Medical Device Alert

MDA/2015/026 Issued: 21 July 2015 at 14:00 Valid until: July 2016

Haemodialysis: CRIT-LINE® blood chamber - product code CL10021021. Manufactured by Fresenius USA Manufacturing Inc. / Hemametrics.

Summary

Recall of all lots due to risk of blood loss caused by leakage at the blood chamber connection.

Action

- Identify and quarantine affected devices listed in the Field Safety Notice.
- Return the reply form to NOTIFYRA@fmc-na.com.
- Contact the manufacturer via email for advice on how to return affected product to the manufacturer.

Action by

- All medical and nursing staff who use these devices or who are responsible for patients with these devices.

Deadlines for actions

Actions underway: 04 August 2015
Actions complete: 18 August 2015

Device details

The CRIT-LINE blood chamber is used as part of the CRIT-LINE monitor system for haemodialysis.

Manufacturer contacts

Fresenius USA Manufacturing Inc
Tel: +1 8556 162 309
Email: Lindsey.trett@fmc-na.com

European Authorised Rep.
MDSS GmbH
Tel: +49 (0)511 6262 8630
Email: vigilance@mdss.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 SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Adult intensive care units
- Biomedical engineering staff
- Haemodialysis nurses

- Haemodialysis units
- Intensive care units
- Paediatrics intensive care units
- Renal medicine departments
- Renal medicine, directors of
- Risk managers
- Satellite dialysis centres
- Staff supporting patients receiving haemodialysis at home

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Hospitals in the independent sector
- Independent dialysis centres

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@dh.gsi.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2015/026** or **2015/005/028/071/006**.

Technical aspects
Roopa Prabhakar or Jenifer Hannon MHRA
Tel: 020 3080 7293 / 7153
Email: roopa.prabhakar@mhra.gsi.gov.uk
jenifer.hannon@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge, MHRA
Tel: 020 3080 7128
Email: mark.grumbridge@mhra.gsi.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 NI SABS 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
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk
http://www.dhsspsni.gov.uk/index/hea/niaic.htm

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
Fax: 0131 314 0722

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: 01267 225 278 / 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).