

# Medical Device Alert

## Action

Ref: MDA/2011/037 Issued: 14 April 2011 at 14:00

### Device

Sterile urine drainage bags – various volumes, tube lengths and presentations.

Manufactured by Unomedical a/s (a ConvaTec Company).

Specific product codes and lot numbers.

Problem	Action
<p>The connector, which attaches the urine drainage bag to the patient's catheter, may be partially or completely blocked, restricting or preventing drainage of urine into the bag. This may result in retention of urine in the bladder.</p> <p>The manufacturer recalled affected products in November 2010. The MHRA is issuing this Medical Device Alert to reach users who may remain unaware of this recall.</p>	<ul style="list-style-type: none"> <li>• Identify and do not use affected products.</li> <li>• Contact end users/patients who have received affected stock and retrieve any unused devices.</li> <li>• Contact Unomedical or your distributor to arrange for credit or replacement product as detailed in the manufacturer's <a href="#">Field Safety Notice (click here)</a>.</li> </ul>
Action by	
<p>All health and social care workers who use these devices, or look after patients who use these devices in their own homes. Personnel involved in the purchase, supply and distribution of these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 28 April 2011 Action complete: 12 May 2011</p>	<p><b>Manufacturer</b> Sara Collins Unomedical Ltd Tel: 01527 583622 Fax: 01527 591198 Email: <a href="mailto:Sara.Collins@convatec.com">Sara.Collins@convatec.com</a></p>

## Device

See the manufacturer's [Field Safety Notice \(click here\)](#) for a list of affected product codes and associated lot numbers.

A picture of the connector is provided below. Please be aware that not all products containing this connector are subject to this recall. Only products that appear in the manufacturer's list of affected product codes and associated lot numbers are affected.



## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- OFSTED (Directors of Children's Services) for information
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

### 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
- All clinical departments
- All wards
- Clinical governance leads
- Continence advisors
- Equipment stores
- Health and safety managers
- Hospital at home units

- Intensive care units
- Medical directors
- Nursing executive directors
- Outpatient clinics
- Purchasing managers
- Risk managers
- Supplies managers
- Theatres
- Urologists
- Urology nurse specialists

### **Primary care trusts**

CAS liaison officers for onward distribution to all relevant staff including:

- Community hospitals
- Community nurses
- Community pharmacists
- Continence advisors
- District nurses
- Health visitors
- Infection control nurses
- Palliative care teams
- Practice managers
- Practice nurses
- Walk-in centres

### **Social services**

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loaned equipment store 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)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

#### **Establishments registered with OFSTED**

This alert should be read by:

- Children's services
- Educational establishments with beds for children
- Residential special schools

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

Sara Collins  
Unomedical Ltd  
First Floor Unit 3 West Wing  
Brooklands Moons Moat Drive  
Redditch B98 9DW

Tel: 01527 583622

Fax: 01527 591198

Email: [Sara.Collins@convatec.com](mailto:Sara.Collins@convatec.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/037** or **2010/004/023/601/002**

### Technical aspects

Ainsley Wickens or Claire Dunne  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7273 / 7162

Fax: 020 8754 3965

Email: [ainsley.wickens@mhra.gsi.gov.uk](mailto:ainsley.wickens@mhra.gsi.gov.uk)  
[claire.dunne@mhra.gsi.gov.uk](mailto:claire.dunne@mhra.gsi.gov.uk)

### Clinical aspects

Jonathan Plumb  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7128

Fax: 020 8754 3965

Email: [jonathan.plumb@mhra.gsi.gov.uk](mailto:jonathan.plumb@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

Health Facilities Scotland

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:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly 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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