

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/47

Issued: 7 August 2006

For:

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



**HEALTH ESTATES**

creating healing environments

	Section								
<p><b>Medical Device/Equipment:</b> Blood collection device: Becton Dickinson Vacutainer<sup>®</sup> Direct Draw adaptor product code 364896 and Vacutainer<sup>®</sup> Luer adaptor product code 367300 (see diagrams).</p>	▶ ①								
<p><b>Problem:</b> Risk of blood leakage during blood collection at the non-patient end of the adaptor.</p>	▶ ②								
<p><b>Action by:</b> All staff responsible for blood collection and for the purchase of these devices.</p>	▶ ③								
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>• Ensure that all relevant staff are aware of the manufacturer's recall notice (see Appendix).</li> <li>• Identify and isolate all affected stock and return to the manufacturer as directed in their recall notice.</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
Chief Executive of each HSS Board	General Medical Practitioners								
Chief Executive of each HSS Trust	Hospices								
Chief Executive of each Agency									
NIAIC Liaison Officers									
<p><b>Contacts</b> Details of manufacturer 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:

Vacutainer® Direct Draw adaptor. Product code 364896.

Lot numbers to be recalled: 5311376, 5312193 and 5312201.

This device has a male adaptor at the patient end with an integral blood collection tube holder as shown in diagram 1.

Vacutainer® Luer adaptor. Product code 367300.

Lot numbers to be recalled: 5307894, 5307896 and 5307900.

This device has a male adaptor at the patient end as shown in diagram 2. Users can select various Vacutainer® blood collection tube holders to attach to the adaptor.

Both devices are single-use, multiple-sample blood collection devices. These are designed for use with devices that have a female Luer fitting for the collection of blood with the Vacutainer® blood collection system. For example, the collection of blood from arterial lines or intravenous devices.

Diagram 1

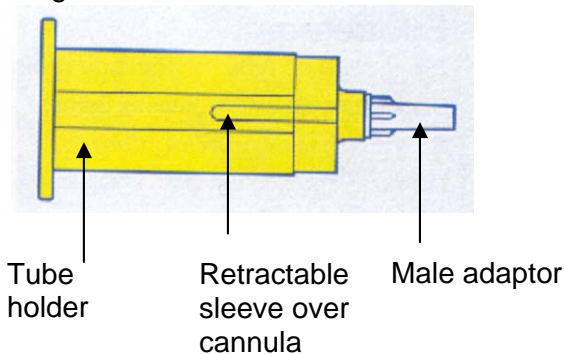
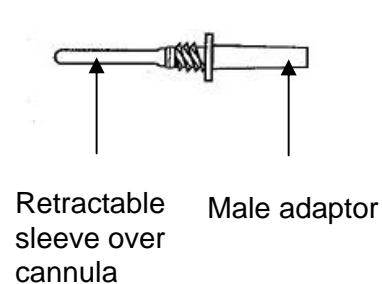


Diagram 2



## 2. PROBLEM:

The non-patient end of these adaptors possess a retractable sleeve over a cannula that reseals the cannula to prevent leakage of blood after each Vacutainer® blood tube is removed. A manufacturing defect has resulted in the poor performance of this sleeve, leading to blood leakage during blood collection.

## 3. ACTION BY:

All staff responsible for blood collection and for the purchase of these devices.

## 4. ACTION:

- Ensure that all relevant staff are aware of the manufacturer's recall notice (see Appendix).
- Identify and isolate all affected stock and return to the manufacturer as directed in their recall notice.

## 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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- All wards
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Special Care Baby Units
- Maternity Wards
- Paediatric Units
- Practice Nurses
- Directors of Public Health
- Social Care Staff
- Community Care Staff
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Operating Theatre Staff
- Outpatient Departments
- Infection Control Staff
- Accident & Emergency Departments
- Coronary Care
- Intensive Care
- Day Procedure Units

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Customer Services  
BD Preanalytical Systems  
21 Between Towns Road  
Oxford  
OX4 3LY

Tel: 01865 781 699

Fax: 01865 781 627

E-mail: [BDUK\\_customerservice@europe.bd.com](mailto:BDUK_customerservice@europe.bd.com)

