Medical Device Alert

Ref: MDA/2013/026 Issued: 01 May 2013 at 14:00

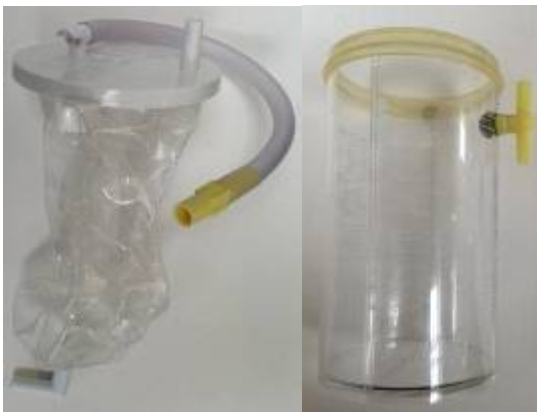
Device

Suction canisters and liners.

All Receptal:
1 litre canisters (List number 43449),
1 litre PVC liners (List number OL212)
and
1litre PE liners (List number OL213).

Manufactured by Hospira (formerly manufactured by Abbott).

All batch numbers are affected.



Problem

Potential failure or loss of suction.

Due to a number of customer complaints, Hospira has issued a Field Safety Notice (dated 12 April 2013) to recall all 1 litre devices and instruct customers to seek alternatives.

The MHRA is not confident that Hospira has sufficient alternative stock available to supply the demand during a recall.

Action by

All staff who use these devices.

Action

Identify affected devices.

Ensure that users are aware of the manufacturer's 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: 15 May 2013

Action complete: 31 May 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 Receptal system is a closed, disposable suction system that is used to isolate suction waste. It is used with adult, paediatric and neonatal patients.

Problem

The vacuum needed to create 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.

Action

Until alternatives are made available, the following pre-use checks should 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.

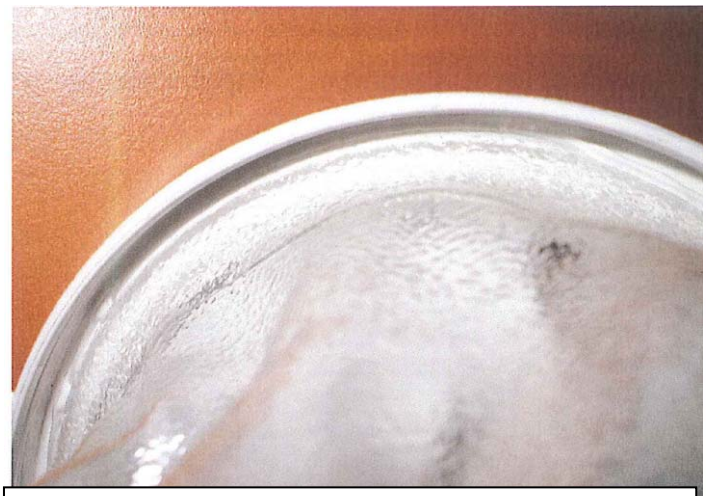


Image depicting misalignment of the Receptal liner within the Receptal liner lid. Towards the top, the liner is close to the edge of the lid; on the right there is a gap

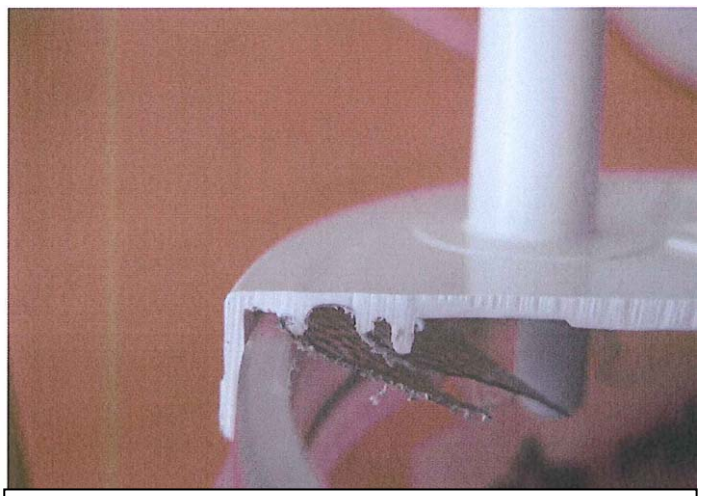


Image highlighting how the misaligned liner prevents a flush connection of the lid with the edge of the canister, which gives rise to inadequate vacuum.

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

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/2013/026** 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 or 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
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