Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/018 Issued: 31 May 2018 at 15:00 Valid until: May 2019

Various Arrow Critical Care devices – recall due to incomplete packaging seals

Summary

Manufactured by Teleflex – various critical care devices manufactured from January to December 2017 inclusive have been placed on the market with incomplete packaging seals potentially leading to infection.

Action

- Refer to the manufacturer's FSN for a list of affected products
- Identify, cease using and quarantine these devices
- Contact Arrow International to return the devices

Action by

All healthcare professionals who are responsible for, or who use these devices

Deadlines for actions
Actions underway: 14 June 2018
Actions complete: 28 June 2018

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

Please refer to the FSN and related Appendix for a complete list of affected products. Note that Devices marked as non-CE marked are not on the EU market.

In addition to the Field Safety Notice which details affected product, please refer to the spreadsheet which accompanies this MDA for additional unique device identification information.

Manufacturer contacts

Ken Oshanksy
Arrow International Inc.
4024 Stirrup Creek Drive
NC 27703
Durham
USA

Tel: +1 919-433-4940
Email: internationalFCA@teleflex.com

Cliodhna Coffey
UK Customer Service

Fax: +44 (0) 1494 524650
Tel: +44 (0) 1494 532761
Email: orders.uk@teleflex.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
- A&E directors
- A&E nurses
- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Biomedical science departments
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses

- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical perfusionists
- Colposcopy departments
- Coronary care departments
- Coronary care nurses
- Day surgery units
- EBME departments
- Equipment stores
- Equipment libraries and stores
- General surgeons
- General surgery
- General surgical units, directors of
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Infection control departments
- Infection control nurses
- Infection prevention and control directors
- In-house maintenance staff
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Microbiologists
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Operating department practitioners
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatrics departments
- Peritoneal dialysis units
- Renal medicine departments
- Renal medicine, directors of
- Resuscitation officers and trainers
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Hospitals in the independent sector
- Independent treatment centres
- 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@mhra.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/018** or **2018/004/013/478/010.**

Technical aspects
Jacques Pouget, MHRA
Tel: 020 3080 6143
Email: jacques.pouget@mhra.gov.uk

Sophie Clewlow, MHRA
Tel: 020 3080 6871
Email: sophie.clewlow@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).