

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/51

Issued: 24 August 2006

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**HEALTH ESTATES**

creating healing environments

	Section								
<p><b>Medical Device/Equipment:</b> Elastomeric infusion pump: Baxter Intermate and Infusor large volume (LV) infusion pumps - all models.</p>	▶ ①								
<p><b>Problem:</b> There is an increased risk of the elastomeric balloon bursting during infusion.</p>	▶ ②								
<p><b>Action by:</b> Oncology and pain management nursing and medical staff, patients and other clinical staff who use this device.</p>	▶ ③								
<p><b>Action:</b> Ensure all users of this device are:</p> <ul style="list-style-type: none"> <li>• Aware of the increase in risk of balloon failure.</li> <li>• Familiar with the steps to take if the balloon bursts during infusion. Details can be found in the guide for patients leaflet that is available from Baxter. A copy is attached in the appendix for reference.</li> </ul>	▶ ④								
<p><b>Distributed by NIAIC to:</b></p> <table> <tr> <td>Chief Executive of each HSS Board</td> <td>General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Hospices</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Hospices	Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
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<p><b>Contacts</b> Details of manufacturer/supplier contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥								
<p><b>Feedback Requirements to NIAIC</b> None Required</p>	▶ ⑦								

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Baxter Intermate and Infusor LV infusion pumps. These are disposable ambulatory pumps used for oncology, pain management, thalassaemia and antibiotics. The elastomeric balloon is filled with drug which is infused as the balloon deflates.

## 2. PROBLEM:

Although balloon failure is inherent with all elastomeric infusion pumps, Baxter has received an increase in the number of reported incidents involving the bursting of the elastomeric balloon of the Intermate LV and Infusor LV devices during infusion. This failure usually occurs towards the end of the infusion with the spillage being contained in the rigid plastic container. The reported failure rate has increased from 48 bursts/million (1 burst in 21,000) in 2004 to 76 bursts/million (1.6 bursts in 21,000) in 2005. The probability of leakage outside the container is significantly lower at less than 1 in 1,000,000.

The manufacturer has determined that the increase in failure rate is due to a variety of manufacturing issues. They are currently validating a corrective action that aims to reduce the failure. This will be implemented at the beginning of 2007.

Baxter considers the overall risk to users as low and is continuing to sell these devices. Therefore devices manufactured prior to the implementation of the corrective action have an increased risk of balloon failure.

## 3. ACTION BY:

Oncology and pain management nursing and medical staff, patients and other clinical staff who use this device.

## 4. ACTION:

Ensure all users of this device are:

- Aware of the increase in risk of balloon failure.
- Familiar with the steps to take if the balloon bursts during infusion. Details can be found in the guide for patients leaflet that is available from Baxter. A copy is attached in the appendix for reference.

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Accident & Emergency Departments
- All Wards
- Clinical Directors
- Consultant Microbiologists
- Directors Of Anaesthetics
- Haematologists
- Health & Safety Managers
- IV Specialist Nurses
- Medical Directors
- Nursing Executive Directors
- Oncology Units
- Pain Teams
- Palliative Care Teams
- Pharmacists
- Purchasing Managers
- Risk Managers
- Safety Officers
- Supplies Managers
- Practice Nurses
- Directors of Public Health
- Social Care Staff
- Independent Health and Social Care Providers – Private Hospitals, Clinics, Residential and Nursing Homes through RQIA

## 6. CONTACTS:

Enquiries to the manufacturer/supplier including requests for copies of the guide for patients should be addressed to:

Baxter Healthcare Ltd  
1 West Bank Road  
Belfast  
BT3 9JL

Tel: 028 90777800  
Fax: 028 90771100  
Email: [tom\\_richardson@baxter.com](mailto:tom_richardson@baxter.com)

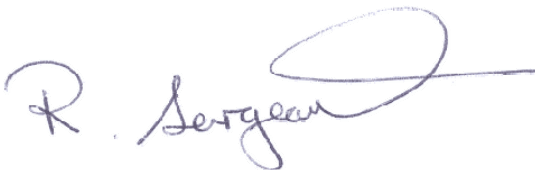
Enquires to NIAIC should quote reference number MDEA(NI)2006/51 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868  
Fax: 028 9052 3900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None Required



Robert Sergeant  
NIAIC Operational Manager

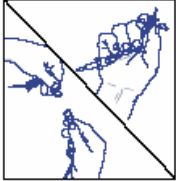
### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*


# Appendix to MDEA(NI)2006/51

## Disconnecting your Infusor



Close the clamp on your catheter and disconnect the Luer Connector end of the Infusor from your catheter by gently twisting anti-clockwise.

