



FDA Releases Final Guidance On The Reprocessing and Reuse of Single-Use Devices

On August 14, 2000, the U.S. Food and Drug Administration released its final guidance on the practice of reusing medical devices that are intended to be used only once. In the guidance, titled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (<http://www.fda.gov/cdrh/comp/guidance/1168.pdf>), FDA states that it will regulate hospitals and third-party reprocessors engaged in reprocessing of single-use devices (SUDs) the same way the agency now regulates original equipment manufacturers.

The reprocessing of medical devices labeled for single-use has grown steadily in recent years, as has the complexity of the devices being reprocessed. This trend has intensified concern about patient safety, informed consent, the ethics of this practice, and the equitable regulation of the original manufacturer and reprocessors. The goal of the new SUDs reuse policy is to protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on good science, while ensuring that the regulatory requirements are equitable to all parties. FDA will rely heavily on hospitals meeting the requirements of the Quality System regulation, since it is most applicable to reprocessing and applies to all device classes.

Under the final guidance, hospitals that reprocess SUDs may be subject to the requirements of the Food, Drug, and Cosmetic Act, including premarket notification and approval; registration and listing; submission of adverse events reports under the Medical Device Reporting (MDR) regulation; good manufacturing practice under the Quality System regulation; device labeling; device tracking; and corrections, removals and recalls.

FDA has developed a list of known reprocessed SUDs that range from technically simple to complex devices. The list varies in types of devices, material, risk of use, and severity of clinical conditions of use. Examples include surgical saw blades, surgical drills, laparoscopy scissors, orthodontic (metal) braces, electrophysiology catheters, electrosurgical electrodes and pencils, respiratory therapy and anesthesia breathing circuits, endotracheal tubes, balloon angioplasty (PTCA) catheters, and biopsy forceps. (See Appendix A of the guidance for the list.)

Background

On February 11, 2000, FDA released for public comment two companion draft documents titled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" and "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (replaced by the August 14, 2000 guidance). As a result of comments received by the agency, FDA has revised the final SUDs regulatory strategy as follows:

- The proposed Prioritization Scheme will not be used to determine the timing of FDA's enforcement priorities for the premarket submissions requirements. Rather, FDA is using the device classification [i.e., class I, class II, or class III as listed in the *Code of Federal Regulations* (CFR)] and has incorporated it into the Enforcement Priorities guidance document.¹
- FDA intends to enforce premarket submission requirements within six (6) months of issuance of the final SUDs enforcement priorities guidance for all class III devices; within twelve (12) months for all class II devices; and within eighteen (18) months for all class I devices.
- For hospital reprocessors, FDA will establish a one (1) year phase-in period for active enforcement of the **non-premarket requirements** (i.e., registration, listing, medical device reporting, tracking, corrections and removals, quality system, and labeling). The agency will use the one-year period to educate hospitals about their regulatory obligations.

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• The "List of Frequently Reprocessed SUDs" has been expanded and is now called the "List of SUDs Known to be Reprocessed." (See Appendix A of the final guidance.) The regulatory premarket submission requirements for reprocessed SUDs not included on this list are based on the device's CFR classification (i.e., class I, class II, or class III).

These enforcement priorities do not apply to:

- permanently implantable pacemakers,
- "open-but-unused" single-use devices,
- healthcare facilities that are not hospitals, and
- hemodialyzers. (The reuse of hemodialyzers is addressed in the "Guidance for Hemodialyzer Reuse Labeling" of October 6, 1995, available at <http://www.fda.gov/cdrh/ode/dilreuse.pdf>.)

Hospitals are urged to become familiar with the final SUDs reuse guidance in order to understand their potential responsibilities. If unable to download the document from the Internet, please FAX us at 301-443-8818 with your name, address, and FAX number and a copy will be sent to you. You may also access CDRH's FAX system, Facts-on-Demand, at 800-899-0381 or 301-827-0111 to request a copy; specify document number 1168 when prompted by the system.

This Fall, FDA plans to mail all hospitals information that will summarize the regulatory requirements that must be met if hospitals plan to reprocess and reuse SUDs. It will contain hyperlinks to other documents developed by FDA, such as the premarket process, the Quality Systems regulation, registration and listing, standards, etc.

