Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2017/028R Issued: 31 August 2017 at 11:30

Replacement bileaflet mechanical heart valves – risk of inverted implantation

Summary

Specific manufacturers – measures to prevent inverted valve implantation resulting from incorrect mounting of the valve on its valve holder

Action

- Do not attempt to reattach a valve to its holder if separated before or during valve surgery – it is contrary to the manufacturers' instructions for use (IFU).
- Ensure the whole surgical team is trained on the handling of each make of valve that they use, including awareness of warnings and precautions in the IFU and any design features influencing its use.

Action by
Cardiothoracic surgeons and theatre staff involved in replacement heart valve procedures

Deadlines for actions
Actions underway: 14 September 2017
Actions complete: 12 October 2017

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Problem / background

MHRA is aware of 5 incidents worldwide over the last 15 years where mechanical bi-leaflet prosthetic valves of different models are believed to have been implanted inverted because they were put on their holder upside-down. The actual figure is likely to be higher as there is under-reporting of these events.

Details of the 5 incidents:

- 2 cases (one known to be fatal) in 2003 and 2004, resulting from a manufacturing quality control release mistake where valves were loaded inverted at the factory
- 1 in 2006 resulting from separation of the valve from the holder (due to suture breakage) during transportation and subsequent remounting prior to surgery
- 1 in 2006 where evidence indicates that the valve was remounted during the valve surgery
- 1 UK incident (2015) involving inverted remounting of a valve in theatre leading to subsequent patient death.

The probability of this error remains very low relative to the millions of valves implanted during this time, but the harm that can result is extreme, sometimes fatal.

Despite warnings in the manufacturers' IFU not to remount a valve on its holder, this has not entirely prevented this practice, with tragic consequences. Although the risk of inverted valve implantation cannot be completely eliminated, the holder itself can be designed to be unidirectional, preventing inverted mounting. One manufacturer's (St. Jude Medical, now Abbott) holder design is currently unidirectional, thereby also eliminating the risk of inversion on the holder during valve assembly. As a consequence of the recent UK incident (coupled with cases cited above), MHRA has acquired agreement from the other 3 manufacturers of mechanical heart valves (Liva Nova, Medtronic, On-X Life Technologies) to redesign their holders to be unidirectional. These undertakings involve long-term design projects, including thorough risk/benefit assessment and regulatory approval. As a result, valves mounted on unidirectional holders are unlikely to become available in the UK for up to a year or more, depending on the manufacturer.

Until all manufacturers have made these changes, it is important that all clinical personnel handling mechanical heart valves are aware of the serious risk associated with inversion of the valve on its holder.

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:

- Cardiologists
- Cardiology departments
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Medical directors

- Radiographer superintendents
- Radiographers
- Radiologists
- Radiology departments
- Radiology directors
- Risk managers

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/028R or 2015/003/027/401/002**

Technical aspects
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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 Fax: 0131 314 0722

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland
NHS Boards and Local Authorities in Scotland – report to Health Facilities 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

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).