Medical Device Alert

Ref: MDA/2013/033 Issued: 10 May 2013 at 16:00

Device

Diacap® Ultra dialysis fluid filter.

Manufactured by B. Braun Avitum AG.

Product code: 7107366.

All devices that are more than 10 months from the date of manufacture are affected.

Problem

Risk of a gradual increased fluid removal, which may cause symptoms of hypotension during dialysis treatment.

Ultrafiltration deviations may not be immediately detected by the machine.

This is due to a decrease in the residual moisture of the filter membrane, which can cause a higher fluid removal from the patient than initially selected.

Action by

All renal unit staff, intensive care physicians, intensive care nurses, theatre managers, staff responsible for home care patients, EBME departments and purchasing managers.

Action

Identify, quarantine and do not use affected devices.

Ensure that all staff are aware of the manufacturer's Field Safety Notice (FSN) dated 22 February 2013.

Develop a system to ensure that these devices are not used more than 10 months from the date of manufacture, until the manufacturer advises otherwise.

Return the 'confirmation of receipt' form in the FSN to the manufacturer.

Contact B. Braun Medical Ltd, Sheffield to arrange replacement of affected product.

CAS deadlines

Action underway: 17 May 2013

Action complete: 24 May 2013

Note: These deadlines are for unused devices to be removed from use.

Contact

Manufacturer
Catherine Clulow, B. Braun Medical Ltd.
Tel: 0114 225 9155
Email: catherine.clulow@bbraun.com

Device

This device is used as a bacteria and pyrogen filter for dialysis fluid purification, as well as for processing substitution solution for online haemodiafiltration and haemofiltration procedures.

The date on the label is in the format YYYY-MM e.g. 2012-07 for July 2012.
The month of manufacture in this case is July 2012 which should be counted as month **one** when calculating the age of filters.

Therefore, product manufactured in July 2012 should not be used after April 2013.
See FSN for further information.

Problem

It has been noted that over time the residual moisture of the membrane used in the Diacap Ultra dialysis fluid filter decreases leading to an alteration in the membrane permeability, which in turn affects the device flow resistance.

When used clinically, the altered functionality of the device can lead to excess fluid of up to 230 ml/hr, being removed under worst case conditions. Although the haemodialysis system will alarm at a set value beyond the pre-set ultrafiltration rate, the higher ultrafiltration rate has the potential to cause symptoms of hypotension in some patients.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS trusts in England (chief executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.–

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Biomedical engineering staff
- Clinical perfusionists
- EBME departments
- Haemodialysis nurses
- Haemodialysis units
- High dependency units
- Hospital at home units
- Intensive care units - adult and paediatric
- Intensive care, directors of
- Medical directors
- Nursing executive directors
- Purchasing managers
- Renal medicine departments
- Renal medicine, directors of
- Renal units
- Risk managers
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers

Independent distribution

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

This alert should be read by:

- Hospices
- Hospitals in the independent sector
- Independent treatment 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.

Contacts

Manufacturer
Catherine Clulow, Team Leader Product Complaints
B. Braun Medical Ltd.
Thorncliffe Park
Sheffield S35 2PW

Tel: 0114 225 9155
Fax: 0114 225 9111

Email: catherine.clulow@bbraun.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/033** or **2013/002/026/601/002**

Technical aspects
Roopa Prabhakar or Claire Dunne
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7293 / 7162

Fax: 020 8754 3965

Email: roopa.prabhakar@mhra.gsi.gov.uk
claire.dunne@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7128
Fax: 020 8754 3965

Email: mark.grumbridge@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group, Room 17, Annex 6, Castle Buildings, Stormont Estate,
Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square,
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk