Medical Device Alert

Action

Ref: MDA/2010/040 Issued: 13 May 2010 at 14:30

Device

All chest drains when used with high-flow, low-vacuum suction systems (wall mounted).

Problem

Direct connection between the chest drain bottle and the wall mounted, high-flow, low vacuum regulator without an intermediate jar or canister can lead to:

- patient injury
- loss of effective suction
- contamination of the hospital vacuum system and infection hazard.

Action by

All clinical staff caring for patients with chest drains.

All technical and purchasing staff with responsibility for maintenance and procurement of these systems and devices.

CAS deadlines

Action underway: 14 June 2010

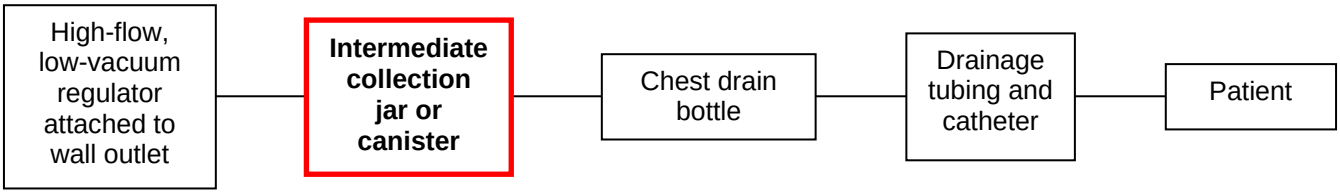
Action complete: 13 July 2010

Action

- Include an intermediate collection jar or canister in the suction system between the chest drain bottle and the regulator (see diagram).
- Change the intermediate collection jar or canister if it becomes contaminated with fluid or froth.
- Ensure that all users are aware of the advice on the use of suction systems given in MDA/2005/035, including the recommendation that all users must receive adequate training and regular refresher training.

Action

Line diagram of suction system including the essential intermediate collection jar or canister



Problem

The MHRA received a report where a patient with a chest drain, which was under active suction, sustained a tension pneumothorax. It was discovered that the high-flow, low-vacuum suction regulator attached to the hospital vacuum system had been directly attached to the patient's chest drain bottle without an intermediate collection jar or canister. Fluid in the form of froth from the chest drain bottle had entered the regulator and the safety valve had closed to prevent contamination of the hospital vacuum pipe work. Suction ceased and this effectively 'clamped' the chest drain preventing air or fluid from draining from the chest.

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)

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
- Anaesthetists
- Biomedical engineering staff
- Biomedical science departments
- Cardiologists
- Cardiology nurses
- Cardiothoracic surgeons
- Clinical governance leads
- EBME departments
- Estates departments
- General surgeons
- Health and safety managers
- Infection control nurses
- Infection prevention and control directors
- Maintenance staff
- Medical physics departments
- Microbiologists
- Paediatric intensive care departments
- Purchasing managers
- Risk managers
- Sterile services departments
- Supplies managers
- Theatre managers
- Theatres

Care Quality Commission (CQC) (England only) to:
The MHRA considers this information to be important to:
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Primary care trusts to:
CAS liaison officers for onward distribution to all relevant staff including:
- Community hospitals
- Walk-in centres

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/040** or **2009/002/012/291/005.**

Technical aspects
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Clinical aspects
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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:

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