Safety Notice
Medical Devices

IRISH MEDICINES BOARD

Baxter Coiled Tube Infusors

Priority 2 – Warning

IMB Safety Notice: SN2014(19) **Issue Date: 24 April 2014**

MANUFACTURER / SUPPLIER	IMB CASE REFERENCE
Baxter	V20533

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.

Product codes	**Product Name**
2C1071KJP	Single Day INFUSOR 2 ml/h System
2C1073KJP	Half Day INFUSOR SV 5 ml/h System
2C1080KJP	Multiday INFUSOR 0.5 ml/h System

ACTION OR RECOMMENDATIONS

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.

TARGET GROUPS

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

BACKGROUND

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.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Ian Gavigan	Telephone:	01 206 5500
Quality Systems Manager	Fax:	01 206 5577
Baxter Healthcare Ltd.	E-mail:	qa_dublin@baxter.com
Deansgrange Business Park		
Blackrock		
Co. Dublin		

Enquiries to the **distributor** should be addressed to:

Ian Gavigan	Telephone:	01 206 5500
Quality Systems Manager	Fax:	01 206 5577
Baxter Healthcare Ltd.	E-mail:	qa_dublin@baxter.com
Deansgrange Business Park		
Blackrock		
Co. Dublin		

IMB CONTACT INFORMATION

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

Irish Medicines Board	Telephone:	+353-1-6764971
Human Products Monitoring	Fax:	+353-1-6344033
Kevin O'Malley House	E-mail:	vigilance@imb.ie
Earlsfort Centre	Website:	www.imb.ie
Earlsfort Terrace		
Dublin 2		