

**AN (NI) 2001/01**

**DATE: 12 January 2001**

**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:**

**VANGUARD™ ENDOPROSTHESES:  
UPPER STENT ROW SEPARATION WITH OR  
WITHOUT NITINOL WIRE FRACTURE**

**MANUFACTURER/SUPPLIER**

Boston Scientific Corporation

**PROBLEM**

Separation of the top two rows of the nitinol frame, with or without fracture of the wire, within the endoprosthesis 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
- Directors of Radiology
- Medical Directors
- Vascular Surgeons
- Nursing Directors
- Radiologists
- Medical, Nursing and Care Staff
- Catheter Laboratory Managers
- General Medical Practitioners

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.

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## **ACTION**

X-ray all implanted Vanguard™ endoprostheses which have not been X-rayed within the last 3 months to identify any separation of the top rows of the stent frame (indicating suture tie breakage) or any fractures of the nitinol wire. Imaging should include adequately coned plain abdominal X-rays in AP, lateral, and bilateral oblique views to ensure a detailed display of the proximal portion of the endoprosthesis. Ensure that the detailed advice regarding X-ray film quality, identifying significant row separation/wire fracture and counting suture tie breakages, provided in Boston Scientific's technical document is followed<sup>1</sup>.

Consider the need for further endovascular/surgical intervention or repeated 3-monthly X-raying if three or more adjacent apices of the top two stent rows have suffered significant separation (3mm or greater) or if this has progressed to stent-wire fracture.

Consider the need for repeated 6-monthly X-raying of Vanguard™ endoprostheses showing significant separation (3mm or greater) of any apices of the top two rows of the nitinol frame to monitor for an increase in the number of suture tie breakages. The patient should also be assessed for continued aneurysmal exclusion using contrast enhanced CT.

Continue to monitor all intact Vanguard™ endoprostheses with plain abdominal X-rays on an annual basis. Also include other imaging modalities such as contrast-enhanced CT in patient follow-up, to monitor for signs of progressive endoleak, mid-graft holes, or significant graft angulation as detailed in Safety Action Notice SAN(NI)99/02<sup>2</sup>. In all cases, the benefit of periodic radiographic screening of the endoprosthesis should be weighed against the risks from radiation exposure on an individual patient basis, in line with the requirements of IR(ME)R(NI)2000<sup>3</sup>.

Report all incidents of nitinol row separation/wire fracture or other adverse incidents involving Vanguard™ Endoprostheses to Boston Scientific and to NIAIC. Ensure that any explanted endoprostheses are retained for analysis, in accordance with the manufacturer's instructions.

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

## **BACKGROUND**

The Vanguard™ endoprosthesis comprises a polyester graft sutured to the outside of a nitinol wire frame. It was among the first to be made commercially available, with approximately 4200 endoprostheses having been implanted worldwide since mid-1996 (232 in the UK).

Boston Scientific issued a letter<sup>4</sup> dated 10 October 2000 to all Vanguard™ cutomers, drawing attention to incidents of separation of the stent apices in the upper two rows of the endoprosthesis, some with associated nitinol wire breakage, which has been identified by X-ray at routine patient follow-up. Row separation can occur due to breakage of the polypropylene sutures joining adjacent apices of the rows of diamonds of the nitinol frame.

To date there have been no confirmed UK reports of row separation, although two cases are currently under investigation. However, a review of Vanguard™ patients in the manufacturer's US clinical study revealed a 21% prevalence of separation of three or more adjacent apices. In some cases the entire upper row separated from the remaining portion of the endoprosthesis, allowing distal graft migration. The progression to total



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row separation, however, occurs slowly and should be detectable by serial X-ray screening. Row separations have been observed between 6 months and 3 years after device implantation and there does not appear to be a characteristic time associated with initial breakage of the sutures between rows. A small proportion of patients with endoprostheses showing row separation also experienced an increase in aneurysmal sac diameter or device migration, or required endovascular repair. The relationship, however, between these clinical sequelae and the row separations remains under investigation.

In December 2000 Boston Scientific followed up their earlier letter with additional advice to customers on how to identify implanted endoprostheses suffering from this phenomenon<sup>1</sup>. Detailed information was provided on the quality and nature of X-ray films required to identify apical separations, how to determine the separation between rows, and the identification of nitinol wire fractures. A series of illustrative X-rays showing the various manifestations of these problems was also provided.

Boston Scientific is continuing to investigate the root cause of the row separations through bench testing and clinical review, to help further define this safety issue and to validate potential design solutions. Further advice will be issued as necessary.

In February 1999, a Safety Action Notice SAN(NI)99/02<sup>2</sup> was issued drawing attention to various late complications associated with Vanguard<sup>TM</sup> endoprostheses including breakage of the sutures attaching the graft to the nitinol wire frame, mid-grafts holes, graft angulation and endoleaks. The advice given regarding the need to monitor for these changes remains applicable.

#### **REFERENCES:**

1. Letter from Boston Scientific dated 10 December 2000 with technical document, "Physician Information: Vanguard<sup>TM</sup> Upper Row Separation".
2. SAN(NI)99/02 February 1999, "Vanguard<sup>TM</sup> Endovascular Aortic Graft: Late Complications".
3. SR2000 No 194. The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000.
4. Letter from Boston Scientific dated 10 October 2000.

#### **ENQUIRIES**

Enquiries to the manufacturer, including requests for copies of their letters/technical document, should be addressed to:

Mr Brian Howlett  
General Manager  
Boston Scientific Ltd  
New England House  
Sandridge Park  
Porters Wood  
St Albans  
Herts  
AL3 6PH

Tel: 01727 797 608  
Fax: 01727 865 862

Enquires to the NIAIC should quote the reference number AN (NI) 2001/01 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](mailto: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) 2001/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided.

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