Medical Device Alert

Ref: MDA/2014/016 Issued: 15 May 2014 at 15:30

Device

Reusable latex breathing bags.

Manufactured by Dräger.

Specific part numbers affected.

Problem

Potential for acute allergic reaction in staff or patients after using a Dräger latex breathing bag.

These breathing bags are marked ‘NR’ for natural rubber (latex) but this may not be immediately obvious to the user.

Action

Identify affected products – Dräger latex breathing bags are blue.

Ensure all staff who use these devices are aware of the guidance in the manufacturer’s Field Safety Notice.

Follow local procedures for latex.

Action by

Those staff who use these devices.

CAS deadlines

Action underway: 30 May 2014

Action complete: 12 June 2014

Contact

Manufacturer
Stuart Norris
Draeger Medical UK Limited
Tel: 01442 213542
Email: stuart.norris@draeger.com

Device

The following part numbers are affected:

Reusable latex breathing bags: 2165686, 2165953, 2165694, 2165708, 2165716, 2165724, 2165763, 2165775 and 2165783.

Reusable latex breathing bags used with test lung: 8403201.

Reusable latex breathing bags used with reusable anaesthesia sets: M33681, M27542, M34822, M34823 and M34824.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- Directors of public health
- Health and Safety Executive
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- 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:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Biomedical engineering staff
- Clinical governance leads
- Day surgery units
- EBME departments
- Equipment libraries and stores
- Equipment stores
- General surgeons
- General surgery
- General surgical units, directors of
- Health and safety managers
- In-house maintenance staff
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maintenance staff
- Medical directors
- Medical physics departments
- Paediatric intensive care units
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

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

This alert should be read by:

- 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
Draeger Medical UK Limited
The Willows
Mark Road
Hemel Hempstead
Hertfordshire HP2 7BW

Tel: 01442 213542
Fax: 01442 240327

Email: stuart.norris@draeger.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/016** or **2014/003/013/081/040**.

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

Tel: 020 3080 6691/6609
Fax: 020 8754 3965

Email: ian.sealey@mhra.gsi.gov.uk
emma.rooke@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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other 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

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