

Medical Device Alert

Ref: MDA/2014/042 Issued: 03 November 2014 at 15:00

Device
<p>Hudson RCI[®] nebulizer adaptors and Aquapak sterile water with nebulizer adaptors.</p> <p>Manufactured by Teleflex Medical.</p> <p>Specific product and lot numbers.</p>

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 minimal risk of infection to patients.</p> <p>Teleflex sent an amended Field Safety Notice (dated 19 September 2014) to its customers recalling affected products but hasn't had enough replies to know that users have received and acted on this information.</p>	<ul style="list-style-type: none"> Identify and quarantine the affected devices using the codes in the FSN. Return affected devices and arrange for replacements from Teleflex. Return the acknowledgement form to the manufacturer.
Action by	
<p>All staff who use these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 17 November 2014</p> <p>Action complete: 01 December 2014</p> <p>Note: These deadlines are for staff to be made aware of the issue and affected devices to be identified.</p>	<p>Manufacturer Hélène Sauvage Teleflex Medical Tel: 01494 532 761 Email: orders.uk@teleflex.com</p>

Device

Check Appendix 2 of the [FSN](#) for the full list of affected product codes.

If relevant to you, the national supply codes are as follows:

England NPC:

NHS Supply chain code	Manufacturer's part number	Product description
FDE115	4044-28	AQUAPAK 428 SW,440 ML W/028 ADAPTOR,INTL
FDE130	403128	ADAPTOR,028 NEB,INTL
FDE369	403728	AQUAPAK 728 SW,760 ML W/028 ADAPTOR,INTL
FDE384	404128	AQUAPAK 1028 SW,1070 ML W/028 ADAPTOR,IN

Northern Ireland:

The products identified in the FSN are not on regional contract within Northern Ireland but may have been acquired as non-stock items.

Scotland SKU:

Supply chain code	Manufacturer's part number	Product description
031498	403128	ADAPTOR, 028 NEB, INTL

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
- 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:

- A&E departments
- Adult intensive care units
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- Community children's nurses
- Community hospitals
- Community nurses
- District nurses
- ENT departments

- Health Visitors
- 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
- Respiratory departments
- Risk managers
- Special care baby units
- Theatre managers
- Theatre nurses
- Theatres

NHS England area teams

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

- Community pharmacists
- General practitioners
- Practice managers
- Practice nurses

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 and requesting this facility.

Contacts

Teleflex Medical

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IDA Business & Technology Park
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Athlone
Co. Westmeath
Ireland

Tel: 01494 532 761

Fax: 01494 524 650

Email: orders.uk@teleflex.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/042** or **2014/009/015/121/010**

Technical aspects

Elke Kerwick and Emma Rooke
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6826 / 6609

Fax: 020 8754 3965

Email: elke.kerwick@mhra.gsi.gov.uk
emma.rooke@mhra.gsi.gov.uk

Clinical aspects

Dr Neil McGuire
Medicines & Healthcare Products Regulatory Agency
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London SW1W 9SZ

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Fax: 020 8754 3965

Email: neil.mcGuire@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

<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

<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

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