

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/40

Update of MDEA(NI)2004/37

Issued: 6 August 2004

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	✓
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
<p>Medical Device/Equipment: Boston Scientific: Taxus™ Express²™ Paclitaxel-Eluting coronary stent systems; Express²™ coronary stent systems.</p>	▶ ①
<p>Problem: Extension of recall relating to potential balloon deflation problems during coronary stent deployment.</p>	▶ ②
<p>Action by: All cardiologists, interventional radiologists and cardiothoracic surgeons who implant Taxus™ Express²™ Paclitaxel-Eluting Coronary Stents and Express²™ coronary stents.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Note that the recommendations in this Update supersede the advice given MDEA/2004/37 issued on 26 July 2004. Do not implant any: <ul style="list-style-type: none"> Taxus™ Express²™ coronary stents labelled with 'use by' dates earlier than October 2005; Express²™ coronary stents labelled with 'use by' date of before June 2006. Review your stocks of coronary stents and identify those affected. Immediately segregate all affected products and return to Boston Scientific in accordance with their instructions. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5</p>	▶ ⑤
<p>Contacts Details of manufacturer, NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC Report all stent deployment difficulties to NIAIC and the stent manufacturer.</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Boston Scientific: Taxus™ Express²™ Paclitaxel-Eluting coronary stent systems; Express²™ coronary stent systems.

2. PROBLEM:

Further to NIAIC's Medical Device Equipment Alert **MDEA/2004/37** issued 26 July 2004, Boston Scientific has now expanded its world-wide recall of 16 July 2004, to include additional products of its Taxus™ Express²™ Paclitaxel-Eluting coronary stent systems and Express²™ coronary stent systems. The Medicines and Healthcare products Regulatory Agency (MHRA) has reviewed the corrective action already taken by the Company.

The further recall was necessary because the manufacturer identified that some affected products, which had been repackaged, had not been listed in the previous recall notification. There is no change to the underlying cause of the problem. The manufacturer has identified that in some cases a narrowing of the balloon deflation lumen in the delivery catheter may occur during catheter manufacture. This narrowing may have inhibited balloon deflation resulting in patient death or the need for surgical conversion.

The manufacturer has confirmed that remaining products have been subject to increased inspection to ensure that all units remaining on the market meet specification. Virtually all products distributed in the UK which pre-date this manufacturing improvement (implemented in May 2003 for Express²™ and in April 2004 for Taxus™ Express²™) are affected by this recall. Therefore, MHRA is advising that identification of products to be returned to the manufacturer should be based upon the product 'use by' date, since this can be correlated with the manufacturing date. Express²™ stent systems have a three-year shelf-life and Taxus™ Express²™ stent systems have an 18-month shelf-life. The 'use by' date for both products is printed on the outer box label and on the inner pouch label in the format: YYYY-MM.

A revised analysis by the manufacturer indicates that this recall now covers approximately 23,000 Express²™, and approximately 16,000 Taxus™ Express²™ stent systems distributed in the UK, and a total of 162,000 stent systems worldwide.

Many of the devices covered by this recall have already been implanted. Patients who have already had stents successfully implanted are not affected by this problem as the issue only affects the delivery of the stent at the time of stent placement.

3. ACTION BY:

All cardiologists, interventional radiologists and cardiothoracic surgeons who implant Taxus™ Express²™ Paclitaxel-Eluting Coronary Stents and Express²™ coronary stents.

4. ACTION:

- Note that the recommendations in this Update supersede the advice given MDEA/2004/37 issued on 26 July 2004.
- Do not implant any:
 - Taxus™ Express²™ coronary stents labelled with 'use by' dates earlier than October 2005;
 - Express²™ coronary stents labelled with 'use by' date of before June 2006.
- Review your stocks of coronary stents and identify those affected.
- Immediately segregate all affected products and return to Boston Scientific in accordance with their instructions.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Medical Directors
- Cardiologists
- Medical and Nursing Staff
- Cardiothoracic surgeons
- Supplies Staff (RSS)
- Catheter laboratory managers
- Independent Health and Care Providers – Private Clinics through HSS Board R& I Units
- Interventional radiologists
- Operating Theatre Staff
- Radiology department managers
- Coronary Care
- Clinical Governance Leads

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Duncan Watson or Jane Roberts
Boston Scientific Ltd.
New England House
Sandridge Park
Porters Wood
St. Albans
Herts AL3 6PH

Tel: 01727 831 666

Fax: 01727 797 675

E-mail: duncan.watson@bsci.com jane.roberts@bsci.com

Enquires to NIAIC should quote reference number MDEA(NI)2004/40 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

Report all stent deployment difficulties to NIAIC and the stent manufacturer



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 MDEA(NI)2004/01. 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

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety