Medical Device Alert

Bag valve mask (BVM) manual resuscitation system – risk of damage to lungs by delivery of excessive pressure

Summary

Manufactured by Intersurgical – Valves may be incorrectly oriented, resulting in overpressure of the bag.

Action

- Identify and immediately quarantine affected devices (see Field Safety Notice (FSN) for model and lot numbers).
- Replace with an alternative device where available.
- If no alternative is available, check the orientation is correct for all valves on quarantined devices before releasing them from quarantine (see Problem). This can be done without opening the packaging. Do not use if the orientation of the valve is incorrect.
- Follow the instructions in the manufacturer’s FSN to return affected devices. Return the response form to Intersurgical, even if you don’t have affected devices left in stock.

Action by

All healthcare professionals involved in the use of these devices.

Deadlines for actions

Actions underway: 23 March 2018
Actions complete: 17 April 2018

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. Do not wait for a communication from MHRA.
Device details

Specific lot numbers from the following models are affected. See FSN for lot numbers.

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<th>Intersurgical Code</th>
<th>UDI No.</th>
<th>NHSSC Code (England only)</th>
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Problem

The images below show the incorrect and correct orientation of the directional valves.

The green nipples on the valves should **not** point in the same direction.
Manufacturer contacts
Intersurgical
Tel: 0118 9656 362
Email: priority@intersurgical.co.uk

Distribution
If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)
CAS and NICAS 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
- All departments
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiothoracic departments
- Cardiothoracic surgeons
- Chief pharmacists
- Clinical perfusionists
- Colposcopy departments
- Community children's nurses
- Community defibrillation officers
- Community dental practices
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- Dental departments
- District nurses
- ENT departments
- ENT medical staff
- Equipment stores
- Gastroenterology departments
- General surgery
- General surgical units, directors of
- Gynaecology departments
- Haemodialysis units
• Hospital at home units
• Intensive care medical staff/paediatrics
• Intensive care nursing staff (adult)
• Intensive care nursing staff (paediatric)
• Intensive care units
• Intensive care, directors of
• Minor injury units
• Maternity units
• Medical directors
• Midwifery departments
• Neonatal nurse specialists
• Neonatology departments
• NHS walk-in centres
• Obstetrics and gynaecology departments
• Obstetrics departments
• Operating department practitioners
• Outpatient clinics
• Outpatient theatre managers
• Outpatient theatre nurses
• Paediatric intensive care units
• Paediatric nurse specialists
• Paediatric oncologists
• Paediatric surgeons
• Paediatric surgery, directors of
• Paediatric wards
• Paediatricians
• Paediatrics departments
• Paramedics
• Patient transport managers
• Peritoneal dialysis units
• Renal medicine departments
• Resuscitation officers and trainers
• Risk managers
• School nurses
• Special care baby units
• Supplies managers
• Theatre managers
• Theatre nurses
• Theatres
• Urology departments
• Walk-in centres

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:
• General practitioners
• General practice nurses

Social services
Liaison officers for onward distribution to all relevant staff including:
• Care at home staff
• Community care staff
• Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
• Education departments for equipment held in schools
• In-house domiciliary care providers (personal care services in the home)
• In-house residential care homes

**Independent distribution**

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

• Care homes providing nursing care (adults)
• Care homes providing personal care (adults)
• Clinics
• Domiciliary care providers
• Further education colleges registered as care homes
• Hospices
• Hospitals in the independent sector
• Independent treatment centres
• Nursing agencies
• Private medical practitioners

**Establishments registered with OFSTED**

• Children’s services
• Educational establishments with beds for children
• Residential special schools

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.

**Enquiries**

**England**

Send enquiries about this notice to MHRA, quoting reference number MDA/2018/009 or 2017/012/022/291/023

**Technical aspects**

Emma Rooke or Sophie Clewlow, MHRA
Tel: 020 3080 6609 or 6871
Email: emma.rooke@mhra.gov.uk and sophie.clewlow@mhra.gov.uk

**Clinical aspects**

Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

**Reporting adverse incidents in England**

Through Yellow Card https://yellowcard.mhra.gov.uk/

**Northern Ireland**

Alerts in Northern Ireland are distributed via the NICAS system.

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

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety
Tel: 028 9052 3868
Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

**Reporting adverse incidents in Northern Ireland**
Please report directly to NIAIC using the forms on our website.

**Scotland**
Enquiries and adverse incident reports in Scotland should be addressed to:
Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland
Tel: 0131 275 7575
Email: nss.iric@nhs.net

**Reporting adverse incidents in Scotland**
Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.
Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

**Wales**
Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government
Tel: 02920 823 624 / 02920 825 510
Email: Haz-Aic@wales.gsi.gov.uk

**Reporting adverse incidents in Wales**

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health
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