

**Urgent Field  
Safety Notice**05<sup>th</sup> July 2016

Dear Sir/Madam

**Affected Product**                      **Product Name:** VASCU-GUARD,0.8X8CM  
**Product Code:** VG0108N  
**Serial number:**SP16C181133138

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 lot until our investigation has concluded.

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.

**Action to be taken by the user**                      Please immediately discontinue use and segregate product with the product code and lot number listed.

1. Locate and quarantine all affected product lots at your facility until further notice.
2. Complete the enclosed customer reply form, and return it to Baxter by either faxing it to 01 206 5577 or scanning and e-mailing it to [QA\\_Dublin@baxter.com](mailto:QA_Dublin@baxter.com) or sending it by post to Quality Department, Baxter Healthcare Ltd, Unit 7 Deansgrange Business Park, Blackrock, Co. Dublin even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
3. Please forward a copy of this letter to other facilities or departments within your institutions to ensure that those locations are aware of this action.

4. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this communication in accordance with your customary procedures.

**Further  
information  
and support**

For general questions regarding this communication, contact your local Baxter Representative.

We apologise for any inconvenience this may cause you and your staff.

Sincerely,



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Ian Gavigan  
Head of CQA UK/Ireland  
Baxter Healthcare Ltd.  
Deansgrange Business Park  
Blackrock  
Co. Dublin  
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Attachment 1: Customer Reply Form