FDA Public Health Notification: Unretrieved Device Fragments

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Issued: January 15, 2008

Dear Healthcare Practitioner:

This is to advise you of serious adverse events associated with unretrieved device fragments (UDFs) and provide recommendations to mitigate these events. A UDF is a fragment of a medical device that has separated unintentionally and remains in the patient after a procedure. Patients may not be aware that this has occurred. The Center for Devices and Radiological Health (CDRH) receives nearly 1000 adverse event reports each year related to UDFs. These have included more than 200 different medical devices and numerous medical specialties.

Nature of the Problem

The adverse events reported included local tissue reaction, infection, perforation and obstruction of blood vessels, and death. Contributing factors may include biocompatibility of the device materials, location of the fragment, potential migration of the fragment, and patient anatomy. During MRI procedures, magnetic fields may cause metallic fragments to migrate, and radiofrequency fields may cause them to heat, causing internal tissue damage and/or burns.

Recommendations

1. Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
2. Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
3. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
4. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
5. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
6. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
    a. The material composition of the fragment (if known);
    b. The size of the fragment (if known);
    c. The location of the fragment;
    d. The potential mechanisms for injury, e.g., migration, infection;
    e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Reporting Adverse Events

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 an unretrieved device fragment, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events related to unretrieved device fragments that do not meet the requirements for mandatory reporting. You can report directly to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail [to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

Getting More Information

If you have questions about this notification, please contact the Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 240-276-3356, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail 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 e-mail each time a new Public Health Notification is added to our web page. To subscribe to this service, visit: http://service.govdelivery.com/service/subscribe.html?code=USFDA_39.

Sincerely,

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

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