When your Infusor is empty, you will need to remove it from your catheter. If you're not sure if it is completely empty, please refer to the next section "Checking the progress of your Infusor".



Flush your catheter the way you have been instructed. Attach a new sterile end cap. Place the Winged Luer Cap you saved earlier on the end of the Infusor. Dispose of the empty Infusor the way you have been directed.

Flush your catheter the way you have been instructed. Attach a new sterile end cap. Place the Winged Luer Cap you saved earlier on the end of the Infusor. Dispose of the empty Infusor the way you have been directed.



## THE INFUSOR A Guide for Patients Prepared by Baxter Healthcare

Please refer to the detailed instruction leaflet for your Infusor for further information

### Receiving your medication at home

Before using the Infusor... Your Infusor is very easy to use, but to make sure it works properly, you will need to follow a few simple directions.

Please read these instructions carefully before you use your Infusor.

### Who will answer my questions?

Your hospital or clinic will allocate a home care advisor and/or give you the name of someone to contact in case you have any questions about your treatment or the use of your Infusor. Write their name and phone number in the space below so it is always at hand.

Name:

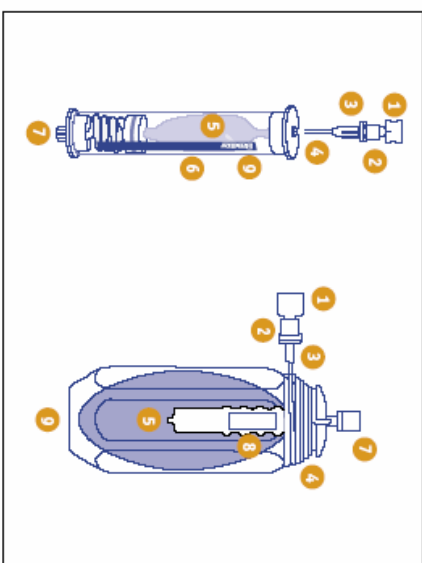
### Phone Number:

### How does it work?

The elastomeric reservoir ("balloon") moves the medication into the delivery tubing and through your catheter. The small part called the flow restrictor controls how fast your medication flows. Different sizes of flow restrictor provide different amounts of medication. Your hospital or clinic has chosen the medication and speed of flow that is appropriate for you.

### What are the different parts of the Infusor?

#### The Infusor

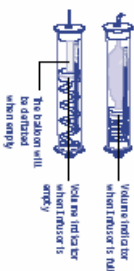


#### The Large-Volume Infusor

**Checking the Progress of your Infusion**  
1. You may have received more than one Infusor to deliver all your medication. It is very important not to change to a new Infusor until the old one is completely empty.

2. Depending on the type of Infusor you were given, it will take approximately 12 hours to 7 days for the Infusor to empty. Your doctor, nurse or pharmacist will tell you how long your Infusor will last.

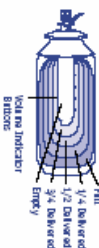
### The Infusor



### Large Volume Infusor

You will know when your Large-Volume Infusor is empty as the balloon will be touching all eight empty indicator bumps on two sides of the Infusor.

The Infusor works very slowly so the balloon will appear to be shrinking over several days. The diagram below shows you approximately how the balloon will deflate over time.



### Frequently asked questions

**Can I take a shower with the Infusor?**  
Yes. The Infusors can get wet, but it is recommended that it should not be submerged in water. A suction cup shower hook is a great place to hang the Infusor while showering. (Can be left in the nylon back bag!)

**How should I position the Infusor while sleeping?**  
Since the Infusor should remain at the same head height as the distal end Luer lock, patient should not place the Infusor on the floor or hanging above their head. Many patients find it

comfortable to tuck the Infusor under their pillow.  
**Is there any medication left in the Infusor once the infusion is complete?**  
Yes. A total residual volume of 3ml will remain in the Infusor reservoir and the administration tubing.  
**What is the best way to carry my Infusor during the day?**  
We provide carrying cases that can be worn around your waist for easy mobility, for all Baxter Infusors. Make sure to keep your Infusor away from direct sunlight and high temperatures.

**Can I fly with my Infusor?**  
Yes, as long as you take your Infusor with you into the pressurized cabin.

**Customer Services**  
Baxter Healthcare Limited  
Waltham Road, Compton,  
Newbury, Berkshire, RG20 7WV  
Northern - Tel: 01635 206060  
Southern - Tel: 01635 206161  
Scotland - Tel: 0141 7733 838

## Medication Delivery



Baxter and INFUSOR are trademarks of Baxter International, Inc.  
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Europe: MD/MD 054 UK: A/DV 2732MD. Date of preparation: August 2003

### How should the Infusor be stored?

You may be instructed to keep your Infusor either at room temperature or in the refrigerator.