FDA has also created a Reuse Homepage (<http://www.fda.gov/cdrh/reuse/index.shtml>) that provides additional information on reprocessing and reusing SUDs. The Homepage is divided into the following topics:

- **Documents.** This button provides a list of documents on reprocessing and reuse of SUDs.
- **FAQs.** This button has "Frequently Asked Questions" about reprocessing and reuse of SUDs. Additional questions and answers will be added as needed.
- **Standards.** This button explains the use of standards in the premarket process and provides a listing of standards that might be useful in the reprocessing of SUDs.
- **Events.** This button provides a listing of FDA participation at meetings and teleconferences. It is divided into past and future events.
- **Info/Questions.** This button allows readers to subscribe for e-mail notification of the latest information on reprocessing. Readers may also electronically mail questions to FDA from this button.

Reuse Meeting Schedule

September 18-22, 2000

Global Harmonization Task Force
Ottawa, Canada
Scheduled FDA Speaker: Larry Kessler

September 29, 2000

Iroquois Healthcare Association
Verona, New York
Scheduled FDA Speaker: Lily Ng

October 13, 2000

Southern Florida Materials Managers Association
Pompano Beach, Florida
Scheduled FDA Speaker: Larry Kessler

October 26, 2000

Waste Management Institute
Alexandria, Virginia (Hilton Hotel)
Scheduled FDA Speaker: Diane Goldsberry

October 30, 2000

AAMI/FDA Reprocessing of Single-Use Devices:
New FDA Requirements for Hospitals
Shady Grove Center - University of Maryland
University College
Rockville, Maryland
Scheduled FDA Speakers: Larry Spears,
Tim Ulatowski, Barbara Zimmerman,
Karen Stutsman, Al Thomas

November 2-5, 2000

American Society of Healthcare Risk Management
New Orleans, LA
Scheduled FDA Speaker: Lily Ng

November 6, 2000

International Association of Healthcare Central
Services Material Managers
Birmingham, AL
Scheduled FDA Speaker: Larry Spears

Watch for additional meeting announcements on the Reuse Homepage:

<http://www.fda.gov/cdrh/reuse/index.shtml>

¹ FDA has established classifications for about 1,700 generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned by FDA to one of three regulatory classes based on the level of control necessary to assure their safety and effectiveness with class I being those devices needing the lowest level of regulation and class III, those needing the most regulation. ☀

Medical Device Tracking: A Case Study*

By Ronald G. Kaczmarek, M.D., M.P.H., Malia D. Beaulieu, MA, and Larry G Kessler, Sc.D.

Case reports were received by the Food and Drug Administration (FDA) of fatal tachycardias caused by a malfunction of an implantable cardioverter defibrillator (ICD). ICDs are medical devices subject to the tracking requirements of the Federal Food, Drug and Cosmetic Act (the Act). The case reports led to a decision to notify 5,604 patients of the need for reprogramming their ICDs to prevent the tachycardia. In the first 60 days, 98.7 percent of the patients were successfully located and their ICDs reprogrammed.

The experience of the recall of this tracked device is highly encouraging, because it demonstrates that most recipients of tracked devices can be successfully located and receive medical intervention. Patients whose regular physicians had more than 5 patients with the ICD subject to the recall were significantly more likely to have their ICDs reprogrammed in the first week. Patients who had changed physicians were significantly less likely to undergo reprogramming in the first week. Although tracking of the medical device is the manufacturer's responsibility, the clinical community plays a critical role in its success. This report highlights the importance of understanding that role among physicians.

Introduction

Pacemakers, heart valves, and implantable defibrillators are permanently implantable medical devices whose failures would likely have serious adverse health consequences. These devices exemplify a class of products that FDA regulates in a special way. One of the mechanisms required of manufacturers of these devices is "tracking." The concept of tracking began during the recall of Bjork-Shiley heart valves. This device was found over time to have a potentially life-threatening risk of mechanical failure; the firm had to contact patients and their physicians about the problems. Unfortunately, at that time there was no system in place to help the firm. Later, the U.S. Congress passed legislation requiring manufacturers to develop and maintain tracking systems.

This report describes a series of events leading to a manufacturer's using its tracking system to inform patients. The focus is on the actual use of the tracking system and where it did or did not work. The role of clinicians in this process is highlighted.

Background

ICDs are designed to recognize life-threatening ventricular arrhythmias and deliver therapy as appropriate. Patients who receive these devices have typically survived cardiac arrest or have experienced ventricular tachycardias. They rely on the functioning of these devices to protect

them from severe consequences of any future tachyarrhythmia episodes.

