

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/49

Issued: 27 August 2004

For:

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



HEALTH ESTATES

**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section								
<b>Medical Device/Equipment:</b> BD Vacutainer <sup>®</sup> needle holder (yellow)	▶ ①								
<b>Problem:</b> Removal of the product from the UK market.	▶ ②								
<b>Action by:</b> All involved in the use, supply and/or distribution of this device.	▶ ③								
<b>Action:</b> Purchasers and users should be aware that BD are withdrawing their reusable BD Vacutainer <sup>®</sup> needle holder (BD Cat No: 364888 – yellow) and replacing it by single-use alternatives, BD Vacutainer <sup>®</sup> needle holder (BD Cat No: 364887 / 364815 – clear).	▶ ④								
<b>Distributed by NIAIC to:</b> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">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
Chief Executive of each HSS Board	General Medical Practitioners								
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Chief Executive of each Agency									
NIAIC Liaison Officers									
<b>Contacts</b> Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥								
<b>Feedback Requirements to NIAIC</b> None	▶ ⑦								

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

## **1. DEVICE/EQUIPMENT:**

BD Vacutainer<sup>®</sup> needle holder (yellow)

## **2. PROBLEM:**

BD has informed the MHRA that, to reduce the risk of needlestick injury and cross contamination of patient blood, they are phasing out the reusable BD Vacutainer<sup>®</sup> needle holder (364888 – yellow) and offering single-use alternatives (364887 / 364815 – clear).

BD ceased taking orders for the BD Vacutainer<sup>®</sup> holder (364888 – yellow) on 25 June 2004.

It is anticipated that all distributors will have sold their stocks by the end of August 2004.

## **3. ACTION BY:**

All involved in the use, supply and/or distribution of this device.

## **4. ACTION:**

Purchasers and users should be aware that BD are withdrawing their reusable BD Vacutainer<sup>®</sup> needle holder (BD Cat No: 364888 – yellow) and replacing it by single-use alternatives, BD Vacutainer<sup>®</sup> needle holder (BD Cat No: 364887 / 364815 – clear).

The single-use, clear holders should be used for a single venepuncture and then disposed of, along with the needle, in a sharps container.

Any yellow holders remaining in stock should be used as single-use devices. If you have any questions regarding this action, please contact the BD representative (see contacts section).

## **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:

- Medical Directors
- Nursing Directors
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Adult and Paediatric Intensive Care Units
- Biochemistry Laboratories
- All Wards and Departments
- Blood Transfusion Laboratories
- Directors and Managers of Pathology and Laboratory Services
- Haematology Laboratories
- Immunology Laboratories
- Infection Control Teams
- Microbiology Laboratories
- Phlebotomists
- Renal Units and Satellites
- Special Care Baby Units
- Theatre Managers
- Medical and Nursing Staff
- Practice Nurses
- District Nurses
- Lead Nurses
- Directors of Public Health
- Consultants in Communicable Disease Control
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSS Board R&I Units
- Accident & Emergency Departments

## **6. CONTACTS:**

Enquiries to the manufacturer should be addressed to:

Mr Aaron Cousins  
Regulatory Affairs Manager, Europe  
BD Diagnostics – Preanalytical Systems  
Belliver Industrial Estate  
Plymouth  
PL6 7BP

Tel: 01752 237 337

Fax: 01752 788 308, E-mail: [aaron.cousins@europe.bd.com](mailto:aaron.cousins@europe.bd.com)

Enquires to NIAIC should quote reference number MDEA(NI)2004/49 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

## 7. FEEDBACK:

None Required



Brian Godfrey  
NIAIC 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)2004/01. 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*