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

(You are encouraged to copy and distribute this information)

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.

- **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,

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