October 23rd 2014

Urgent Field Safety Notice- Product Recall

Dear Customer

Affected Product	Vivia Blood Set Product Code: 5H12101 Lot Numbers: H14E21066, H14E23021 Distributed June 6, 2014
Problem Description	Baxter Healthcare Corporation is issuing a voluntary recall for specific lots of 5H12101 (H14E21066, H14E23021) due to leaks between the pneumatic side and the fluid (blood) side of the blood pump diaphragm.
Hazard Involved	In case of a leak of the diaphragm of the blood set, the following harms are considered possible: 1) Air embolism 2) Blood stream infection (BSI) due to biological contamination of the fluid (blood) path 3) Microembolism due to potential particulate contamination 4) Blood loss as a result of blood not being returned (max. 254mL) 5) Loss of effective therapy due to inability to perform dialysis. Considering all mitigation measures and good detectability of this defect (such as air in system alarms or inability to prime the blood set), as well as functional and clinical worst-case scenarios, we estimate that the probability of occurrence of harm is remote in the higher-risk population, and improbable in the general exposed population. Baxter has not been made aware of any adverse events associated with these lots.
Action to be taken	Baxter is requesting that you take the following actions: 1. Locate all affected product from all locations in your facility and segregate them for pick-up by Baxter (the product code and lot numbers can be found on the individual product package or shipping carton). A Baxter representative will contact you to schedule a service visit to the clinic. 2. Complete the enclosed customer reply form, and return it to Baxter by either fax or scanned e-mail. During the scheduled service visit, the Baxter service representative will

collect all unused Vivia Blood Sets as well as remove the Blood Set(s) currently installed on the Vivia Treatment Device(s). The Vivia Treatment device will be disconnected from the Water Device, turned off, and a visual out-of- service tag will be placed on the instrument.

The Vivia Water device will remain powered on, to allow for automatic periodic internal flushing. Turning off the Water Device for an extended time will require the device to be replaced prior to using the Vivia system for treatments.

When new Blood Sets are available, Baxter Service will perform the required activities to power on the Treatment device and prepare it for treatment mode.

Further information and support

If you have questions regarding the content of this communication, please contact me at the number below.

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

The HPRA has been notified.

Yours Sincerely,

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