

Medical Device Alert

Immediate action

Ref: MDA/2010/065 Issued: 16 August 2010 at 15:00

Device

Suction liners.

Receptal 1, 1.5 and 2 litre PVC liners.

Manufactured by Hospira (formerly manufactured by Abbott).



Problem

Due to a manufacturing fault, the lid of Receptal PVC suction liners may not be correctly aligned. When fitted to the suction canister this can result in an inadequate seal and loss of suction. To date, up to 10% of the affected suction liners have exhibited misaligned lids.

Action by

All staff who use this device.

Action

- Ensure that users are aware of the risk of failure.
- Perform the pre-use checks described in Hospira's [Field Safety Notice](#).
- Ensure that spare suction liners are available at the point of use.

CAS deadlines

Action underway: 23 August 2010
Action complete: 06 September 2010

Contact

Manufacturer
Geraint Morgan
Hospira UK Limited
Tel: 01926 834 400
Email: medinfouk@hospira.com

Device

Details of affected devices:

Description	Hospira list number	NHS Supply Chain reference
Receptal 1L PVC liner	OL2129701	L21205014
Receptal 1L PVC liner	OL21297W1	Not available in the UK
Receptal 1.5L PVC liner	OF8079701	440G90401
Receptal 2L PVC liner	OG6619701	Not available in the UK
Receptal 2L PVC liner	OG9159701	Not available in the UK
Receptal 2L PVC liner	OE0989701	E09805014
Receptal 2L PVC liner	OF8069701	440G90201

Action

All liners should be checked according to the Hospira Field Safety Notice, including those which have already been placed into a suction canister ready for use.

In addition to the recommendations in Hospira's Field Safety Notice, the MHRA recommends referring to the instructions for use provided by the manufacturer of the suction unit or suction canister for their assembly instructions and recommended pre-use checks.

Hospira implemented a corrective action in June 2010, but as the manufacturing date cannot easily be identified, pre-use checks should always be carried out.

The MHRA has issued this Medical Device Alert to ensure that users are aware of this problem and to remind them of previously published guidance – [MDA/2005/035](#).

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

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

- A&E departments
- Adult intensive care units
- All wards and clinical departments
- Ambulance staff
- Clinical governance leads
- Day surgery units
- Dentists
- EBME departments
- General surgery
- Intensive care units
- Medical directors
- Outpatient clinics
- Outpatient theatre managers
- Physiotherapists
- Resuscitation officers and trainers
- Surgeons
- Theatres

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Care homes providing nursing care (adults)
- Hospices
- Hospitals in the independent sector

OFSTED to:

The MHRA considers this to be important to:

- Educational establishments with beds for children
- Residential special schools

Primary care trusts to:

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

- Community dental practices
- Community hospitals
- Minor injury units
- NHS walk-in centres

Social services to:

Liaison officers for onward distribution to all relevant staff including:

- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- In-house residential care homes

Contacts

Manufacturer

Geraint Morgan
Manager, Medical Information
Hospira UK Limited
Queensway
Royal Leamington Spa
Warwickshire CV31 3RW

Tel: 01926 834 400

Email: medinfouk@hospira.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/065** or **2010/005/028/081/037**.

Technical aspects

Graham Nash or Nicole Small
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3125 / 3310

Fax: 020 7084 3209

Email: graham.nash@mhra.gsi.gov.uk

nicole.small@mhra.gsi.gov.uk

Clinical aspects

Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3128

Fax: 020 7084 3111

Email: jonathan.plumb@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.irc@nhs.net

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

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

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

MHRA is an executive agency of the Department of Health
© Crown Copyright 2010

Addressees may take copies for distribution within their own organisations