Potential Risk of Severe Bleeding and Hematomas Associated with VASCU-GUARD Peripheral Vascular Patch – Letter to Health Care Providers

September 1, 2016

Dear Vascular Surgeons, General Surgeons, Cardiothoracic Surgeons, and Neurosurgeons:

The FDA has recently received multiple adverse event reports associated with Baxter International Inc.'s Vascu-Guard Peripheral Vascular Patch (also referred to as the Vascu-Guard patch) during carotid endarterectomy (CEA). These reports from 2016 include intraoperative or postoperative bleeding and hematomas, some of which required additional clinical intervention, and three patient deaths potentially related to this issue that occurred shortly after CEA surgery. The device manufacturer, Baxter International, Inc., alerted the FDA to these adverse events.

The FDA is concerned that the Vascu-Guard patch may not be performing as intended and that patients who are treated with the product may be at risk for serious adverse health consequences, such as severe bleeding, hematomas, and death. After CEA surgery in particular, arterial bleeding in the neck could rapidly lead to airway obstruction, hypoxia, diminished brain perfusion, stroke and/or cardiac arrest.

We are alerting health care providers to these potential risks, so you can consider this information when deciding which vascular patch material to use, or whether to employ other reconstructive techniques, for CEA surgery. We recommend that you discuss all available treatment options with patients, including the risks and benefits of each, before deciding the best treatment approach.

ANALYSIS OF THE PROBLEM

The Vascu-Guard patch is intended for use in peripheral vascular reconstruction including carotid, renal, iliac, femoral, profunda, and tibial blood vessels and arteriovenous access revisions. Patients with obstructive (atherosclerotic) or

aneurysmal peripheral vascular disease who require surgical reconstruction could be exposed to this device, as could patients undergoing surgery on the carotid, renal, iliac, femoral, profunda, and tibial arteries. While this product can be used in other areas of the body, the FDA is aware of adverse events following CEA surgery.

Other vascular patches include those made from pieces of a saphenous vein or prosthetic patches made out of Dacron or polytetrafluoroethylene (PTFE).

In June 2016, Baxter International, Inc. sent a safety alert to its customers, voluntarily recalling specific lots of the Vascu-Guard patch because of reports of intraoperative or postoperative bleeding and hematomas following CEA surgery, some of which required additional clinical intervention. The lots covered in this recall can be found in the FDA's recall database.

As noted in the device labeling, possible complications from using the Vascu-Guard patch include dehiscence (wound separation) at the surgical site, which could cause serious bleeding, hematomas, and infection. However, we are concerned about the cluster of bleeding cases that have been reported following CEA so far this year, and are actively investigating possible causes.

RECOMMENDATIONS

The FDA recommends that health care providers:

- Discuss with your patients all available treatment options, including the risks and benefits of each, before deciding the best treatment approach.
- Until FDA completes its investigation of the adverse events reported following CEA surgery, consider the following actions if using this device:
    1. Employ heightened post-operative vigilance on the part of the patient and physician for signs of early bleeding (e.g., neck swelling, difficulty breathing).
    2. Follow all manufacturer instructions for patch preparation.
- Report any adverse events related to the Vascu-Guard Peripheral Vascular Patch that come to your attention. Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations. Health care personnel employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

FDA ACTIONS

As outlined above, since Baxter International, Inc.'s voluntary recall in June 2016, the

FDA has been working with the manufacturer to address concerns about the safety and effectiveness of the Vascu-Guard patch. While the adverse events received by the FDA are associated with the lot numbers covered in the voluntary recall, the FDA is working with the manufacturer to determine whether other lots may be associated with similar adverse events.

On August 12, 2016, the FDA classified Baxter International Inc.'s voluntary recall as a Class II recall. Class II recalls involve situations in which products might cause a temporary health problem, or pose only a slight threat of a serious nature or death.

The FDA will keep the public informed if significant new information becomes available.

CONTACT US

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

Sincerely,
/s/
William Maisel, MD, MPH
Deputy Center Director for Science
Center for Devices and Radiological Health
U.S. Food and Drug Administration

More in Health Care Providers (Medical Devices)

Letters to Health Care Providers

Page Last Updated: 09/01/2016
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA

- Combination Products
- International Programs
- Consumers
- Advisory Committees
- News & Events
- Health Professionals
- Regulatory Information
- Training & Continuing Education
- Science & Research
- Safety
- Inspections & Compliance
- Industry