

# Medical Device Alert

Ref: MDA/2014/023 Issued: 17 June 2014 at 14:00

Device
Adaptors for Shelfpak humidifier and Aquapak sterile water.
Manufactured by Teleflex Medical.
Specific product and lot numbers.

Problem	Action
<p>The packaging of these devices might not be sealed properly.</p> <p>However, the adaptors are used as part of a non-sterile system, so there is limited risk to patients.</p> <p>Teleflex published a <a href="#">Field Safety Notice</a> recalling affected products in April 2014 but has not had sufficient confirmation from users that they have received and acted upon this information</p>	<ul style="list-style-type: none"> <li>Identify the affected devices using the <a href="#">FSN</a> and quarantine them.</li> <li>Return affected devices and arrange for replacements from Teleflex.</li> <li>Return the acknowledgement form to the manufacturer.</li> </ul>
Action by	
All staff who use these devices.	
CAS deadlines	Contact
<p>Action underway: 17 July 2014</p> <p>Action complete: 17 September 2014</p> <p><b>Note: These deadlines are for staff to be made aware of the issue and affected devices to be identified.</b></p>	<p><b>Manufacturer</b> Hélène Sauvage Teleflex Medical Tel: 01494 532 761 Email: <a href="mailto:orders.uk@teleflex.com">orders.uk@teleflex.com</a></p>

## Device

The adaptors may be sold separately or with the Aquapak sterile water.

## 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 area teams for information
- NHS trusts in England (chief executives)
- Social services in England (directors)
- Special health authorities for information

### 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:

- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- Hospital at home units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Operating department practitioners
- Paediatric intensive care units
- Risk managers
- Special care baby units
- Theatre managers
- Theatre nurses
- Theatres

### Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes

### 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

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

### Teleflex Medical

Hélène Sauvage  
Teleflex Medical  
IDA Business & Technology Park  
Dublin Road  
Athlone  
Co. Westmeath  
Ireland  
Tel: 01494 532 761  
Fax: 01494 524 650  
Email: [orders.uk@teleflex.com](mailto:orders.uk@teleflex.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/023** or **2014/004/016/081/016**

### Technical aspects

Emma Rooke and Louise Mulroy  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 6609 / 7344  
Fax: 020 8754 3965  
Email: [emma.rooke@mhra.gsi.gov.uk](mailto:emma.rooke@mhra.gsi.gov.uk)  
[louise.mulroy@mhra.gsi.gov.uk](mailto:louise.mulroy@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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other 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

Email: [improvingpatientsafety@wales.gsi.gov.uk](mailto:improvingpatientsafety@wales.gsi.gov.uk)