Medical Device Alert

Ref: MDA/2013/048 Issued: 02 July 2013 at 14:00

Device

Update to MDA/2013/026

Recall of Hospira 1 litre suction canisters and liners - additional products recalled.

Suction canisters and liners with Abbott labels and list numbers are now included in the recall.

1 litre suction canisters - Abbott list number 770462.

1 litre suction liners - Abbott list numbers L212A52 and L213A52.

Manufactured by Hospira (formerly manufactured by Abbott).

All batch numbers are affected.

Problem

Potential loss of suction.

Hospira has issued an updated Field Safety Notice (dated 07 June 2013) to extend the recall of 1 litre devices to those marked with Abbott labels, and to instruct customers to seek alternatives.

This MDA is an extension of MDA/2013/026 published in May 2013 to include these additional devices.

Action by

All staff who use these devices

Action

Identify affected devices.

Ensure that users are aware of the manufacturer's updated Field Safety Notice.

Seek alternative devices immediately and return affected devices to the manufacturer.

Until alternative devices are available:

- Perform pre-use checks (see below). If defective units are identified, remove from use.
- Exercise caution in use, as failure can occur **despite** the pre-use checks.
- Ensure that a back-up suction device is available at all times.

CAS deadlines

Action underway: 16 July 2013

Action complete: 02 August 2013

Note: These deadlines are for systems to be in place to identify and arrange for replacements of affected devices.

Contact

Manufacturer

Wilson Kennedy
Hospira UK Limited

Tel: 0192 682 0820

Email: devicesfieldactions@hospira.com

Device

The affected products are part of a closed, disposable suction system that is used to isolate suction waste. They are used for adult, paediatric and neonatal patients.

Hospira has issued an updated Field Safety Notice (dated 07 June 2013) to extend the recall detailed in MDA/2013/026, to include 1 litre devices supplied under the legacy Abbott model numbers.

The Abbott labelled products are no longer in production, but may still be in stock.

The Abbott and Receptal products are manufactured to the same design and both are, therefore, affected. To clarify, the full list of devices affected by this problem is:

Receptal 1 litre canisters (List number 43449), previously marketed as Abbott 1L suction canisters (List number 770462);

Receptal 1 litre PVC liners (List number OL212), previously marketed as Abbott 1L suction liners (List number L212A52);

Receptal 1 litre PE liners (List number OL213), previously marketed as Abbott 1L suction liners (List number L213A52).

Problem

The vacuum needed to generate the suction cannot be created if the hard canister and the single-use liner are not properly seated during use, or if the liner separates from the canister during use.

Hospira has not yet identified the root cause of this failure. An investigation is ongoing.

Hospira cannot guarantee that the pre-use checks (listed below) will identify all defective units. Therefore, a unit could pass the pre-use checks and still fail during use.

Hospira is unable to trace customers who purchased products marked with Abbott labels.

Action

Until alternatives are made available, the following pre-use checks must be carried out:

1. During assembly, check the underside of the liner lid to ensure that the liner is not misaligned and there is a flush connection.
2. Verify that the correct vacuum pressure can be achieved and that there is no loss of suction.

Image depicting misalignment of the Receptal liner within the Receptal liner lid. Towards the top, the liner is close to the edge of the lid; on the right there is a gap

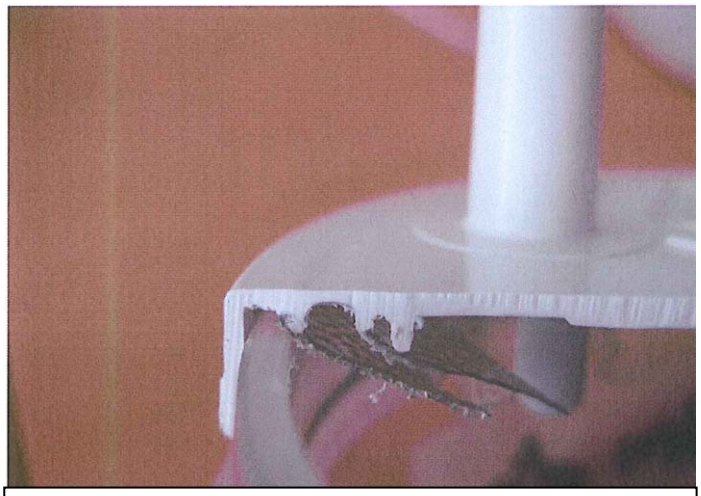

Image highlighting how the misaligned liner prevents a flush connection of the lid with the edge of the canister, which gives rise to inadequate vacuum.

Distribution

This MDA has been sent to:

- HSC trusts in Northern Ireland (chief executives)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS England area teams (chief executives)
- NHS England regional teams
- 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:

- All clinical departments
- All clinical staff
- All wards
- Ambulance staff
- Clinical governance leads
- Community hospitals
- Directors of nursing
- Equipment stores
- Medical directors
- NHS walk-in centres
- Outpatient clinics
- Resuscitation officers and trainers
- Risk managers
- Supplies departments
- Theatres

NHS England (formerly PCTs)

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

- General dental practitioners
- General practitioners
- Palliative care teams

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Hospices
- 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@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer
Hospira UK Limited
Queensway
Royal Leamington Spa
Warwickshire, CV31 3RW

Tel: 0192 682 0820
Fax: 0192 683 5250

Email: devicesfieldactions@hospira.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/048** or **2013/004/004/081/021**

Technical aspects
Emma Rooke or Louise Mulroy
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6609 / 7344
Fax: 020 8754 3965

Email: emma.rooke@mhra.gsi.gov.uk
louise.mulroy@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
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