

AN (NI) 2000/07

DATE: 27 November 2000

**For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency**



HEALTH ESTATES
ESTATE POLICY

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

AneuRx Stent Graft System

MANUFACTURER/SUPPLIER

Medtronic AVE

PROBLEM

Nitinol Frame Fracture after Implantation

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Device Managers
- Medical Directors
- Nursing Directors
- Medical Nursing & Care Staff
- Vascular Surgeons
- Directors of Radiology
- Radiologists
- Catheter Laboratory Managers

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

ACTION

X-ray all implanted AneuRx Stent Grafts which have not been X-rayed within the last 3 months, to confirm the condition of the nitinol wire frame. Imaging should include adequately coned plain abdominal X-rays in AP, lateral, and two bilateral oblique views to ensure a detailed display of the integrity of the Stent Graft.

Consider the need for further endovascular or surgical intervention, or repeated 3-monthly X-raying, where there is evidence of nitinol wire fracture, dependent upon the patient's symptoms, wishes and overall state of health.

Consider the need for repeated 6-monthly X-raying of AneuRx Stent Grafts showing significant separation (2mm or greater) of adjacent apexes of the rows of nitinol diamonds (indicating suture breakage) or progressive angulation/migration, to monitor for any changes.

ADVISE

NOTICE

Continue to monitor all intact AneuRx Stent Grafts with plain abdominal X-rays on an annual basis. In all cases, the benefit of periodic radiographic screening of the AneuRx Stent Graft should be weighed against the risks from radiation exposure on an individual patient basis, in line with the requirements of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000.

Follow-up of all patients should also include other imaging modalities such as contrast-enhanced CT, to monitor for signs of progressive endoleak or aneurismal growth. See Advice Notice (NI) 2000/04.

Report all incidents of loss of device integrity or other adverse incidents involving AneuRx Stent Grafts to Medtronic AVE and NIAIC. Ensure that any explanted Stent Grafts are retained for analysis by Medtronic AVE, according to their explant analysis procedure.

Send copies of any X-rays showing confirmed/suspected nitinol wire fracture, or significant nitinol row separation, together with details of any clinical sequelae and the patient's overall state of health, to NIAIC. This will enable a clearer understanding of the true prevalence of Stent Graft fractures and their clinical significance to be gained.

BACKGROUND

The AneuRx Stent Graft System is used to treat abdominal aortic aneurysms and comprises a polyester graft sutured to the inside of a nitinol wire-frame. There are no proximal fixation hooks as attachment is achieved by radial force. Approximately 20,000 bifurcated AneuRx Stent Grafts have been distributed worldwide since March 1997, some 700 of which are within the UK.

NIAIC has recently been advised of two UK incidents in which nitinol wire fracture was confirmed following explantation of bifurcated AneuRx Stent Grafts. Both patients underwent successful surgical conversion. In one case plain radiographs of the Stent Graft 12 months after implantation identified separation of the apexes of the diamonds of the nitinol wire-frame, due to breakage of the sutures joining adjacent rows, although the patient remained asymptomatic. Follow-up 12 months later identified fractures in the nitinol wire-frame, fragments of which had broken away completely, together with a proximal endoleak due to graft angulation and distal migration during the intervening period. In the other case, imaging of the Stent Graft revealed evidence of graft migration and endoleak. The nitinol wire fracture was identified when the Stent Graft was removed 27 months after implantation and graft holes/weave separation were also evident in places.

Medtronic AVE has confirmed that fatigue fractures were observed in 3 of the other 8 explanted AneuRx Stent Grafts which they have analysed to date. Although the total number of Stent Grafts in which nitinol fractures were confirmed at explant represents only 0.05% of the distributed population, a clearer understanding of the true prevalence of fractures and their clinical significance is required. Copies of X-rays showing signs of nitinol fracture/row separation in other AneuRx Stent Grafts will therefore be reviewed and correlated with any corresponding patient symptoms, to enable further patient management advice to be issued as appropriate.

In May 2000 Medtronic AVE issued a Safety Notice to customers providing details of 10 incidents of aneurysm rupture among 1112 patients enrolled within a US pre-market clinical trial of the bifurcated AneuRx Stent Graft. This Notice, and Advice Notice (NI) 2000/04, issued in June 2000, provided advice on optimum patient selection and monitoring to minimize the risk of aneurysm rupture. The advice contained in this Advice Notice supplements that provided in Advice Notice (NI) 2000/04 which remains applicable.



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References:

1. SR2000 No 194. The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000.
2. Advice Notice (NI) 2000/04 June 2000 "AneuRx Stent Graft System: Risk of Aneurysm Rupture".

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Ms C McGrath
QA Section Head
Medtronic AVE
Parkmore Business Park West
Galway
Ireland

Tel: 00353 91 708 686
Fax: 00353 91 757 524

Enquires to the NIAIC should quote the reference number AN (NI) 2000/
and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Marked for the attention of Mr Brian Godfrey

Tel: 02890 523714
Fax: 02890 523900
Email: brian.godfrey@dhsspsni.gov.uk

Brian Godfrey
NIAIC Manager



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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 Safety Notice SN (NI) 2000/NIAIC. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided.

*Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Áisíneacht Feidhmeannach don Roinn Sláinte. Serbhíst Sóisialta agus Sábháilteacht Phoiblí*