

**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

Baxter

**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.

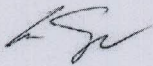
Please contact your local Baxter representative if you have any further queries.

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,



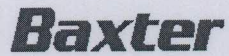
Ian Gavigan
Quality Systems Manager
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph. 01 2065500



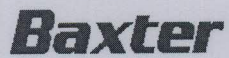
Attachment 1

Safety Alert – INFUSOR / FOLFUSOR / INTERMATE Product Code Listing

PRODUCT CODE	DESCRIPTION
INFUSOR – Portable Elastomeric Infusion System	
2C1071KJP	Single day INFUSOR
2C1073KJP	Half Day INFUSOR
2C1075KJP	Two Day INFUSOR
2C1080KJP	Multiday INFUSOR
2C1082KJP	Seven Day INFUSOR
S2C1083KJP	Desferrioxamine INFUSOR
INFUSOR LV - Portable Elastomeric Infusion System	
2C1087KP	INFUSOR LV 1.5
2C1008KC	INFUSOR LV 2
2C1008KP	INFUSOR LV 2
2C1009KC	INFUSOR LV 5
2C1009KP	INFUSOR LV 5
2C1156KP	INFUSOR LV 7
2C1063KP	INFUSOR LV 10
INFUSOR SV - Portable Elastomeric Infusion System	
2C1700KP	INFUSOR SV 0.5
2C1701KP	INFUSOR SV 1
2C1702KP	INFUSOR SV 2
INFUSOR XLV - Portable Elastomeric Infusion System	
2C1168K	INFUSOR XLV 8
FOLFusor - Portable Elstomeric Infusion System	
2C4700K	FOLFusor SV 0.5



2C4701K	FOLFusor SV 1
2C4702K	FOLFusor SV 2
2C4711K	FOLFusor SV 2.5
S2C4704K	FOLFusor SV 4
2C4705K	FOLFusor SV 5
2C4087K	FOLFusor LV 1.5
2C4008K	FOLFusor LV 2
2C4009K	FOLFusor LV 5
2C4156K	FOLFusor LV 7
2C4063K	FOLFusor LV 10
D2C4700K	FOLFusor SV 0.5
D2C4701K	FOLFusor SV 1
D2C4702K	FOLFusor SV 2
D2C4711K	FOLFusor SV 2.5
D2C4704K	FOLFusor SV 4
D2C4705K	FOLFusor SV 5
D2C4087K	FOLFusor LV 1.5
D2C4008K	FOLFusor LV 2
D2C4009K	FOLFusor LV 5
D2C4156K	FOLFusor LV 7
D2C4063K	FOLFusor LV 10
Basal/Bolus INFUSOR - Portable Elastomeric Infusion System	
2C1955KJP	Basal/Bolus INFUSOR 0.5 ml/h x 2 ml/h System
2C1976KJ	Basal/Bolus INFUSOR 2 ml/h x 2 ml/h System
MULTIRATE INFUSOR - Portable Elastomeric Infusion System	
2C1154KP	MULTIRATE INFUSOR SV 1.0-2.0-3.0
2C1155KP	MULTIRATE INFUSOR LV 2.0-3.0-5.0
2C9960KP	MULTIRATE INFUSOR LV 5-7-12



2C9961KP	MULTIRATE INFUSOR LV 2.0-4.0-6.1
Regional Analgesia INFUSOR System with Patient Control Module	
2C1079K	INFUSOR Patient Control Module 0.5 ml
2C1811K	Regional Analgesia INFUSOR System with Patient Control Module 5.0-7.0-12.0
INTERMATE - Portable Elastomeric Infusion System	
2C1710K	INTERMATE SV 50 -Single-pack
2C1730K	INTERMATE SV 50 -Multi-pack
2C1712K	INTERMATE SV 100 - Single-pack
2C1732K	INTERMATE SV 100 - Multi-pack
2C1714K	INTERMATE SV 200 - Single-pack
2C1734K	INTERMATE SV 200 - Multi-pack
S2C1715	INTERMATE NUTRIPLUS LV 28
2C1720K	INTERMATE LV 50 - Single-pack
2C1740K	INTERMATE LV 50 - Multi-pack
2C1722K	INTERMATE LV 100 - Single-pack
2C1742K	INTERMATE LV 100 - Multi-pack
2C1743K	INTERMATE LV 167
2C1724K	INTERMATE LV 250
2C1744K	INTERMATE LV 250
2C1754K	INTERMATE XLV 250
2C1064K	INTERMATE XLV 250