Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/016 Issued: 19 March 2019 at 11:00 Valid until: March 2020

enFlow® IV fluid and blood warmer - risk of unsafe levels of aluminium leaching from the device – updated safety advice from manufacturer

Summary

Manufactured by Vyaire – Cartridges with an aluminium warming plate in the fluid pathway can lead to an IV infusion containing aluminium above currently recommended safe levels.

Action

- Use an alternative fluid warming device if available.
- If alternatives are available, follow the instructions in the manufacturer's updated Field Safety Notice.
- In the short term, if no alternative is available, carry out and document a local risk assessment based on a clinical risk-benefit analysis before using this fluid warmer. Overriding clinical need for fluid warming should take precedence over considerations of risk of aluminum release.
- Put measures in place to source alternative fluid warming systems.
- Report suspected or actual 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 professionals who are responsible for or who use these devices.

Deadlines for actions
Actions underway: 26 March 2019
Actions complete: 10 April 2019

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.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

The intended use of the enFlow IV Fluid/Blood Warming System is for warming blood, blood products and intravenous solutions prior to administration. It is designed to be used by healthcare professionals in the hospital, clinical and field environments to help prevent hypothermia. The system consists of the enFlow heating system and the disposable cartridge.

Description	Manufacturers reference	NHS Supply Chain reference
Blood and fluid warming unit	980105VS	FSB1143
Blood and fluid warming disposable cartridges	980200EU	FSB1144
Blood and fluid warming disposable cartridges with extension (30)	980202EU	FSB1145

Problem / background

This MDA replaces MDA/2019/015.

The manufacturer has provided MHRA with additional evidence that suggests using the enFlow system with lactated Ringer's, platelets, plasma, whole blood, packed red blood cells and Sterofundin may lead to a risk of administering potentially harmful concentrations of aluminium.

Following comprehensive and continuing investigation by MHRA, we recommend measures are put in place to source alternative fluid warming devices as soon as possible. If no alternative devices are available in the short term, overriding clinical need for fluid warming should take precedence over considerations of risk of aluminum release.

MHRA continues to investigate whether other devices on the market also release higher than recommended levels of aluminium and will take action where necessary.

Manufacturer contacts

Vyaire Medical
26125 North Riverwoods Blvd.
Mettawa
60045
USA
Tel: +1 833 327 3284
Email: Bob.Arnott@vyaire.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
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Biomedical engineering staff
- Biomedical science departments
- Cardiac laboratory technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Clinical perfusionists
- Community hospitals
- Community midwives
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- EBME departments
- Endocrinology units
- Endocrinology, directors of
- ENT departments
- ENT medical staff
- ENT services, directors of
- Equipment stores
- Equipment libraries and stores
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- General surgical units, directors of
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists

- 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
- Maternity units
- Maxillofacial departments
- Medical directors
- Medical oncologists
- Medical oncology, directors of
- Medical physics departments
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Oncology nurse specialists
- Operating department practitioners
- Oral surgeons
- Orthopaedic surgeons
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Paramedics
- Purchasing managers
- Radiation & medical oncology departments
- Radiation oncologists
- Radiation oncology, directors of
- Renal medicine departments
- Renal medicine, directors of
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Sterile services departments
- Supplies managers
- Theatre managers

- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments

Public Health England

Directors for onward distribution to:

- Heads of health, safety and quality
- Risk manager
- Safety officers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only) 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 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/2019/016** or **2019/003/013/291/001**

Technical aspects

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

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

Tel: 0208 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

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

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 250986 / 03000 255510

Email: haz-aic@wales.gov

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).