On January 3, 1997, a patient's death was reported to the manufacturer through its field product monitoring process. Information obtained by the hospital documented a malfunction of the device at the time of death. Analysis of the device and others like it indicated a potential for a failure mode that could affect device performance in a variety of ways, usually with benign results. Because of the patient's death, a software modification was developed. A non-invasive reprogramming of the device was recommended to minimize the potentially harmful effects of the failure mode. The manufacturer met within 10 days with the FDA regarding the device malfunction and was given an immediate approval to begin using the new software version and issue the device notification. Patients were having their ICDs reprogrammed by January 16, 1997.

Device Tracking

In its device tracking system, the manufacturer maintains basic information about the patient and the device. This includes the model and serial number of the implanted device; the patient's name, address, telephone number; and the names of the implanting physician and the following physician with their addresses and telephone numbers. The manufacturer maintains this information in a database. Although, a patient has the right to refuse to provide complete information, few exercise that right.

Tracking regimen. The information is audited to evaluate its accuracy. When necessary, physicians are requested to update the information contained in the database. The manufacturer sends letters to physicians recorded as following patients, requesting them to verify the patient list, to confirm the accuracy of the patient and device information, and to add information for any new patients they might be following. For patients they are no longer following, physicians are requested to provide any information they have about the new physicians following the patients. In this update process, the manufacturer contacts patients directly only when no following physician can be determined.

In the above case study, the manufacturer began the device notification by contacting all physicians who were listed as following patients implanted with the recalled ICDs. Each physician was sent a letter describing the events that led to the notification and instructing them to

"Although tracking of the medical device is the manufacturer's responsibility, the clinical community plays a critical role in its success."

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contact their patients about the need for having their ICDs reprogrammed. The letter further informed physicians of the effect of reprogramming on the ICDs. Certain features would no longer be available after the reprogramming, and patients using these features would be offered replacement ICDs at no cost to the patient. This was done to ensure that there was no disincentive to reprogramming of ICDs. Finally, the letter indicated that FDA was aware of the situation and would be monitoring it.

In order to reprogram patients' devices, each ICD Programmer Device across the country had to be upgraded with a new software revision. The manufacturer's field personnel made locating and upgrading all ICD Programmer Devices their top priority. These efforts contributed to the rapid pace at which patients' ICDs were reprogrammed.

When physicians were no longer following certain patients and did not have information on their new physicians, the manufacturer contacted the patients at the addresses on record via certified letters. Patients were briefly informed of the device problem and requested to immediately contact their physicians to have their devices reprogrammed. A few patients refused to accept the certified letters sent to them, although they were apparently at the address on record. Such patients were then contacted by telephone if possible. In some of these cases, the local police department was contacted and requested to inform the patient of the need to see a physician.

In cases when patients were no longer at the addresses on record, more extensive measures were taken. Directory Assistance and the Internet

White Pages were helpful in locating some patients. Other useful methods to locate patients included the change-of-address service of a large research and investigation firm, contact with family members, and contact with other physicians in the area where the patient was believed to reside. Patients without a home address were difficult to locate, but family members were generally able to assist in locating the patient or to otherwise convey the information to them. When these methods failed, the services of a private investigative firm were used.

Currently, more than 99.8 percent of the 5,604 patients identified in the manufacturer's database at the time of the notification have been located. Of these patients, 87.6 percent were alive and still had their devices implanted. Of the remaining 12.4 percent of patients, 86.4 percent had died and 13.6 percent had already had their devices explanted before the notification.

"However, the cooperation of physicians and the quality of information maintained in the device tracking database were critical."

Discussion

Although few manufacturers have had to use their tracking systems, this case demonstrates that a device tracking system can be used to quickly locate patients to inform them of device problems. In contrast with previous device recalls, this device notification resulted in greater than 98.7 percent of patients being located and treated within the first 60 days. This was due in large part to the implemented device tracking system, cooperative physicians, mobile field personnel, and recognition of ICDs as life-saving devices. ICD patients are also monitored on a regular basis by their physicians. This frequent contact between physicians and patients facilitated location of patients during the notification period. A simple and fast non-invasive ICD reprogramming was all that was required to resolve

the safety issue. Reimbursement of all non-covered expenses incurred by the patients was covered by the manufacturer, which eliminated any financial disincentive for patients.

