



Medical Device Alert

10 October 2018

Parc Cathays
Caerdydd CF10 3NQ

**Llywodraeth Cymru
Welsh Government**

Cathays Park
Cardiff CF10 3NQ

Device: Flex connectors in Halyard Closed Suction Kits – risk of interruption of ventilation

- Identify the affected devices as stated in the manufacturer's Field Safety Notice (FSN).
- Ensure that all users receive the manufacturer's FSN and that they understand the problem and actions to be taken.
- Refer to the FSN for actions to be taken.
- Report adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Sent to:
NHS Wales Shared Services Partnership
Directors of Public Health,
Chief Executives, NHS Trusts
Chief Executives, LHBs
Medical Directors, NHS Trusts
Nurse Directors, LHBs
Executive Nurses, NHS Trusts
NHS Direct
CSSIW
Social Services
HIW

A list of people who need to have early sight of this information is given in the Notice.
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

Points of particular importance in Wales:

**Healthcare Quality Division
Welsh Government
Cathays Park
Cardiff CF10 3NQ**



Medical Device Alert

MDA/2018/030

Issued: 19 September 2018 at 11:00

Valid until: September 2019

Flex connectors in Halyard Closed Suction Kits – risk of interruption of ventilation

Summary

Manufactured by Halyard Health – risk of some Flex Connectors in Closed Suction Kits becoming loose or disconnecting, which may interrupt patient ventilation.

Action

- Identify the affected devices as stated in the manufacturer's [Field Safety Notice \(FSN\)](#).
- Ensure that all users receive the manufacturer's FSN and that they understand the problem and actions to be taken.
- Refer to the FSN for actions to be taken.
- Report adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: [England](#), [Scotland](#), [Northern Ireland](#), [Wales](#). You should also report directly to manufacturers if your local or national systems do not.

Action by

All healthcare staff involved with patient ventilation.

Deadlines for actions

Actions underway: 03 October 2018

Actions complete: 17 October 2018

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an [FSN](#) from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Problem / background

The manufacturer found certain Flex Connectors supplied with Halyard Closed Suction Kits with Flex Connector may become loose or disconnect before use or during use.

If disconnection occurs during use, it will result in an open respiratory circuit and interrupt patient ventilation.

Manufacturer contacts

Halyard Health
Veronique Paulin
Tel: +32 (2) 7112668
Email: Veronique.Paulin@hyh.com / _EMEAFieldAction@hyh.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

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

- A&E consultants
- A&E departments
- Adult intensive care units
- All wards
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Community children's nurses
- Community hospitals
- Community nurses
- ENT departments
- ENT medical staff
- ENT services, directors of
- 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
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paramedics
- Patient transport managers
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

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

- Hospitals in the independent sector

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@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/030** or **2018/003/009/478/014**.

Technical aspects

Zarah Naeem or Richard Adu-Ntow, MHRA

Tel: 020 3080 6930/7072

Email: zarah.naeem@mhra.gov.uk / richard.adu-ntow@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

Reporting adverse incidents in England

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

Northern Ireland

Alerts in Northern Ireland are distributed via the [NICAS system](#).

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

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
<https://www.health-ni.gov.uk/niaic>

Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the [forms on our website](#).

Scotland

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

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.irc@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to [Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to [Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

Wales

Enquiries in Wales should be addressed to:

Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

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

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.

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