

**AN (NI) 2002/05**

**DATE: 15 May 2002**

**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:**

**TALENT STENT GRAFT SYSTEM: CONNECTOR  
BAR AND STENT SPRING FRACTURE AFTER  
IMPLANTATION**

**MANUFACTURER/SUPPLIER**

Medtronic AVE

**PROBLEM**

Fracture of the nitinol connector bar and stent springs within the TALENT stent graft following implantation (time of occurrence unknown).

**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
- Medical Directors
- 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.

**IMMEDIATE ACTION**

1. Ensure that recent X-rays (taken within the last 6 months) of all implanted TALENT stent grafts are available for review, illustrating the appearance of the ipsilateral connector bar and stent springs. Where new X-rays are needed, these 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.
2. Review the most recent X-rays for evidence of connector bar or stent spring fracture, or for evidence of significant limb kinking which might be indicative of connector bar fracture.
3. Consider 6-monthly X-raying of all TALENT stent grafts with evidence of wire fracture/significant limb kinking, but no clinical sequelae, to monitor for any changes in appearance. Where no changes occur over a two year period, normal annual X-raying should be resumed.
4. Consider the need for further endovascular or surgical intervention if stent fracture/kinking is accompanied by clinical complications such as limb thrombosis, significant device migration, or Type I endoleak.
5. Continue to monitor all intact endovascular prostheses, including TALENT stent grafts with plain abdominal X-rays on an annual basis. In all cases, the benefit of periodic radiographic screening of the TALENT stent graft should be weighed against the risks from radiation exposure on an individual patient basis, in line with the requirements of IR(ME)R 2000<sup>1</sup>.

**ADVISE**

**NOTICE**

6. Ensure, for all future implantations of TALENT stent grafts, that the connector bar of the contralateral limb is orientated in the medial position, ie the outside of the bend at the natural iliac bifurcation.
7. Report all adverse incidents involving TALENT grafts, including confirmed or suspected cases of connector bar or spring fracture, to Medtronic AVE and to NIAIC. Ensure that any explanted stent grafts are retained for analysis by Medtronic AVE, according to their explant analysis procedure.
8. Send copies of any X-rays showing confirmed/suspected connector bar or spring fracture, together with details of any associated clinical sequelae, to Medtronic AVE and to NIAIC. This will enable a clearer understanding of the longer-term clinical significance of stent fracture to be gained.



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## **BACKGROUND**

The TALENT stent graft system is used to treat abdominal aortic aneurysms and comprises a polyester graft sutured to a nitinol wire-frame. Approximately 17,000 TALENT stent grafts have been distributed worldwide since 1995, over 400 of which are within the UK.

The TALENT stent graft has been undergoing US pre-market clinical trials since 1997. Among this trial population, 24 connector bar fractures and 6 spring fractures have been confirmed to date from review of patient X-rays, representing a prevalence of 5.6% and 1.4% respectively. The prevalence of reported fractures among the worldwide patient population is considerably lower, although this may be due to less scrutiny of plain X-rays of the device after implantation. Within the UK there has been only one confirmed incident of connector bar fracture.

It is important that all patients are screened during follow-up for evidence of device fracture or kinking of the iliac limbs, which may be indicative of connector bar fracture. Imaging with multiple projection plain abdominal X-ray will illustrate device integrity most clearly, although potentially related characteristics such as limb kinking etc may also be evident using contrast enhanced CT or angiography.

Statistical analysis of the connector bar fractures has confirmed a possible correlation with thrombotic events. However, this analysis is based upon only three events, and the reasons behind any apparent link with connector bar fracture are not known. To date there have been only limited clinical sequelae in general associated with the incidents of connector bar or spring fracture, but as yet the long-term effects of fracture are unknown.

The TALENT stent graft incorporates a longitudinal nitinol wire (known as the connector bar) joining the circumferential stent rings or springs, along the length of both the ipsilateral (integral) and contralateral (separate) device limbs. Within the ipsilateral limb, the connector bar lies along the inside of the curve (lateral position) formed by the natural iliac bifurcation (see diagram). For the contralateral limb, however, the clinician is able to choose to orientate the connector bar along the outside (medial position) of this curve where the angle is usually less acute.

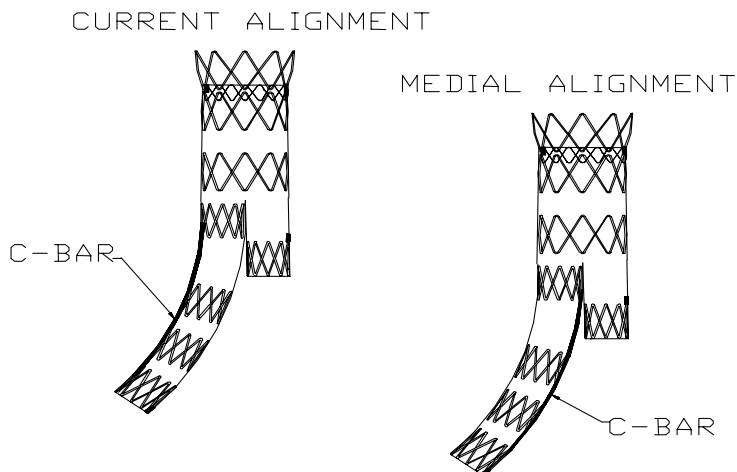
The vast majority of connector bar fractures have occurred in the ipsilateral limb. Explant analysis has confirmed these to be fatigue fractures which began some time after device implantation. It is believed that the tighter angle to which the lateral connector bar in the ipsilateral leg is subjected, compared with medial placement for the contralateral leg, may be giving rise to these fatigue fractures.

Medtronic has therefore redesigned the TALENT stent graft to reduce the risk of fracture, by moving the connector bar of the ipsilateral limb to the medial position (see diagram). Modified devices will shortly be made available. In addition, the surface uniformity of the nitinol wire has been improved to remove irregularities, which may have given rise to fatigue crack propagation.

**ADVICE**

**NOTICE**

**Diagram of TALENT stent graft: Connector Bar (C-Bar) Orientation  
(copied from Medtronic Product Update of April 2002)**



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Medtronic AVE issued a Product Update to customers in April 2001, and more recently one dated April 2002, confirming the presence of connector bar and stent spring fractures among patients implanted with the TALENT stent graft. This latest communication provided detailed advice on patient screening to monitor the integrity and effectiveness of the TALENT stent graft, together with examples of X-rays illustrating the typical appearance of connector bar and spring fractures.

References:

SI 2000 No. 1059. The Ionising Radiation (Medical Exposure) Regulations 2000.

### **ENQUIRIES**

Enquiries to the manufacturer should be addressed to:

Ms C McGrath – QA Section Head

Medtronic AVE

Parkmore Business Park West

Galway

Ireland

Tel: 00 353 91 708 686

Fax: 00 353 91 757 524

Enquires to the NIAIC should quote the reference number AN (NI) 2002/05 and be addressed to:

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

Tel: 02890 523714

Fax: 02890 523900

Email: [brian.godfrey@dhsspsni.gov.uk](mailto:brian.godfrey@dhsspsni.gov.uk)

Brian Godfrey  
NIAIC 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 Safety Notice SN (NI) 2002/01. 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](http://www.dhsspsni.gov.uk/niaic)

*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*

**ADVICE  
NOTICE**