Medical Device Alert

Ref: MDA/2013/028 Issued: 02 May 2013 at 14:00

Device

Retrievable inferior vena cava (IVC) filters.
All models and manufacturers.

Problem

Serious complications associated with attempted IVC filter retrieval.

This MDA updates and replaces MDA/2007/029 ‘Retrievable permanent inferior vena cava (IVC) filters’.

Action by

All physicians who insert IVC filters.

CAS deadlines

Action underway: 10 May 2013

Action complete: 24 May 2013

Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up and testing.

Action

Be aware of the various maximum implant durations for safe retrieval for each IVC filter model. The relevant clinical evidence and advice can be found in the manufacturer’s instructions for use.

Ensure patients are fully aware of the importance of attending future assessments, to reduce the number lost to follow-up.

Retrieve the device as soon as possible once it is no longer clinically required.

Consider, and ideally schedule, the retrieval date at the time of implantation.

Base the decision on the filter’s suitability for retrieval on a thorough implant assessment, including venography immediately prior to attempted retrieval. Be aware that some retrievable filters become unsafe to remove due to progressive changes in their position, condition, orientation or thrombus within the filter.

Report all adverse events associated with the use of these devices to the manufacturer and the MHRA.

Problem

The option to retrieve certain IVC filter models when no longer needed has only become available within the last 10 years. The MHRA has received relatively few adverse incident reports, but is aware of a high prevalence of retrieval related complications, through published papers and anecdotal reports. For example complications have arisen during attempted retrieval of filters with massive trapped thrombus, or which have undergone significant tilting, caval wall penetration, or loss of structural integrity while in situ. It is therefore important that, immediately prior to filter removal, the patient undergoes a venogram which is reviewed to enable an up-to-date assessment of the risks and benefits associated with the procedure.

It is also important to ensure that adequate systems are put in place to minimise the risk of patients being lost to follow-up.

The MHRA reminds clinicians of the importance of reporting problems that they encounter with these devices, so that we can monitor device performance. We would appreciate feedback on experience of any negative short or long term outcomes, including cases where the device could not be retrieved, despite being within its labelled implant duration for doing so.

This Medical Device Alert has been prepared in consultation with the BSIR (British Society of Interventional Radiology) and is intended to complement any broader guidance which the BSIR may issue, on the safe implantation and retrieval of these 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:

- Anti-coagulation nurse specialists
- Consultant haematologists specialising in thromboprophylaxis
- Clinical governance leads
- Medical directors
- Nursing executive directors
- Orthopaedic surgeons
- Radiographers
- Radiologists
- Radiology departments
- Radiology directors
- Risk managers
- Vascular surgeons

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/2013/028** or **2013/001/024/291/004.**

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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