FDA Public Health Notification: Paralysis from Absorbable Hemostatic Agent

(You are encouraged to copy and distribute this notification.)

Issued: 4-2-2004

Dear Surgeon:

This is to remind you of a rare but devastating adverse event that can occur with the use of an absorbable hemostatic agent, a device used to promote coagulation and stop internal bleeding during surgical procedures. Unfortunately, these events continue to occur despite specific advice and warnings in the device labeling. We ask that you take action to minimize the risk in your patients and help spread the message in this announcement.

Nature of Problem

Since 1996, FDA has received reports of over 110 adverse events related to absorbable hemostatic agents. Eleven of the events resulted in paralysis or other neural deficits. The last reported paralysis occurred in October, 2003. The common thread in all 11 events was an absorbable hemostatic agent that was used on or near a bony or neural space and left inside the patient. When wetted, the material swelled and exerted pressure on the spinal cord or other neural structures, resulting in pain, numbness or paralysis. In some cases, blood pooled behind the implanted absorbable hemostatic agents, forming a hematoma that exerted pressure on neural tissues and caused a range of neural deficits.

Although these events are rare, they can have serious consequences. These consequences ***are preventable.***

Recommendations

FDA recommends that users of absorbable hemostatic agents review the device labeling, especially the contraindications, warnings and precautions.

If you use an absorbable hemostatic agent on or near bony or neural spaces:

- use the minimum amount necessary to achieve hemostasis; and,
- remove as much of the agent as possible after hemostasis is achieved.

This will reduce the likelihood of neural and other soft tissue damage from swelling of the absorbable hemostatic agent, and/or migration and swelling of fragments of the agent.

Reporting Adverse Events 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 absorbable hemostatic agent, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events related to absorbable hemostatic agents that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer. You can also report to 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

If you have questions about this notification, please contact Ms. Quynh Hoang, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail message at 301-594-0650 and we will return your call as soon as possible.

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Sincerely yours,

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