Results of this study also indicate that patients who changed their following physician information before the notification and without informing the manufacturer were significantly less likely to have their ICDs reprogrammed early. These unreported changes were often due to patients changing their physicians without notifying their previous physicians. In some cases, the former following physician had been informed of the change, but had not yet notified the manufacturer. Patients with tracked devices should be encouraged to inform their former physicians of their new physicians. Physicians should report to the manufacturer when they are following a new patient with a tracked device or are no longer following a patient.

Many factors contributed to the rapid protection of patients by the manufacturer and physicians. However, the cooperation of physicians and the quality of information maintained in the device tracking database were critical. The implementation and use of a device tracking system were vital to the successful location and treatment of patients affected by the device notification. ☀

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*Adapted from an article in the *American Journal of Cardiology* 2000; 85: 588-592.

Safe Infusions*

By Audry Morrison, R.N., B.S.N.

While undergoing surgery to excise a bone cyst, an 82 year-old patient required a transfusion. A fluid warmer was used to warm the blood and replacement fluids. Despite fluid and blood replacement, the patient developed hypotension and tachycardia. An echocardiogram showed air in the right atrium and right ventricle. The patient subsequently died.

What went wrong?

When a liquid is warmed, gases in the liquid become less soluble and form tiny bubbles. Fluid-warming systems use an air eliminator to vent microbubbles, but the patient may inadvertently receive air with the fluids. In this case, although the healthcare provider did not observe bubbles in the system, air reached the right side of the patient's heart.

What precautions can be taken?

- Be aware of the potential for air emboli when using a blood and fluid warmer.
- Follow the manufacturer's instructions to prevent inadvertent infusion of air into the bloodstream.
- Fully prime all filters, lines, and disposable sets before starting an infusion.
- Closely observe for air in the line when priming disposable sets and replacing filters.
- Do not transfuse blood or infuse fluids if there are air bubbles in the line. Thoroughly check the line for bubbles before opening a roller clamp.
- If you see bubbles, remove the air from the fluid pathway according to your facility's procedure before continuing the infusion.

*Adapted from the July issue of *Nursing 2000*.

Audrey Morrison is a nurse consultant in the Center's Office of Surveillance and Biometrics.

Protecting Your Patient's Eyes*

By Eileen K. Woo, R.N., B.S.N.

A woman went to her optometrist complaining of photophobia (light sensitivity), eye pain, and blurred vision after using a brand-name cleaning and wetting solution on her contact lenses. The optometrist diagnosed keratitis (inflammation of the cornea) and treated her with prednisolone acetate, neomycin, and gentamicin. He referred her to an ophthalmologist for further treatment to prevent permanent injury.

Although cleaning and wetting solutions for contact lens are relatively safe, improper handling and misuse can cause irritation, burning, and edema of the eyes. The optometrist believed that the woman had inadvertently used the cleaning solution to wet her lenses before inserting them.

Tell your patients to take these precautions when using cleaning and wetting solutions for contact lens:

- Wash their hands before and after handling contact lenses.



- Thoroughly read the directions and warnings that come with the solutions.
- Before opening, inspect the containers and make sure that they are sealed. If a container is not sealed, do not use it. Avoid touching anything with the bottle tip.
- Do not confuse a cleaning solution with a wetting solution. To avoid confusion, colorcode the solution bottles.
- After using a cleaning solution, thoroughly rinse it from the lens.
- Do not use homemade solutions as cleaning or wetting solutions. ☀

*Adapted from the May issue of *Nursing 2000*.

Eileen Woo is a nurse consultant in the Center's Office of Biometrics and Surveillance.

FDA Warns About EMI Risk With Telemetry Systems

By Nancy Pressly, B.S. Engineering

Existing wireless medical telemetry systems may be at increased risk of electromagnetic interference (EMI), if they continue to operate in the range of frequencies in which most medical telemetry devices are currently operating. To address this risk, the Federal Communications Commission (FCC) has created a new Wireless Medical Telemetry Service (WMTS) that will allow medical telemetry systems to operate on an interference-protected basis. The Food and Drug Administration (FDA) and the FCC recommend that you evaluate whether your medical telemetry systems are at risk and take appropriate measures to reduce that risk. We believe the best way to reduce this risk is to use telemetry systems operating in the new WMTS frequency bands.

