Medical Device Alert

Ref: MDA/2013/056 Issued: 25 July 2013 at 14:00

Device

Protect-A-Line extension set.
Manufactured by Vygon.
Product codes: 0832.01, 0832.04 and 0832.211.
NHS Supply Chain codes (England only): FSB128, FSB124 and FSB0146.

Problem

Risk of false occlusion alarms and interruption to therapy.

This is due to a new anti-syphon valve supplied with the sets, which has a higher opening pressure and may require adjustment of infusion pump occlusion alarm settings to avoid false occlusion alarms.

Vygon are validating a further modification to the anti-syphon valves to marginally reduce the required opening pressure and will supply sets incorporating these once verification has been completed.

Action

- Ensure that all members of staff are made aware of the recommended actions in the manufacturer's Field Safety Notice.
- As some hospitals may be using both types of anti-syphon valve, be vigilant if you alter your infusion pump occlusion alarm settings for the new valves. Make sure you do not have the previous design of valve (which operates at a lower opening pressure) on the line. The product codes for these previous devices are: 0832.01R, 0832.04R and 0832.211R.

Action by

All healthcare workers who use these devices, and personnel involved in the purchase, supply and distribution of these devices.

CAS deadlines

Action underway: 15 August 2013

Action complete: 05 September 2013

Note: These deadlines are for staff to be aware of the problems and to have systems in place to address pressure issues.

Contact

Manufacturer
Kate O'Connell
Vygon UK
Tel: 01793 748 800
Email: kate.o'connell@vygon.co.uk

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England areas teams for information
- NHS trusts in England (chief executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- Adult intensive care units
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Biomedical engineering staff
- Clinical governance leads
- Health and safety managers
- Hospital at home units
- Intensive care medical staff/paediatrics
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Maternity units
- Medical directors
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Nursing executive directors
- Nutrition nurses
- Oncology nurse specialists
- Outpatient clinics
- Palliative care teams
- Paramedics
- Pharmacists
- Risk managers
- Supplies managers
- Theatre managers

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/056** or **2013/002/005/601/004**

Technical aspects
Roopa Prabhakar or Sharon Knight
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7293 / 7202
Fax: 020 8754 3965

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Clinical aspects
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How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk