

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/30

Issued: 29th March 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

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	Section
Medical Device/Equipment: Retrievable permanent inferior vena cava (IVC) filters.	▶ ①
Problem: Complications associated with filter retrieval.	▶ ②
Action by: Vascular surgeons and interventional radiologists.	▶ ③
Action: Clinicians should bear in mind when assessing filter options for individual patients, that there is currently little clinical evidence supporting the safe removal of the majority of retrievable permanent IVC filters beyond three months of implant duration.	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤
Contacts Details of NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC None required.	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

All models of retrievable permanent IVC filter.

2. PROBLEM:

Originally, IVC filters were either temporary (attached to an olive on the surface of the skin) or permanent in which case they were left in place for the patient's lifetime. Now there is a third option, the retrievable permanent filter, which is becoming increasingly popular. Retrievable permanent IVC filters have come into existence in one of two ways: manufacturers expanded the indications for existing filter designs to permit the permanent filter to be retrieved at any time after placement; or manufacturers have brought out new filters designed specifically for the purpose of retrieval.

However, having reviewed available clinical data, the MHRA has concluded that there is currently very limited clinical evidence to demonstrate the safe retrieval of most of these filters once they have been implanted for a longer period. In particular we have received a number of reports of serious complications associated with the attempted removal of filters labelled as retrievable, which have been in place for between 3 and 18 months. We are aware of cases where this has resulted in the decision to leave the filter implanted permanently. Retrievals have typically been hampered by characteristics such as:

- filter leg/arm endothelialisation
- fracture and potential loss of filter wires/hooks
- filter tilt (the degree of which may increase in the event of a filter leg/arm or hook fracture)
- caval wall perforation.

It is therefore important that clinicians are aware of retrieval limitations both at the initial stage of filter selection and at the time of a subsequent decision to remove the filter. Since there is the possibility that a retrievable IVC filter may not be removable, the benefits should outweigh the potential risk of leaving the filter in place permanently. Users should always consult the product labelling and consider discussing device performance with the relevant manufacturer when selecting the most appropriate filter.

Report all adverse incidents involving IVC filters to both the NIAIC and the relevant manufacturer.

3. ACTION BY:

Vascular surgeons and interventional radiologists.

4. ACTION:

Clinicians should bear in mind when assessing filter options for individual patients, that there is currently little clinical evidence supporting the safe removal of the majority of retrievable permanent IVC filters beyond three months of implant duration.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Cathlab managers
- Clinical governance leads
- General surgeons
- Haematologists
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- Interventional cardiologists
- Interventional radiologists
- ITU physicians
- Medical directors
- Obstetricians
- Orthopaedic surgeons
- Risk managers
- Supplies managers
- Theatre managers
- Vascular surgeons

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2007/30 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

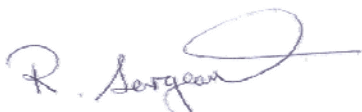
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety