Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: June 4, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Baxter International Inc. – RECALL [Medical Product]

AFFECTED PRODUCT: **VASCU-GUARD Peripheral Vascular Patch**

SUMMARY: **Unclassified Recall; This recall is due to a deviation in the surface texture of the vascular patch in a new packaging configuration. Incorrect orientation of the patch with the rough side toward the bloodstream may increase the risk of vessel thrombosis and/or embolism.**

Following are the product codes affected by this recall:

Product Codes	Product Description
1504026	VASCU-GUARD TS 1x6cm
1504028	VASCU-GUARD TS 0.8x8cm
1504030	VASCU-GUARD TS 1x10cm
1504032	VASCU-GUARD TS 2x9cm

The recalled products were distributed in the U.S.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time, or e-mail Baxter at onebaxter@baxter.com.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Baxter Initiates Voluntary Recall of Select Product Codes of Peripheral Vascular Patch

Contact:
Consumer:
1-800-422-9837
onebaxter@baxter.com

Media:
John O'Malley
(224) 948-5353
media@baxter.com

FOR IMMEDIATE RELEASE – June 1, 2015 – Deerfield, Ill. – Baxter International Inc. announced today it is voluntarily recalling four product codes of its VASCU-GUARD Peripheral Vascular Patch. Baxter received customer complaints of difficulty in distinguishing the smooth from rough surface of the VASCU-GUARD patch as described in the labeled instructions for use. This is due to a deviation in the surface texture of the vascular patch in a new packaging configuration. Incorrect orientation of the patch with the rough side toward the bloodstream may increase the risk of vessel thrombosis and/or embolism.

To date, Baxter has received a limited number of adverse event reports, including postoperative thrombosis and stroke, in which the recalled product codes have been used. Baxter is continuing to investigate these reports. There is an inherent risk of thrombosis associated with vascular procedures in this patient population with underlying vascular diseases. At this point, no causal association has been established. Following are the product codes affected by this recall:

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Baxter's VASCU-GUARD Peripheral Vascular Patch is intended for use in peripheral vascular reconstruction including carotid, renal, iliac, femoral, profunda, and tibial blood vessels and arteriovenous access revisions.

Baxter began notifying all U.S. customers on May 2, 2015. Customers have been directed to locate and remove all affected product from their facilities. Recalled products should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m., Central Time. Customers can still order this product presented in a plastic jar filled with sterile water and 1% Propylene Oxide; it is unaffected by this recall.

Consumers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time, or e-mail Baxter at onebaxter@baxter.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these products.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form http://www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Baxter
Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

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