

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/017

Issued: 18th March 2008



HEALTH ESTATES

creating healing environments

For:

| | |
|------------------|---|
| IMMEDIATE ACTION | |
| ACTION | ✓ |
| UPDATE | |
| INFORMATION | |

| | Section |
|---|---------|
| Medical Device/Equipment: Needle-free intravascular connectors. All brands. | ▶ ① |
| Problem: There is a risk of infection if the top/septum of the connector remains recessed within its housing. Swabbing of the connector in this condition may lead to inadequate decontamination. | ▶ ② |
| Action by: All medical and nursing staff, particularly infection control nurses and IV specialist nurses. | ▶ ③ |
| Action: <ul style="list-style-type: none"> • Prior to accessing the device and following use of the device, ensure that the top/septum of the connector is in its closed/home position. This position may vary between brands. • Follow the manufacturer's instructions for use with regard to any warnings and recommendations relating to a recessed connector. • For application of clamps to IV line/catheters fitted with these connectors, follow the manufacturer's instructions for use. • After following the above, if the top/septum remains recessed, replace the connector and report the incident to the MHRA. | ▶ ④ |
| Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers Hospices | ▶ ⑤ |
| Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects. | ▶ ⑥ |
| Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS) | |
| Acknowledge Receipt of Alert: 21 st March 2008 | ▶ ⑦ |
| Action Under Way: 18 th April 2008 | |
| Action Complete: 19 th May 2008 | |

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

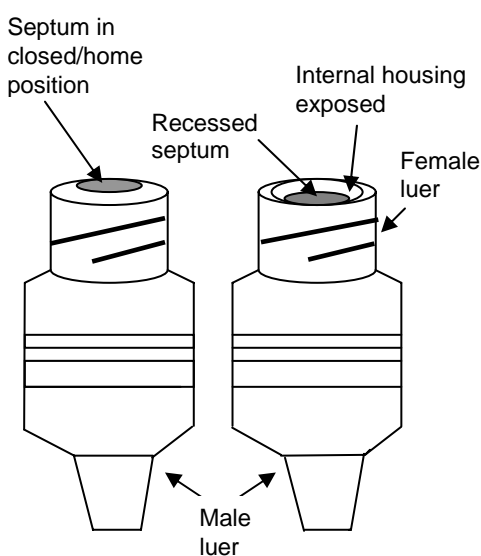
1. DEVICE/EQUIPMENT:

All brands of needle-free connectors for vascular access. This includes extension and administration sets with integral connectors.

When the valve is activated by an IV device with a male Luer fitting, such as a syringe (without a needle) or an administration set, the fluid pathway is opened to allow the administration of fluids or aspiration of blood for sampling. Upon removal of the device, the top/septum should automatically return to its closed/home position and seal the fluid pathway. These connectors are **not** IV caps, bungs or obturators.

2. PROBLEM:

The MHRA has received several reports of the top/septum of these devices remaining in a recessed position following use. Swabbing of the connector in this condition may lead to inadequate decontamination.



Example of connector

Contributory factors include:

- application of a downstream clamp to an IV line/catheter during positive pressure technique (to maintain catheter patency) may result in a recessed septum in some brands of connector due to the negative pressure generated between it and the closed clamp. When the clamp is removed, the top/septum should return to its closed/home position. Follow the manufacturer's instructions on application of clamps.
- damage to the connector.
- build-up of thick medium in connector.

However, in some cases the root cause has not been determined.

3. ACTION BY:

All medical and nursing staff, particularly infection control nurses and IV specialist nurses.

4. ACTION:

- Prior to accessing the device and following use of the device, ensure that the top/septum of the connector is in its closed/home position. This position may vary between brands.
- Follow the manufacturer's instructions for use with regard to any warnings and recommendations relating to a recessed connector.
- For application of clamps to IV line/catheters fitted with these connectors, follow the manufacturer's instructions for use.
- After following the above, if the top/septum remains recessed, replace the connector and report the incident to the MHRA.

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 clinical departments
- All wards
- Anaesthesia, directors of
- Clinical governance leads
- Directors of infection prevention and control
- Health and safety managers
- Infection control nurses
- IV nurse specialists
- Medical directors
- Medical microbiologists
- Modern matrons
- Nursing executive directors
- Nutritional nurse specialists
- Occupational health departments
- Outpatient clinics
- Phlebotomists
- Risk managers
- Specialist IV nurses
- Supplies department
- Theatre managers
- Community children's nurses
- Community hospitals
- Community nurses
- Directors of public health
- District nurses
- Prison healthcare managers
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Consultants in communicable disease control
- Health protection nurses
- HPA laboratories
- Regional epidemiologists
- Regional microbiologists
- Nursing agencies

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Enquiries to NIAIC should quote reference number MDEA(NI)2008/017 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

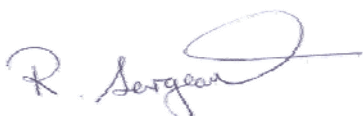
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
21st March 2008

Action Under Way:
18th April 2008

Action Complete:
19th May 2008



Robert Sergeant
NIAIC Operational Manager