U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

"Getting More Information"

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

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November 25, 1992

FDA Safety Alert:
MRI RELATED DEATH OF PATIENT WITH ANEURYSM CLIP

To: Radiologists, Neurologists, Neurosurgeons and their staffs

This is to alert you to the possibility that information in the medical literature and in product labeling concerning the " MRI compatibility" of metallic aneurysm clips may not be reliable and could endanger patients with these implants who are undergoing MRI procedures. FDA is cautioning physicians that, at present, the only way to be certain that a metallic implant is truly safe for use with MRI procedures is to verify that the device was tested for ferromagnetic properties before it is implanted.

FDA has learned of a fatal injury sustained by a patient with a cerebral aneurysm clip while she was being prepared for an MRI procedure. It was reported that upon exposure to the magnetic field in the room, the clip moved and lacerated the patient's middle cerebral artery. The explanted device was subsequently shown to be magnetically active This particular style or clip , which was implanted in 1978, was listed in several articles and recent medical texts as non-deflecting in a magnetic field.

We are currently investigating this occurrence to confirm the association between the MRI and the patient's death. We are also re-reviewing the accuracy of labeling claims for presently-manufactured aneurysm clips with regard to their MRI compatibility.

In the meantime, unless an aneurysm clip has been tested prior to implantation to establish whether it has ferromagnetic properties, it should not be scanned with MRI .

Note that caution should also be exercised when considering an MRI scan on any patients with a magnetically, electrically or mechanically activated implant containing metallic components.

FDA is interested in information concerning other adverse incidents associated with MRI scans. We encourage you to report such incidents to the Product Problem Reporting Program at 1-800-638-6725.

If you have medical questions about this Safety Alert, you may phone Gordon Johnson, M.D. director of our Office of Health Affairs at 301-427-1060.

Sincerely yours,

Acting Director,
Center for Devices and
Radiological health

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