Baxter

Safety Alert
(to be adapted locally)

April XX, 2014 (to be adapted locally)

Dear Director of Pharmacy (to be adapted locally)

Issue Description

Baxter Corporation (to be adapted locally) is providing you with important safety information regarding the Colied-Tube INFUSOR system (to be adapted locally). Baxter has continued to investigate complaints for over-infusion and wants to make you aware that labeling for the placement of the device (Direction for Use #5 below) is incorrect.

Product Codes

Please see Attachment 1 for a listing of all product codes (to be adapted locally).

Hazard Involved

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

Action to be taken by healthcare providers

Follow the device Instructions for Use which explain the following factors that may impact resulting flow rate, noting the change to Direction for Use #5 below for the coiled tube INFUSOR (to be adapted locally) This labeling discrepancy, combined with all other use factors, can contribute to infusion rates in excess of 30% greater than the nominal (labeled) flow-rate.

1. The choice of medication: Refer to the drug manufacturer's package insert for drug reconstitution/dilution and storage procedures.
2. 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 (labeled) fill volume.
3. Temperature change, as flow rate will decrease approximately 2.3% per 1°C decrease in temperature and will increase approximately 2.3% per 1°C increase in temperature.
4. Choice of the diluents (5% Dextrose vs. 0.9% Sodium Chloride) e.g., a ~10% increase in nominal flow rate may result when 0.9% Sodium Chloride is used.
5. Nominal flow rate of the INFUSOR is realized when the Elastomeric Reservoir and the Distal End Luer Lock are positioned at the same height. 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.

Direction for Use #5 above is incorrect for the coiled-tube INFUSOR (to be

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adapted locally). Recent review of flow rate testing has shown that the nominal (labeled) flow rate is achieved when the Elastomeric Reservoir is positioned 6-8 inches (15-20cm) (to be adapted locally) below the distal Luer lock and **NOT** when positioned at the same height as stated above.

6. Length, diameter, and location of catheter.

Baxter will be implementing a change to Directions for Use #5 to reflect the correct placement of the device for all coiled-tube INFUSORS. Short term, Baxter will be adding the Safety Alert letter to each customer shipment or carton of product.

Action to be taken in response to this notification

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

1. Acknowledge your receipt of this Safety Alert notification by completing the attached Customer Reply Form (Attachment 1) and return it to Baxter by either faxing it to XX (to be adapted locally) or scanning and e-mailing it to (to be adapted locally). Returning the Customer Reply Form promptly will prevent you from receiving repeat notifications.
2. 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. (to be adapted locally)
3. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this action. (to be adapted locally)

Further information and support

If you have questions regarding this communication, please call... (to be adapted locally)

Any adverse reactions or quality problems experienced with the use of these products must be reported through your local Baxter Sales Representative (to be adapted locally)

The local MOH (to be adapted locally) has been notified of this action. (to be adapted/removed locally)

Sincerely,

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

Attachment 1: INFUSOR Product Code Listing

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Attachment 2: Customer Reply Form

ATTACHMENT 1
Important Product Information
INFUSOR Product Code Listing
(to be adapted locally)

Product Code#	Product Name	Affected Lot Numbers
2C1071KJP	Single Day INFUSOR 2 ml/h System	All Lot Numbers within Expiration Dating
2C1073KJP	Half Day INFUSOR SV 5 ml/h System	
2C1075KJP	Two Day INFUSOR 2 ml/h System	
2C1080KJP	Multiday INFUSOR 0.5 ml/h System	
2C1082KJP	Seven Day INFUSOR 0.5 ml/h System	
S2C1083KJP	Desferrioxamine INFUSOR 1 ml/h System	
2C1954KJP	Basal/Bolus INFUSOR 0.5 x 0.5 ml/h System with 60 Minute Lockout	
2C1955KJP	Basal/Bolus INFUSOR 0.5 x 2 ml/h System with 15 Minute Lockout	
2C1976KJ	Basal/Bolus INFUSOR 2 x 2 ml/h System with 15 Minute Lockout	