scripts/medwatch/; by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

Getting more information

If you have questions regarding this letter, please contact Marian Kroen, 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. Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

All of the FDA 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 e-mail on the day they are released by subscribing to our list server. You may subscribe at http://list.nih.gov/archives/dev-alert.html.

Sincerely yours,

/s/
David W. Feigal, Jr., MD, MPH
Director
Center for Devices and Radiological Health
Food and Drug Administration

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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