

AN (NI) 2002/09
DATE: 2 September 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



TITLE:
NIROYAL CORONARY STENT: RADIAL STENT FRACTURE AFTER IMPLANTATION

NORTHERN IRELAND ADVERSE INCIDENT CENTRE

MANUFACTURER/SUPPLIER
Boston Scientific Scimed, Inc.

PROBLEM

There have been nine reports of radial fractures of NIRoyal coronary stents occurring at varying times after implantation. In eight cases the patients presented with recurrent angina.

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
- Clinical Directors
- Consultant Cardiologists
- 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. Be aware of the possibility of a radial fracture if patients implanted with NIRoyal coronary stents present with angina. (No change to clinical management is indicated for asymptomatic patients).
2. Report any suspected or known cases of radial stent fracture to Boston Scientific and to NIAIC.
3. Take the information contained in this Notice into account when making a future choice of coronary stent.

BACKGROUND

NIRoyal stents have been available since 1998 and approximately 200,000 stents have been distributed world-wide. Since March 2000, Boston Scientific Scimed, Inc. has received nine reports of radial fracture following implantation of a NIRoyal Coronary stent. Eight events have occurred in the US and one in Germany. Five premounted stent systems have been affected:

- NIRoyal stent
- NIRoyal premounted stent system
- NIRoyal Advance premounted stent system
- NIRoyal Elite Monorail premounted stent system
- NIRoyal Elite over-the-wire premounted stent system

ADVICE NOTICE

BACKGROUND(continued)

In eight out of the nine cases the patients have presented with angina and six patients underwent re-intervention or CABG. The fractures have been detected between three weeks and nine months post implantation. The nine incidents have involved stents 15 mm to 32 mm long. In four cases, two or more overlapping stents were used.

Boston Scientific has been conducting a review of these incidents and, from the fluoroscopy available, the condition appears as "a discrete linear gap in the mesh pattern of the stent with varying degrees of stent deformation". At present no root cause has been determined.

Boston Scientific issued a Product Information Alert to users in June 2002.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Mr Brian Howlett or Mr Peter Dekkers
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) 2002/09 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

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

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



HEALTH ESTATES

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**NORTHERN
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ADVICE

NOTICE