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Urgent Field Safety Notice

September XX, 2013

Subject: Field Safety Notice – Infusor / Folfusor / Intermate portable elastomeric infusion systems

Product codes: Refer to Attachment 1

Lot numbers: All

Dear XX,

Issue Description

Baxter would like to provide you with Urgent Field Safety Notice regarding the INFUSOR, FOLFUSOR, and INTERMATE portable elastomeric infusion systems. Please refer to Attachment 1 for listing of all applicable product codes.

Baxter has received complaints for infusion flow rates greater than intended for the above referenced portable elastomeric infusion systems. In many cases, the complaint details an overinfusion of medication that are the result of uses inconsistent with the Instructions for Use.

Hazard Involved

Delivery of medication at an infusion rate faster than intended may lead to toxicity and changes to efficacy that require medical intervention.

Action to be taken by healthcare providers

Baxter is requesting that healthcare providers continue to follow the device Instructions for Use which explains the following factors that may impact resulting flow rate:

- The choice of medication: Refer to the drug manufacturer's package insert for drug reconstitution/dilution and storage procedures.
- Instructions for calculating the correct fill volumes including the potential for increase in flow rate which may result from a fill volume below the stated nominal fill volume.
- Temperature change on the device.
- Choice of the diluents (5% Dextrose vs. 0.9% Sodium Chloride) as a ~10% increase in nominal flow rate may result when 0.9% Sodium Chloride is used.
- The position of the Elastomeric Reservoir in relation to the Distal End Luer Lock. Flow rate will decrease ~0.5% for every inch the Elastomeric Reservoir is positioned below the distal end luer lock and increase ~0.5% for every inch the elastomeric reservoir is positioned above the distal end luer lock.
- Length, diameter, and location of the catheter used

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Action to be taken in response to this notification

Baxter is requesting that you take the following actions in response to this notification:

- If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them to ensure that they are aware of this notice.
- Communicate the requirement to follow the device Instructions for Use to your patients.
- If you are a dealer, wholesaler, or distributor/reseller that distributed this or affected product to other facilities, please notify your customers of this action.

Further information and support

If you have questions regarding this communication, please contact me on the below number.

Please contact your local Baxter representative if you have any further queries.

The Irish Medicines Board has been informed about this action.

Please report any suspected adverse reactions to the Irish Medicines Board via the website at www.imb.ie

Any suspected adverse reactions observed during use may also be reported to Baxter Healthcare directly by calling 01-206-5500 or by email on qa_dublin@baxter.com.

Sincerely,

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