



Medical Device Alert

MDA/2019/015

Issued: 08 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

Summary

Manufactured by Vyair – 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, quarantine affected devices as per the manufacturer's [Field Safety Notice](#).
- 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.
- 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: 15 March 2019

Actions complete: 29 March 2019

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

A recent paper¹ published by the journal of Anaesthesia concluded that uncoated aluminium plates in fluid warming systems can lead to a risk of administering potentially harmful concentrations of aluminium, when using balanced electrolyte solutions.

Following comprehensive and continuing investigation by MHRA we are alerting healthcare professionals who use, maintain or are involved in purchasing these medical devices and their local and national healthcare organisations.

To date no adverse incident reports associated with this issue have been received and operators are encouraged to report any suspected adverse events related to any type of these devices to MHRA.

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

Reference:

1. Aluminium release by coated and uncoated fluid-warming devices T. Perl et al, Anaesthesia 2019 doi:10.1111/anae.14601

Manufacturer contacts

Vyaire Medical
26125 North Riverwoods Blvd.
Mettawa
60045
USA
Tel: +1 833 327 3284
Email: Bob.Arnott@vyair.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
- Patient transport managers
- Pharmaceutical advisors

- Pharmacists
- 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:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses
- PHE laboratories
- Laboratory managers
- Regional business managers
- Regional directors
- Regional epidemiologists
- Regional leads
- Regional microbiologists
- Risk manager
- Safety officers

NHS England area teams

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

- Community optometrists
- Community pharmacists
- Dispensing opticians
- General dental practitioners
- General practitioners (for information only)
- Nutritional nurse specialists
- Occupational health departments
- Optometrists
- General practice managers
- General practice nurses

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

Independent distribution

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

- 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 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/2019/015** or **2019/001/004/302/001**.

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.irc@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 \(Wales\)](#).

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

© Crown Copyright 2019

Addressees may take copies for distribution within their own organisations