

**FOLLOW-UP
Urgent Field Safety
Notice**

Follow-up Communication: VASCU-GUARD Peripheral Vascular Patch

xx September 2016

Dear Sir/Madam,

On the 06th July 2016 Baxter Healthcare Corporation issued a Safety Alert in response to an increase in post-marketing reports of intraoperative and postoperative bleeding received for the VASCU-GUARD Peripheral Vascular Patch in the United States. At that time, Baxter instructed customers globally to discontinue use and quarantine a broad scope of VASCU-GUARD product lots while Baxter investigated the post-marketing reports.

Baxter has since completed its thorough investigation, and has not identified any causal relationship between VASCU-GUARD and the reported events. Baxter's investigation confirmed that the VASCU-GUARD product met all finished device specifications, and that there were no product design, manufacturing, or supplier changes to the product that would have contributed to the reported adverse events. Intraoperative and postoperative bleeding are inherent risks of the surgeries in which VASCU-GUARD is used, and may be caused by various factors, including the medical devices and surgical techniques used during the surgical procedure.

Baxter has concluded that the lots from the initial Safety Alert can be removed from quarantine and are acceptable for clinical use.

**Clinical
Considerations**

Post-marketing reports related to intraoperative and postoperative bleeding and the use of certain lots of VASCU-GUARD Peripheral Vascular Patch have been received by Baxter. Some of these reports related to the use of the VASCU-GUARD patch in carotid endarterectomy (CEA) procedures. The significant potential complications that are recognized after CEA include bleeding from, or rupture of, the patched artery, reoperation, wound infection, and wound hematoma. These potential complications can be fatal.

**Action to be
taken by the
user**

Baxter is kindly asking that you take the following actions:

1. Follow the local process at your facility for returning product back to active inventory.



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 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, please contact your local Baxter Representative.

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

Sincerely,

Ian Gavigan
Head of CQA UK/Ireland
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph: 01 2065500

Attachment 1: Customer Reply Form

Attachment 2: Safety Alert Dated 05th July 2016 (Including Affected Product Table)