WESTCHESTER REGIONAL
EMERGENCY MEDICAL ADVISORY COMMITTEE

POLICY STATEMENT

Supercedes/Updates: New

No. 04 - 03

Date: April 19, 2004

Re: Use of Absorbable Hemostatic Agents

Pages: 2

Use of Absorbable Hemostatic Agents By Certified EMS Agencies

PURPOSE

To provide EMS agencies with regional guidelines on the appropriate possession and use of hemostatic agents for hemorrhage control.

BACKGROUND

Brought first into use through the United States Military, the United States Food and Drug Administration (FDA) has regulated absorbable hemostatic agents since the late 1970s. Addressed separately from surgically used vascular constricting agents under regulation number 21 CFR §878.4490, "Absorbable hemostatic agent and dressing, " these agents are defined as "a device intended to produce hemostasis by accelerating the clotting process of blood." Within the past decade these agents have been commercially developed for use by civilian emergency medical services. Recent studies presented in medical journals have found that the use of these hemostatic dressing can improve survival and decrease bleeding associated with lethal vascular and soft tissue injuries.T[1]

AUTHORIZATION

Any Westchester Regional certified EMS agency wishing to include the use of hemostatic agents among other tools for hemorrhage control may do so under the advice and consent of their Agency Medical Director. Any absorbable hemostatic agent purchased and supplied on an EMS unit must be approved by the FDA for that purpose.

TRAINING

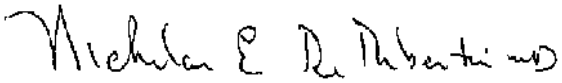
The NYS DOH EMT and AEMT curriculums do not include instruction on the use of hemostatic agents for hemorrhage control. The EMS agency, in conjunction with the Agency Medical Director, shall create a training program to familiarize all the members/employees of that agency with the indications for and use of the agent as per the FDA approved manufacturer's instructions[2], as well as emergency treatment for

exposures to non-injured areas and accidental ingestion. Application of the agents will be consistent with the direction of care for hemorrhage-control found in the current NYS DOH BLS protocols.

STORAGE

The certified EMS agency must ensure that the hemostatic agent is stocked and stored in accordance with manufacturer recommendations.

Issued and Authorized by:



Dr. Nicholas DeRobertis, MD, FACEP
Chair, Westchester Regional Emergency Medical Advisory Committee

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[1] Comparative Analysis of Hemostatic Agents in a Swine Model of Lethal Groin Injury, H. Alam, G., Uy, et al. The Journal of Trauma: Injury Infection and Critical Care. June 2003; 54(6): 1077-1082.

[2] Attachment - FDA Public Health Notification: Paralysis from Absorbable Hemostatic Agent (4/2/2004)

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.

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 listserv. To subscribe, visit: 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