Background

Currently, most wireless medical telemetry devices operate as secondary users in the commercial broadcast TV bands and in the private land mobile radio service (PLMRS) band. As secondary users, medical telemetry must accept interference from primary licensed users and not interfere with their transmissions. Typically, if there is interference from a primary user, the medical telemetry system will be unusable. This happened in 1998 when DTV transmissions disrupted medical telemetry systems in two Texas hospitals. As digital TV and high power PLMRS operators use these frequency bands more extensively, an increased risk of interference with medical telemetry is likely to result.

FDA Recommendations

FDA recommends the following:

- Consult with the telemetry equipment manufacturer to determine at which frequencies your telemetry systems are currently operating (i.e., what frequency band, channel)
- Compare that data with the frequencies allocated to digital television (DTV) in your area and the PLMRS band; a list of all DTV allocations can be found on the FCC web site <http://www.fcc.gov/healthnet/dtv.html>.
- If you and/or the telemetry equipment manufacturer determine that your medical telemetry equipment is at risk of EMI from other in-band radio frequency (RF) sources (e.g., DTV or PLMRS transmitters), you should either
 - replace your existing telemetry systems with equipment that operates in the WMTS bands (608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz), when this equipment is available, or
 - modify it to operate in the WMTS band;

NOTE: If you and/or the telemetry equipment manufacturer determine that your medical telemetry equipment is not at risk of EMI from other in-band RF sources (e.g., DTV or PLMRS transmitters), then no change is necessary.

- Assess the risks and make necessary changes to your equipment as soon as possible because:
 - licensed TV stations are authorized to begin testing and transmitting in DTV channels as soon as they are ready,
 - the FCC will begin accepting applications for high-powered users in the 450-460 MHz band on January 29, 2001.

Again, we recommend use of medical telemetry systems that operate in the WMTS bands, particularly for new purchases, to minimize the risk of EMI with wireless medical telemetry.

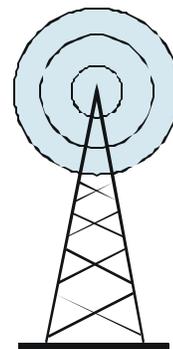
Reporting Adverse Events to FDA

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious illnesses and injuries associated with the use of medical devices. This means that if interference with a medical device results in a death or serious injury, you must report that event. We request that you follow the procedures established by your facility for such mandatory reporting.

If a telemetry system fails to function due to electromagnetic interference or any other reason, it is a device malfunction. Such malfunctions should be reported to the manufacturer. Alternatively, they can be reported directly to MedWatch, the FDA's voluntary reporting program. Submit reports to 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.

More Information from FDA

If you have questions that are related to this article regarding FDA issues, please contact Nancy Pressly, FDA, CDRH, Office of Surveillance and Biometrics, 1350 Piccard Drive, HFZ-510, Rockville, MD 20850; fax 301-594-2968; or by e-mail at phann@cdrh.fda.gov. A voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible. The July 10, 2000, *Public Health Advisory: Risk of Electromagnetic Interference with Medical Telemetry Systems*, as well as all of



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FDA's medical device postmarket safety notifications, can be found on FDA's website at:

<http://www.fda.gov/cdrh/safety.html>.

The July 10th Advisory also contains additional detailed technical information.

More information regarding EMI and medical devices can be found on the FDA EMC web site at:

<http://www.fda.gov/cdrh/emc/index.html>.

If you are interested in receiving Safety Alerts, Public Health Advisories and other FDA medical device safety notices by e-mail when they are released, subscribe to our list server. To subscribe, send an e-mail message to fdalists@archie.fda.gov. In the text of the e-mail, put: subscribe dev-alert.

More Information from FCC

For additional information regarding FCC issues, please contact Hugh L. Van Tuyl, FCC, Office of Engineering and Technology, 445 12th Street, SW, Room 7-A162, Washington, D.C., 20554, phone 202-418-7506, FAX 202-418-1944, or e-mail him at hvantuyl@fcc.gov. A copy of the FCC final rules can be found on FCC's website at:

http://www.fcc.gov/Bureaus/Engineering_Technology/Orders/2000/fcc00211.doc.

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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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Coming in the Fall Issue:

Information about the
Quality Systems regulation
and reprocessing of SUDs.