



DEFECT & INVESTIGATION CENTRE

FOR ACTION BY:

Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
General Manager/Chief Executive of each Agency
General Practitioners

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ADVICE NOTICE (NI) 2000/04

Date: 16 June 2000

Product	:	AneuRx Stent Graft System Risk of Aneurysm Rupture
Manufacturer/ Supplier	:	Medtronic AVE
Issue	:	Abdominal aortic aneurysm rupture among patients implanted with the bifurcated AneuRx Stent Graft System at times ranging from a few hours to over 2 years after implantation
Action	:	See Section 2 overleaf

ADVICE NOTICE

1. ATTENTION CHIEF EXECUTIVES/GENERAL MANAGERS

This Advice Notice should be brought to the immediate attention of all who need to know, or be aware of it including those listed below, in accordance with local procedures, and immediate action should be taken as detailed overleaf:

- ◆ Medical Directors
- ◆ Nursing Directors
- ◆ Vascular Surgeons
- ◆ Directors of Radiology
- ◆ Theatre Staff
- ◆ Radiologists
- ◆ Catheter Laboratory Managers
- ◆ R & I Units
- ◆ Safety Liaison Officers
- ◆ Risk Managers

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



2. IMMEDIATE ACTION

Ensure that imaging undertaken immediately pre-operatively accurately shows the aorta/aneurysm anatomy and morphology. Do not implant the AneuRx Stent Graft System in patients in whom the aortic neck for proximal attachment is:

- ◆ angulated more than 60°, or
- ◆ angulated more than 45°, and shorter than 1.5 cm, or
- ◆ shorter than 1.0 cm, or
- ◆ heavily calcified.

Ensure that proximal placement of the AneuRx Stent Graft System is as high as safely possible in the infrarenal aorta, while maintaining good aneurysmal coverage.

Follow-up patients in whom pre-discharge imaging reveals evidence of mild to moderate endoleak, aneurysmal growth, or device migration, at no more than 3-monthly intervals, to assess the need for further intervention. Follow-up all other patients at no more than 6-monthly intervals.

Patient follow-up should include plain abdominal X-rays to monitor device integrity and/or migration, and contrast enhanced CT imaging to detect signs of progressive endoleak or aneurysmal growth.

Consider the need for endovascular or surgical intervention in view of the risk of aneurysm rupture, in patients with:

- ◆ tenderness to abdominal palpation, or
- ◆ successive images showing evidence of aneurysmal growth of more than 5mm, or
- ◆ persistent or late endoleak, or
- ◆ graft migration.

Report all incidents of AneuRx Stent Graft System migration/loss of integrity, aneurysmal rupture or other adverse events to Medtronic AVE and to NIDIC. Ensure that any explanted stent grafts are retained for analysis according to Medtronic AVE's explant procedure.

3. BACKGROUND

The AneuRx Stent Graft System is used to treat abdominal aortic aneurysms and has been available since March 1997. Nearly 10,000 bifurcated stent grafts have been distributed world-wide, with approximately 330 in the UK. It is estimated that about 90% of these will have been implanted to date. Medtronic AVE recently issued a Safety Notice (dated May 2000) to customers, providing details of 10 incidents of aneurysm rupture, 4 of which were fatal, among 1112 patients enrolled within a US pre-market clinical trial of the bifurcated stent graft. The Department is aware of one further incident of aneurysm rupture involving a UK patient, 17 months after stent graft implantation.

The cause of the aneurysm ruptures is not fully understood. However a number of cases involved proximal endoleaks associated with patients in whom the aneurysm had a short or severely angulated proximal neck. The AneuRx Stent Graft System comprises a polyester graft sutured to the inside of a nitinol wire-frame with no proximal fixation hooks as attachment is achieved by radial force alone. In order to minimize the risk of proximal migration or endoleak, it is important to apply rigorous patient selection criteria to ensure anatomical compatibility with the stent graft design.

More than half of the reported aneurysm ruptures occurred over a year after the devices were implanted, and there is limited data yet available associated with longer implant durations. Therefore continued assessment of implanted stent grafts at regular intervals is essential.

Following these incidents Medtronic AVE has reviewed films from the periodic follow-up of 250 AneuRx patients, comparing those with optimal and sub-optimal outcomes in order to refine the recommendations in their instructions for use. The Company has confirmed that within the next two weeks they will issue a Technical Bulletin to supplement their Safety Notice, providing detailed information on the important changes to the patient selection, imaging and follow-up requirements for the AneuRx Stent Graft System.

Recall of AneuRx Stent Graft Systems with 21F Tapered Nosecone and Integrated Delivery Systems

The Department has also recently been informed of the imminent recall of a small population of AneuRx Stent Graft Systems for reasons which are entirely unrelated to the risk of aneurysm rupture and the refinement of recommendations in the instructions, detailed above.

The recall is being undertaken because of the potential for partial or full detachment of the nosecone from the delivery catheter during stent graft deployment, affecting only devices supplied with either the 21F catheter with Tapered Tip, or the Integrated Delivery System. There are no implications for successfully implanted stent grafts.

If you are one of the 10 UK hospitals to which affected stent grafts were distributed, you will shortly receive a communication from Medtronic AVE with full details of the recall and relevant serial numbers. The Department will be reviewing this action and further advice will be issued if necessary.

4. 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

Enquiries regarding this notice should be addressed to:

NORTHERN IRELAND DEFECT & INVESTIGATION CENTRE (NIDIC)

Health Estates
Estate Policy
Stoney Road
Dundonald

Belfast BT16 1US *marked for the attention of Mr Brian Godfrey*

Tel: 028 90 523714

Fax: 028 90 523900

Email: brian.godfrey@dhsspsni.gov.uk

Yours faithfully

Brian Godfrey
Defect Centre Manager

HOW TO REPORT DEFECTS

Professional Estate Letter PEL(93)36 issued by Estate Services Directorate, on 27th July 1994 advises Health and Social Services Boards, HSS Trusts and agencies how to notify HPSS about accidents with and defects in medicinal products, buildings and plant, medical devices and other medical and non medical equipment and supplies.