Enquires to NIAIC should quote reference number MDEA(NI)2006/ 47 and be addressed to:

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

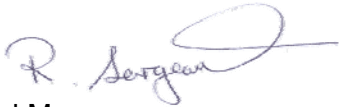
Tel: 028 9052 3868

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) 2006/47

BD Diagnostics  
Preanalytical Systems  
21 Between Towns Road,  
Cowley, Oxford,  
OX4 3LY, UK  
www.bd.com



## ATTENTION: PRODUCT RECALL

BD Vacutainer<sup>®</sup> Direct Draw Adaptor

Catalogue #	Lot #
364896	5311376
364896	5312193
364896	5312201

BD Vacutainer<sup>®</sup> Luer Adapters,

Catalogue #	Lot #
367300	5307894
367300	5307896
367300	5307900

23<sup>rd</sup> June 2006

Dear *Customer Name*,

BD is conducting a recall of specific lots of the BD Vacutainer<sup>®</sup> Direct Draw Adaptor, catalogue number 364896 and BD Vacutainer<sup>®</sup> Luer Adaptor, catalogue number 367300.

Some product from the above listed catalogue and lot numbers may have sleeves that will not function properly. The sleeve covers the non-patient end of the needle and prevents leakage during blood collection. We have identified the root cause and corrective actions have been taken to resolve this issue.

The recall only applies to the catalogue and lot numbers listed above and does not impact any other product.

## APPENDIX TO MDEA (NI) 2006/47

The following actions are required of you:

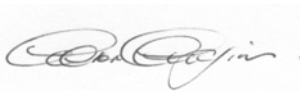
- **Please examine your inventory immediately** for the specific catalogue and lot numbers.
- **Please contact your local customer services department** on the following number, 01865 781699 and ask them for a **Returned Goods Authorisation number (RGA)**.
- **Please return product from these lots, together with the attached ( completed ) packing slip.** Our Customer Service Department will arrange this with you. Upon receipt of this product, together with the completed packing slip, credit will be issued to you.

**Note :** Small quantities may be scrapped by your facility. Please refer to your standard operating procedures for the disposal of medical products. Credit will be issued for scrapped product upon receipt of a completed packing slip.

We apologise for any inconvenience this issue may have caused you and we thank you in advance for helping us to resolve this matter as quickly and effectively as possible. In order that we can close this recall in a timely fashion we require that you complete the above actions within 3 months of the date of this letter.

If you require any further information regarding this recall, please contact our customer services hotline on the following number – 01865 781699

Yours sincerely,



**Aaron Cousins**  
**Regulatory Affairs Manager, Europe**  
**BD Diagnostics, Preanalytical Systems**  
E-mail: [aaron\\_cousins@europe.bd.com](mailto:aaron_cousins@europe.bd.com)  
WWW: [www.bd.com](http://www.bd.com)

Enclosures

## APPENDIX TO MDEA (NI) 2006/47

### **PRODUCT RECALL – PACKING SLIP**

BD Vacutainer® Luer Adaptor, Catalogue Number 367300

BD Vacutainer® Direct Draw Adapters, Catalogue Number 364896

Name :

Phone number :

Establishment name :

Establishment address :

Returned Goods Authorisation Number ( RGA ) :  
( supplied by your local customer services department ( 01865 781699 ) )

	<b>Catalogue #</b>	<b>Batch #</b>	<b>Quantity Scrapped</b>	<b>Quantity Returned</b>
<b>Luer Adaptor</b>	<b>367300</b>	<b>5307894</b>		
	”	<b>5307896</b>		
	”	<b>5307900</b>		
<b>D. D. Adaptor</b>	<b>364896</b>	<b>5311376</b>		
	”	<b>5312193</b>		
	”	<b>5312201</b>		

If you wish to destroy product ( small quantities only ) please return this form by fax to your local customer services team on 01865 781528. Credit will be issued upon receipt of this form.

If you wish to return product please contact our Customer Service Hotline on 01865 781699. Please box the product and enclose this form. Please label the box as follows; BD European Distribution Centre, Lagastraat 57, Temse 9140, Belgium. Credit will be issued upon receipt of the product, together with this form.

If you have any questions regarding this recall, please contact your local customer services team on 01865 781699.