Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

# 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.

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Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

## 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.iric@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).