Medical Device Alert

Ref: MDA/2013/013 Issued: 19 March 2013 at 14:00

Device

Mitral Valve Repair System.

MitraClip Clip Delivery System.

Manufactured by Abbott Vascular.

Problem

Risk of death or serious harm to the patient.

If the Actuator Knob on the Clip Delivery System (CDS) is turned in the wrong direction, this can prevent successful deployment of the clip, leading to the need for open surgical repair.

Action by

Interventional Cardiologists
Cardiothoracic Surgeons

Action

- Follow the manufacturer's guidance given in the device's Instructions for Use (IFU) and in their recent Field Safety Notice (FSN) with regards to the correct operation of the CDS Actuator Knob.
- Observe the blue arrow on the Actuator Knob, which is present on newer devices, indicating the direction in which it should be turned.

CAS deadlines

Action underway: 28 March 2013

Action complete: 12 April 2013

Note: These deadlines are for systems to be in place to implement actions

Contact

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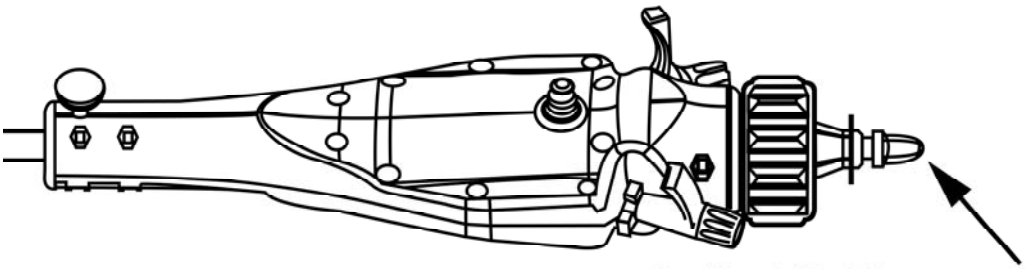
Problem

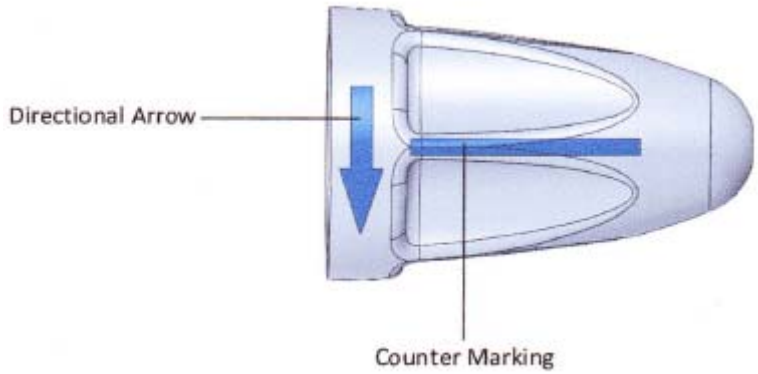
The MHRA has been notified by the manufacturer that there have been four reports (including one UK report), of the Actuator Knob of the Clip Delivery System (CDS) being turned in the wrong direction (i.e. clockwise instead of anti-clockwise) when attempting to disengage and deploy the clip from the CDS. Turning the Actuator Knob incorrectly could lead to a fracture of the CDS internal assembly, leading to an inability to control the release of the clip from the CDS. Since the clip may already have a firm grasp on the mitral valve at this point, open surgery may be required to disengage the clip from the CDS.

The UK incident led to the need for emergency open surgical repair. The bulk of the CDS could only be removed from the clip using surgical bolt cutters and the remaining shaft of the CDS unscrewed from the clip using forceps. Unfortunately, the patient died one week later, following renal complications.

In order to help prevent further incidents of this type, the manufacturer issued a FSN on 27 February 2013 providing advice. In addition, new devices will have a blue directional arrow on the Actuator Knob to help operators visualise the correct direction of turn. The manufacturer has also confirmed to the MHRA that they intend to make a number of design changes which should ultimately make it impossible to turn the Actuator Knob in the wrong direction. The implementation of the final stages of the design changes will not, however, be completed for up to two years.



From Figure 3 of the IFU,
Identifying the Actuator Knob



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)
- Primary care trusts in England (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:
- Cardiac surgical assistants
- Cardiologists
- Cardiothoracic surgeons
- Clinical governance leads
- Medical directors
- Nursing executive directors
- Supplies departments
- Theatre managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
This alert should be read by:
- Private hospitals

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.

Contacts

Manufacturer's Authorised Representative
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Local contact for Manufacturer
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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/013** or **2013/002/022/081/015**

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
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