To store your Infusor at room temperature choose a cool, dry place that is also

- clean
- away from direct sunlight
- away from heat sources such as a cooler or radiator
- out of the reach of children
- where the Infusor won't get damaged

To store your Infusor in the refrigerator

- clean the inside of the refrigerator before putting the Infusor inside
- make sure the Infusors are not touching each other so air can circulate around them
- keep the Infusors in a separate compartment of the refrigerator
- let the medication warm up to room temperature before use

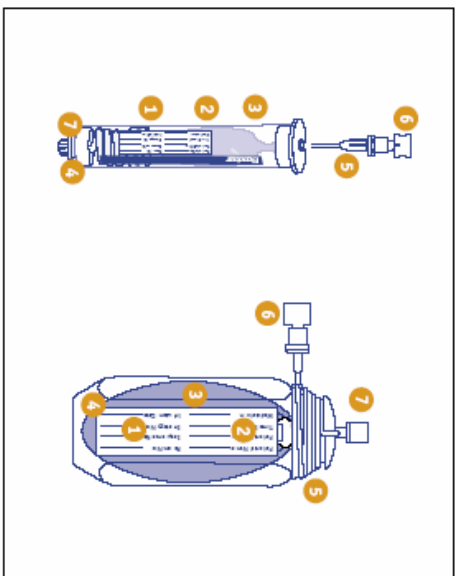
Small volume Infusors should be removed from the refrigerator 4-6 hours before use.

Large-Volume Infusor Systems should be removed from the refrigerator 6-8 hours before use.

While your Infusor is warming up, follow the instructions under "To store your Infusor at room temperature".

### Don't use your Infusor if...

The Infusor



The Large-Volume Infusor

1. The expiry date on the label has passed.
2. The name on the label is incorrect.
3. The balloon has burst or is split.
4. There is any sign of leaking drug.
5. There is a split or break in the tubing.
6. The Winged Luer Cap has been removed or is missing.
7. The Fill Port Protector Cap is missing or has fallen off.
8. If in doubt contact your doctor, nurse or homecare advisor

### What to do if...

The Infusor leaks or bursts

1. Immediately clamp your catheter.
2. Disconnect the Infusor and replace the Winged Luer Cap on the end of the Infusor tubing.

3. Attach a new Infusor or cap your catheter.

4. Immediately notify your doctor, nurse or home care advisor.

5. If your medication comes into contact with your skin,

immediately wash the area with warm soapy water. If the medication leaks on a surface, use the spill kit as instructed.

6. Make a note of the Infusor's code number, and save the Infusor for return.

The medication does not infuse

1. Remember the Infusor flows extremely slowly, so make sure you have waited long enough.
2. If in doubt contact your doctor, nurse or homecare advisor

### Getting Ready to use your Infusor

1. Make sure your Infusor is at room temperature.

Infusors should be removed from the refrigerator 4-6 hours before using.

Large-Volume Infusor Systems should be removed from the refrigerator 6-8 hours before using.

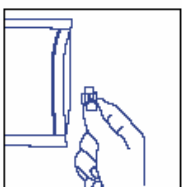
2. Clean a flat surface with soap and water, then dry it.
3. Assemble everything you're going to need on the clean surface. Lay out these instructions where you can follow them, without having to touch them as you connect your Infusor.
4. Check the name of the medication on the label.
5. Check the expiration date on the label.
6. Check that your name is correct on the label.
7. Wash your hands with hot water and soap. Dry thoroughly.
8. If your home care advisor suggests you wear gloves, put them on after you have washed your hands.

### Connecting your Infusor to your Catheter



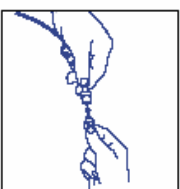
Remove the Winged Luer Cap from the end of the Infusor tubing. Check to make sure that liquid has moved to the end of the tubing.

Replace the Winged Luer Cap.



Store the Winged Luer Cap in the bag your Infusor came in. (You will need it later.)

Uncrimp your catheter so that the fluid can start flowing.

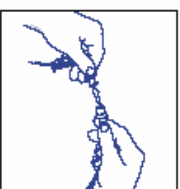


If recommended by your nurse, flush your IV line as instructed. Make sure that your catheter is clamped, then remove and discard the end cap.



Place the Infusor in its carrying sock and pin it to your clothing or put it in a pocket where it won't fall out or get damaged.

While still holding the IV line, pick up the Infusor tubing, remove the Winged Luer Cap and connect it to the catheter with a quarter clockwise turn.



**Baxter**