

# Medical Device/Equipment ALERT

Ref.MDEA(NI)2008/55

Issued: 21<sup>st</sup> July 2008

For:

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



**HEALTH ESTATES**

creating healing environments

	Section			
<b>Medical Device/Equipment:</b> Kimal safety fistula needle (all product codes and lots).	▶ ①			
<b>Problem:</b> Kimal is aware of the potential for the unintentional retraction of the cannula into the protection sheath, which can result in exsanguination. As a result, Kimal is recalling all lots of the device.	▶ ②			
<b>Action by:</b> All staff associated with performing dialysis and plasmapheresis treatments.	▶ ③			
<b>Action:</b> <ul style="list-style-type: none"> <li>– Do not use these devices.</li> <li>– Identify and isolate any affected devices.</li> <li>– Contact manufacturer to arrange for return of device.</li> </ul>	▶ ④			
<b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers <b>For onward distribution see Section 5</b>	▶ ⑤			
<b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.	▶ ⑥			
<b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b>				
<table border="1" style="width: 100%;"> <tr> <td style="width: 33%;"> <b>Acknowledge Receipt of Alert:</b>                      22<sup>nd</sup> July 2008                 </td> <td style="width: 33%;"> <b>Action Under Way:</b>                      24<sup>th</sup> July 2008                 </td> <td style="width: 33%;"> <b>Action Complete:</b>                      28 July 2008                 </td> </tr> </table>	<b>Acknowledge Receipt of Alert:</b> 22 <sup>nd</sup> July 2008	<b>Action Under Way:</b> 24 <sup>th</sup> July 2008	<b>Action Complete:</b> 28 July 2008	▶ ⑦
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This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

The Kimal safety fistula needle is used for both dialysis and plasmapheresis treatments.

The recall affects all safety needles under the following product codes:

K67/15/SFN – Safety needle 15G x 1” (all lots)

K67/16/SFN – Safety needle 16G x 1” (all lots)

K67/17/SFN – Safety needle 17G x 1” (all lots)

## 2. PROBLEM:

Kimal is aware of the potential for the unintentional retraction of the cannula into the protection sheath, which can result in exsanguination. As a result, Kimal is recalling all lots of the device.

## 3. ACTION BY:

All staff associated with performing dialysis and plasmapheresis treatments.

## 4. ACTION:

- Do not use these devices.
- Identify and isolate any affected devices.
- Contact manufacturer to arrange for return of device.

## 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:

- All intensive care units
- Anti-coagulation clinics
- Equipment stores
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Medical directors
- Nurse executive directors
- Oncology nurse specialists
- Staff supporting patients receiving haemodialysis at home
- Sterile services departments
- Supplies managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Amanda Makemson

Device Vigilance Quality Assurance Representative

Kimal Plc

Arundel Road

Uxbridge

UB8 2SA

Tel: 01895 270 951

Fax: 01895 274 035

E-mail: [amanda\\_makemson@kimal.co.uk](mailto:amanda_makemson@kimal.co.uk)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/55 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)

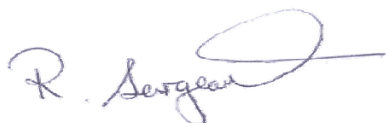
## 7. FEEDBACK:

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

Acknowledge Receipt of Alert:  
22<sup>nd</sup> July 2008

Action Under Way:  
24<sup>th</sup> July 2008

Action Complete:  
28 July 2008



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*