


# Medical Device Alert

Ref: MDA/2013/067 Issued: 19 August 2013 at 14:00

Device	
<p>Protect-A-Line IV extension set (supplied with vented caps)</p> <p>Product code: 0832.04</p> <p>All batch numbers ending in the letters BA only.</p> <p>Manufactured by Vygon.</p>	

Problem	Action
<p>Risk of air embolus because affected devices have been supplied with vented caps on the female port (Y-site) instead of non-vented caps.</p>	<ul style="list-style-type: none"> <li>• Identify affected devices.</li> <li>• Prior to use, remove vented caps from the female port (Y-site) of affected devices and replace them with non-vented caps (or a needle free connector) if this port is to remain unused when the set is connected to a patient</li> </ul>
Action by	
<p>All healthcare workers who use these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 02 September 2013</p> <p>Action complete: 16 September 2013</p> <p><b>Note: These deadlines are for staff to be aware of the problem and to have systems in place to replace caps</b></p>	<p><b>Manufacturer</b> Kate O'Connell Vygon UK Tel: 01793 748 800 Email: <a href="mailto:kate.o'connell@vygon.co.uk">kate.o'connell@vygon.co.uk</a></p>

## 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

### Independent distribution

#### 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](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### Manufacturer

Kate O'Connell  
Vygon (UK) Ltd  
The Pierre Simonet Building  
V Park  
Gateway North  
Latham Road  
Swindon SN25 4DL  
Tel: 01793 748 800  
Fax: 01793 748 899  
Email: [kate.o'connell@vygon.co.uk](mailto:kate.o'connell@vygon.co.uk)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/067** or **2013/002/005/601/004**

### Technical aspects

Roopa Prabhakar or Gica Leclerc  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7293/6610  
Fax: 020 8754 3965  
Email: [roopa.prabhakar@mhra.gsi.gov.uk](mailto:roopa.prabhakar@mhra.gsi.gov.uk)  
[gica.leclerc@mhra.gsi.gov.uk](mailto:gica.leclerc@mhra.gsi.gov.uk)

### Clinical aspects

Mark Grumbridge  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7128  
Fax: 020 8754 3965  
Email: [mark.grumbridge@mhra.gsi.gov.uk](mailto:mark.grumbridge@mhra.gsi.gov.uk)

## 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](mailto: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.irc@nhs.net](mailto:nss.irc@nhs.net)

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

## 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](mailto:Haz-Aic@wales.gsi.gov.uk)

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