



## 1. DEVICE/EQUIPMENT:

BD anaesthesia kits and epidural filters are used during either dural puncture or epidural procedures.

**See appendix (attachment 1) for models and lot numbers of affected devices.**

## 2. PROBLEM:

The manufacturer's internal testing revealed the potential for holes to be present in the packaging of these devices which may not be obvious on inspection. These holes are a potential source of infection and the identified devices should not be used.

The manufacturer issued a Field Safety Notice in October 2008 to alert users to this recall. However not all users of these devices may have received it.

## 3. ACTION BY:

- All staff using these devices.
- All those responsible for purchasing and distributing these devices

## 4. ACTION:

- Quarantine and do not use any affected devices (see appendix)
- Follow the instructions given in the manufacturer's Field Safety Notice to obtain replacement stock.

## 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:

- A&E departments
- A&E directors
- Adult intensive care units
- All wards
- Anaesthesia, directors of
- Anaesthetists
- Day surgery units
- General surgical units, directors of
- Gynaecology departments
- Gynaecology nurses
- Health and safety managers
- Infection control departments
- Infection control nurses
- Infection prevention and control directors
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- Maternity units
- Medical directors
- Medical oncologists
- Medical oncology, directors of
- Medical physics departments
- Microbiologists
- Midwifery departments
- Midwifery staff
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics nurses
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Purchasing managers
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr Jeremy Allen  
Regulatory Affairs and Compliance Manager / Regulatory Affairs  
BD Medical - Medical Surgical Systems  
The Danby Building  
Edmund Halley Road  
Oxford Science Park  
Oxford OX4 4DQ  
  
Tel: 01865 781 608  
  
E-mail: [jeremy\\_allen@europe.bd.com](mailto:jeremy_allen@europe.bd.com)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/090 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)

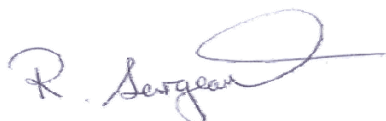
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:  
19<sup>th</sup> Dec 2008

Action Under Way:  
22<sup>nd</sup> Dec 2008

Action Complete:  
6<sup>th</sup> Jan 2009



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)2007/01. 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)2008 – 090

The Danby Building  
Edmund Halley Road  
Oxford Science Park  
Oxford OX4 4DQ  
Tel: 01865 748844  
Fax: 01865 717313  
www.bd.com



## URGENT: FIELD SAFETY NOTICE Recall Notification

October 2008

Subject: **BD Anaesthesia Kits and Epidural Filter**

REF **Limited REF Numbers are Affected**  
Numbers: (see Attachment 1 of this document for full listing)

Lot Numbers: **Limited Lot Numbers are Affected**  
(see Attachment 1 of this document for full listing)

**For the Attention of the Medical Director, Heads of Purchasing / Intensive Care Units /  
Emergency Room / Anaesthesia / Operating Departments / Nursing / Obstetrics &  
Gynaecology / Midwifery**

Dear valued customer,

**Becton Dickinson is requesting that you immediately cease use of BD Anaesthesia Kits and Epidural Filter bearing the REF and product lot numbers listed in Attachment 1.**

BD has become aware of holes in a number of BD Anaesthesia Kits and Epidural Filter unit packages, potentially compromising the integrity of the devices.

Although current information indicates that this fault is likely to affect a limited number of products, we have taken the decision to recall all potentially affected lots.

**Only particular REF (catalogue) numbers and lots of BD Anaesthesia Kits and Epidural Filter are affected. Please refer to the listing in Attachment 1.**

**Becton, Dickinson U.K. Limited**  
Registered in England: 0852702 Registered Office: The Danby Building, Edmund Halley Road, Oxford Science Park, Oxford, Oxfordshire OX4 4DQ

## APPENDIX to MDEA(NI)2008 – 090

### What you need to do

To assist us with this action, please locate and quarantine any affected products listed in **Attachment 1**. The products can be identified by the REF and lot numbers printed on the unit and shelf/shipper box container labelling.

Complete and return the attached Recall Response Card to the local BD office identified. Upon receipt of the Recall Response Card, we will quickly contact you to make the necessary arrangements for the replacement of product.

Please pass this information to all in your institution who are using, or ordering these products. Additionally, please ensure that a copy of this letter is provided to any other organisations to which affected devices have been transferred.

Please accept our apologies for the inconvenience caused by this action. However, we trust that you will agree that this is a sensible measure, and appreciate your understanding as we take action to ensure patient and customer satisfaction.

If you have any questions regarding this communication, please contact the following telephone number 01865 781504.

Yours faithfully,



**Julie Cotterell**  
**Marketing Manager**  
**BD Medical – Medical Surgical Systems**

**Please Note: The MHRA has been advised of this recall action.**

# APPENDIX to MDEA(NI)2008 – 090



**CUSTOMER RECALL RESPONSE CARD for:**

**BD Anaesthesia Kits and Epidural Filter**

Please complete by checking the appropriate box. Even if you have no inventory of listed product lots, please indicate this below and return this card by fax. If you currently have stock, complete the form noting quantity in units next to the lot number and return this card by fax.

- We do not have any of the stock listed (in Attachment 1) on hand.
- We have the following stock that we will be returning (**Please list below**)

REF	LOT NUMBER	Purchased via (Direct / NHSSC / SSS/ Other)	QUANTITY

Please fax to Val Mummery at 01865 781501  
 If you have any questions concerning this, please contact BD Customer Service on 01865 781666, Option 1 between 9.00 am – 5.00 pm, Monday – Friday.

**Please do not return affected products without having made arrangements with your local BD Office.**

Contact Name (please print) \_\_\_\_\_ Title \_\_\_\_\_ Signature and date \_\_\_\_\_

Facility Name \_\_\_\_\_ Address \_\_\_\_\_ Phone Number \_\_\_\_\_ Fax Number \_\_\_\_\_

# APPENDIX to MDEA(NI)2008 – 090

## ATTACHMENT 1

### List of Affected Product Lots

Product Code	Product Description	Lot Number
401500	BD Perisafe™ Plus KIT 17G Closed End	207554 230646 246427
401501	BD Dursafe™ Plus Adjustable CSE17G 27GW	149062 160933 178584 223028 230649 230649 246428
401502	BD Durasafe™ Plus Adjustable CSE 18G 27GW	152140/A28
401503	BD Durasafe™ CSE Kit 17G+27G	155220 160934
401506	BD Perisafe™ Plus 17G Closed End	152135/A27 155221 160935 230654 247776 249891 261566
401508	BD Perisafe™ Plus 18G Closed End	153724 155223 167807 185319 185319 207560 208325 213632 249892 258975 261567 277749

## APPENDIX to MDEA(NI)2008 – 090

<b>401509</b>	<b>BD Perisafe™ Plus 18G Open End</b>	150320 160937
<b>401510</b>	<b>BD Mini-Perisafe™ 17G Open End</b>	155224
<b>401511</b>	<b>BD Mini-Perisafe™ 18G Open End</b>	147001 246432
<b>401600</b>	<b>BD Perisafe™ Plus 18G Closed End</b>	167805 173739
<b>401700</b>	<b>BD Perisafe™ Plus 17G Open End</b>	247784
<b>401800</b>	<b>BD Perisafe™ Plus 18G Open End</b>	149058
<b>405056</b>	<b>BD Durasafe™ Plus Adjustable CSE 17G 27GW</b>	158866 171536 235467
<b>405057</b>	<b>BD Durasafe™ Plus Adjustable CSE 18G 27GW</b>	160939 246434
<b>405090</b>	<b>BD Durasafe™ Plus CSE 17G+25G</b>	256860
<b>401490</b>	<b>BD Epidural Filter 0.22 µM</b>	146995 181107 194467 198816 240212