SAFETY ALERT

Jul 7, 2016

Dear Healthcare Professional:

Baxter Healthcare Corporation is issuing this safety alert in response to postmarketing reports received for the VASCU-GUARD Peripheral Vascular Patch. We are actively investigating these reports, and will provide additional information as it becomes available. In the interim, and out of an abundance of caution, we are requesting that customers immediately discontinue the use of the identified product lots on the affected product table attached until our investigation has concluded.

Reported Events

To date, Baxter has received four postmarketing reports for the VASCU-GUARD product for intraoperative or postoperative bleeding episodes, which required additional clinical intervention. One report involved a case with a fatal outcome. At this point, it is unknown whether there is any causal relationship between VASCU-GUARD and the reported events. We are investigating these reports and will provide additional information as soon as it becomes available.

Actions to be taken:

Please immediately discontinue use and segregate product with the product codes and lot numbers listed on the affected product table.

1. Locate and quarantine all affected product lots at your facility until further notice.

2. Complete the enclosed Baxter customer reply form and return it to Baxter by faxing it to 224-270-5457 or scanning and e-mailing to fca@baxter.com. Returning the Baxter customer reply form promptly will prevent you from receiving repeat notices.

3. If you distribute this product to other facilities or departments within your institution (e.g., Pharmacy, ER, ICU, NICU, PICU), please forward a copy of this communication to them.

4. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please conduct a consumer-level notification of the safety alert letter to your customers where affected product lots were distributed.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options: (To be adapted locally)

- Calling Baxter Product Surveillance at 800-437-5176 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
- Emailing to Baxter at: corporate_product_complaints_round_lake@baxter.com.
- Reporting to the FDA MedWatch Adverse Event Reporting Program:
  - **Online:** By completing and submitting the report online at: www.fda.gov/medwatch/report
  - **Regular mail:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form:
    MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

- **Fax:** Submit to 800-332-0178

We appreciate your immediate attention and apologize for any inconvenience this may cause you and your staff. A follow up communication will be provided when additional information becomes available.

Sincerely,

Camil Chamoun
Vice President, Product Quality
Baxter Healthcare Corporation
cc: Director of Materials Management

Enclosures: Affected Product Table