Baxter

FOLLOW-UP SAFETY ALERT

Follow-up Communication: VASCU-GUARD Peripheral Vascular Patch

September XX, 2016 (To be adapted locally)

Dear Sir/Madam: (To be adapted locally)

On XX XX, 2016 (To be adapted locally with the local date), Baxter Healthcare Corporation issued a Safety Alert in response to an increase in postmarketing 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 postmarketing 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

Postmarketing 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 *(insert local contact information)* or scanning and e-mailing it to *(insert local contact information)* or sending it by post to *(insert local contact information),* 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 *(to be adapted locally)*

For general questions regarding this communication, contact Baxter at *(insert local contact information)*, between the hours of *(insert local information)*.

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

Sincerely,

Name *(to be adapted locally)*
Title *(to be adapted locally)*
Medical Products *(to be adapted locally)*
Baxter Healthcare Corporation *(to be adapted locally)*

Attachment 1: Customer Reply Form
Attachment 2: Safety Alert Dated XX XX, 2016 (Including Affected Product Table) (To be adapted locally)