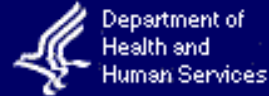




U.S. Food and Drug Administration



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FDA Public Health Notification: Deaths reported following Radio Frequency Ablation of Lung Tumors

Issued : December 11, 2007

Dear Healthcare Practitioner:

This is to alert you to reports of deaths associated with the use of radio frequency (RF) ablation devices during lung tumor ablation.

Public health concerns

FDA has received reports of patient deaths associated with lung tumor ablation using RF ablation devices, and similar reports have appeared in the literature.^{1,2,3,4} Patient selection, subsequent treatment, and technical use of the RF device, including placement and operation, may have contributed to the fatalities.

Regulatory status of the devices

FDA has cleared many RF ablation devices as tools for **general** ablation of soft tissue by thermal coagulation necrosis. These devices have also been cleared for certain specific indications, including partial or complete ablation of non-resectable liver lesions and palliation of pain associated with metastatic lesions involving bone. It is important to note that they have **not** been cleared specifically for lung tumor ablation. Manufacturers of ablation devices cannot legally market them for use in lung tumor ablation because clinical data establishing their safety and effectiveness for this purpose have not been submitted to the agency. This includes promoting their safety and effectiveness in training programs.

Recommendations

Use special caution when operating RF ablation devices, adhering strictly to information contained in the labeled operating instructions, Operators Manual, the Manufacturer's Instructions for Use and any training provided.

If you wish to use an RF ablation device to treat patients with lung tumors, you should

consider enrolling them in an approved clinical study, where training is available. Clinical trial information can be found at www.clinicaltrials.gov. Enter the search terms “ablation lung tumor.”

Reporting to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of an RF ablation device, you should follow the reporting procedure established by your facility.

Reporting adverse events is everyone’s responsibility, even if the procedure involves off-label usage of medical devices.

To report your experience regarding the devices in this Notification, please use MedWatch, the FDA’s voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at <http://www.fda.gov/medwatch/report.htm>.

Getting More Information

For the most recent information on adverse events due to lung tumor ablation please check the MAUDE database

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm?searchoptions=1>

Enter the Event Type – Death and Product Code – GEI for all reported deaths caused by electrosurgical, cutting and coagulation devices and accessories for various indications. To determine which of these adverse events may be related to lung tumor ablation, please read the detailed adverse event description.

The level of evidence required to obtain FDA clearance for general claims as compared to a specific claim related to general and specific indications of use of a device can be found in FDA’s published industry guidance: Guidance for Industry: General/Specific Intended Use – November 4, 1998 (<http://www.fda.gov/cdrh/modact/genspec.pdf>)

The FDA cleared indications for use of a particular RF ablation device can be found in the FDA 510 (k) database: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. The Product Code for these devices, GEI, includes electrosurgical, cutting and coagulation devices and accessories for various indications. Each cleared device will be associated with a specific 510(k) number, as will the indication for use that FDA has cleared for each cleared device. The database is updated as new products are cleared. FDA requires medical device manufacturers to provide sufficient data to demonstrate that the device is safe and effective for each stated indication. FDA will clear each device for the stated indication once they have reviewed this data and the appropriate training programs for these indications are available from the manufacturer.

In February 2003, FDA’s General and Plastic Surgery Devices Advisory Committee’s met and discussed the subject of thermal ablation of lung tumors. Concerns were raised about the safety

and adverse event reporting associated with RF Ablation of lung tumors. To read a transcript of the FDA Panel's deliberations, please refer to FDA Panel meeting Emphysema and Ablation devices Clinical Issues Discussion Session, February 28, 2003. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=385>

If you have questions about this notification, please contact Ann Ferriter, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by Fax at 240-276-3356, or by e-mail at phann@cdrh.fda.gov. You may also leave a voicemail message at 240-276-3357 and we will return your call as soon as possible.

FDA medical device Public Health Notifications are available on the Internet at <http://www.fda.gov/cdrh/safety.html>. You can also be notified through email on the day the safety notification is released by subscribing to our list server. To subscribe, visit: http://service.govdelivery.com/service/subscribe.html?code=USFDACDRH_10.

Sincerely yours,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

¹ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>, MDR numbers 1717344-2007-00212, 1717344-2007-00213, 17344-2007-00214, 1717344-2007-00215, and 1717344-2007-00216

² Simon C, Dupuy D. Pulmonary Radiofrequency Ablation: Long Term Safety and Efficacy in 153 Patients. Radiology. 2007; 243: 268-275

³ Lee J, Jin G, Goldberg N, et al. Percutaneous Radiofrequency Ablation for Inoperable Non-Small Cell Lung Cancer and Metastases: Preliminary Report. Radiology. 2004; 230: 125-134.

⁴ Steinke K, Sewell P, Dupuy D, Morris D. Pulmonary Radiofrequency Ablation-an international study. Anticancer Res. 2004; 24(1): 339-343.

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