

**Notice Information: - Warning  
24 April 2014**

**Part 1. Product Information**

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

**Part 2. Target Audience**

a) Target Audience:

A&E Departments  
Ambulance Service  
Anaesthetic medical/nursing staff  
Biomedical Engineering staff  
Cardiology Departments  
Cardiothoracic Departments  
Chief Executive Officers  
Clinical Directors  
Day Surgery Units  
Emergency Medical Technicians  
Gastroenterology Departments  
Haemodialysis Units  
High Dependency Units  
Hospital Managers  
Hospital Pharmacists  
Intensive Care Units  
IV Nurse Specialists  
Maternity Units  
Midwifery Departments  
Neonatology Departments  
Nursing Managers  
Nursing staff  
Obstetrics and Gynaecology Departments  
Oncology Nurse Specialists  
Orthopaedic Departments  
Paediatric Departments Paramedics Peritoneal Dialysis Units Purchasing Mana

Paediatric Departments

Paramedics

Peritoneal Dialysis Units

Purchasing Managers

Renal Medicines Departments

Resuscitation Officers

Risk Managers

Special Care Baby Units

Supplies Managers

Theatre Managers and nurses

Urology Departments

### **Part 3. Problem/Issue**

a) Problem/Issue:

Following a review of customer complaints for over-infusion, Baxter has identified an error in the Directions For Use for the Coiled Tube Infusor system. As outlined in the attached FSN, direction for use #5 is incorrect for the coiled tube infusor. The nominal (labelled) flow rate is achieved when the Elastomeric Reservoir is positioned 6-8 inches (15-20cm) below the distal luer lock and NOT when positioned at the same height as stated in the directions for use.

Baxter has indicated that the following products which have been supplied to the Irish market are impacted by this issue.

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```

Product codes

```
</td>
```

```
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Product Name

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</tr>
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solid; padding-top: 0cm">

2C1071KJP

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Single Day INFUSOR 2 ml/h System

</td>

</tr>

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2C1073KJP

</td>

<td width="287" valign="top" style="border-bottom: black 1pt solid; border-left: #ece9d8; padding-bottom: 0cm; background-color: transparent; padding-left: 5.4pt; width: 215.1pt; padding-right: 5.4pt; height: 9.45pt; border-top: #ece9d8; border-right: black 1pt solid; padding-top: 0cm">

Half Day INFUSOR SV 5 ml/h System

</td>

</tr>

<tr style="height: 13.35pt">

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2C1080KJP

</td>

<td width="287" valign="top" style="b

2C1080KJP	
<td &gt;="" 287"="" <div="" style="text-align: center;" valign="top">Multiday INFUSOR 0.5 ml/h System</td>	Multiday INFUSOR 0.5 ml/h System

#### Part 4. Background Information

a) Background Information:

The direction for use #5 is incorrect for the coiled tube infusor. Delivery of medication at a faster rate than intended may lead to toxicity and changes to efficacy that require medical intervention.

Baxter will be implementing a revision to the Directions for use to reflect the correct placement of the device for all coiled tube infusors.

#### Part 5. Action to be taken

a) Action to be taken:

The IMB advise that users:

(1) Follow the instructions outlined by the manufacturer in the field safety notice (FSN) attached.

(2) Forward this IMB Safety Notice to all those within your organisation that need to be aware of this information. Please also pass this Safety Notice and the attached FSN on to any end users or organisations where these devices may have been distributed.

## Part 6. Enquiries

- a) All enquiries should be made to:

Enquiries to the manufacturer should be addressed to:

Ian Gavigan

Quality Systems Manager

Baxter Healthcare Ltd.

Deansgrange Business Park

Blackrock

Co. Dublin

Telephone: 01 206 5500

Fax: 01 206 5577

E-mail: [qa\\_dublin@baxter.com](mailto:qa_dublin@baxter.com)

Enquiries to the distributor should be addressed to:

Ian Gavigan

Quality Systems Manager

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IMB CONTACT INFORMATION

All adverse incidents relating to a medical device



## IMB CONTACT INFORMATION

All adverse incidents relating to a medical device should be reported to:

Irish Medicines Board

Human Products Monitoring

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: [vigilance@imb.ie](mailto:vigilance@imb.ie)

Website: [www.imb.ie](http://www.imb.ie)

[Please click here to view a PDF version of this safety notice](#)

[Please click here to view a copy of the field safety notice](#)