Medical Device Alert

Ref: MDA/2013/015 Issued: 21 March 2013 at 14:30

Device

Gas pressurised spray devices for application of sprayable fibrin sealants used for intra-operative haemostasis.

Problem

The risk of life-threatening/fatal gas or air embolism.

This appears to be related to the use of spray devices to apply fibrin sealants when:

- the pressure setting is greater than recommended, or
- when the device is held closer to the tissue surface than is recommended by the manufacturer, or
- when the appropriate gas for spraying under pressure is not used.

A European wide review on the safety of these products has now been completed. Updated advice to healthcare professionals has been issued in relation to maximum pressure, minimum distance, and type of gas to use for the spray application of fibrin sealants authorised for use in the UK.

Details are provided in Drug Safety Update volume 6 Issue 7 February 2013 and in the information provided to users by the manufacturers of the spray device, and with the fibrin sealants and their delivery devices.

Action

This alert replaces MDA/2012/019.

Ensure that all those preparing and/or using the gas pressurised spray system for these products are aware of, and have systems in place to follow, the advice in this review and the updated advice to healthcare professionals that has been issued in Drug Safety Update volume 6 Issue 7 February 2013

CAS deadlines

Action underway: 28 March 2013

Action complete: 11 April 2013

Note: These deadlines are for systems to be in place to take actions. They are not deadlines for actions to be complete.

Action by

- All theatre staff involved in setting up gas pressurised delivery systems for delivery of these products.
- All surgeons applying these products using gas pressurised spray devices.

Distribution

This MDA has been sent to:
- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (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 surgeons
- Chief pharmacists
- Clinical governance leads
- Nursing executive directors
- Operating department practitioners
- Outpatient theatre managers
- Outpatient theatre nurses
- Pharmacists
- Purchasing managers
- Risk managers
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

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

This alert should be read by:
- 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.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/015** or **2012/012/012/081/001.**

Technical aspects

Ainsley Wickens or Catriona Blake
Medicines & Healthcare products Regulatory Agency, Floor 4, 151 Buckingham Palace Road,
London SW1W 9SZ

Tel: 020 3080 7273 / 7219 Fax: 020 8754 3965

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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:
Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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