Medical Device Alert

Action

Ref: MDA/2009/032 Issued: 29 April 2009 at 14:30

Device

Bioprosthetic heart valves.

All makes and models.

Problem

Early valve revision with associated morbidity or mortality risks if these valves are not adequately washed or rinsed prior to implantation.

Residues of chemicals typically used in the storage of bioprosthetic heart valves can adversely affect the patient's annular tissue and lead to premature failure of the valve.

Action by

Cardiothoracic surgeons
Theatre managers
Theatre nurses

CAS deadlines

Action underway: 07 May 2009

Action complete: 14 May 2009

Action

- Accurately follow the manufacturer's instructions for use (IFU) on valve preparation prior to its implantation.
- Ensure that all relevant members of the surgical team are familiar with the manufacturer's instructions on valve washing or rinsing, specific to each valve model.

Contact

Manufacturer/supplier

This MDA applies to all bioprostheitc heart valves. Contact the relevant manufacturer.

Link to full Medical Device Alert

Problem

The MHRA has been investigating a small number of serious adverse incidents, including patient deaths, due to premature failure of bioprosthetic heart valves. Our findings have highlighted the importance of precisely following the manufacturer's instructions on thorough pre-implantation valve washing or rinsing.

Each model of valve is supplied with the manufacturer's specific IFU. Users should be aware that the requirements for valve preparation can vary significantly between models – in particular, the rinsing times and number of water baths required. Users should therefore ensure that they are familiar with the instructions specific to the valve that they intend to implant.

Bioprosthetic replacement heart valves have been available for many years. It is common practice for these valves to be stored in a low concentration of aldehyde solution, which acts to protect and preserve the valve during its transport and storage. These solutions can be toxic to the body. It is therefore essential that any residual solution is removed prior to implantation. Since the valve will be sewn into the patient's native annulus, failure to adequately rinse off these toxic chemicals is likely to adversely affect annular healing. This may give rise to an abscess or necrosis around the valve and/or endocarditis-like syndromes (without positive microbiological cultures) presenting at an unpredictable period of time after implantation.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- HSC Trusts in Northern Ireland (Chief Executives)
- NHS Boards in Scotland (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:

- Cardiologists
- Cardiothoracic surgeons
- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- Medical directors
- Radiologists
- Radiology departments
- Risk managers
- Theatre managers
- Theatre nurses

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

Headquarters for onward distribution as appropriate to:

- Hospitals in the independent sector
- Private medical practitioners

Change of address or removal from address list for Care Quality Commission:

National Contact Centre
Care Quality Commission
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 03000 61 61 61

E-mail: enquiries@cqc.org.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/032 or 2008/008/029/401/005**

Technical 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 (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523 704
Fax: 02890 523 900

E-mail: 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 https://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

E-mail: iric@shs.csa.scot.nhs.uk

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

Wales

Enquiries in Wales should be addressed to:

Dr Jane Ludlow
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff
CF10 3NQ

Tel: 029 2082 3505 / 3922

E-mail: Haz-Aic@wales.gsi.gov.uk