

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/37

Issued: 26 July 2004

For:

<b>IMMEDIATE ACTION</b>	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



HEALTH ESTATES

**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<p><b>Medical Device/Equipment:</b> Boston Scientific: Taxus™ Express<sup>2™</sup> Paclitaxel-Eluting Coronary Stent Systems Express<sup>2™</sup> Coronary Stent Systems</p>	▶ ①
<p><b>Problem:</b> Recall of certain batches due to potential balloon deflation problems during coronary stent deployment.</p>	▶ ②
<p><b>Action by:</b> All cardiologists, interventional radiologists and cardiothoracic surgeons who implant Taxus™ Express<sup>2™</sup> Paclitaxel-Eluting Coronary Stents and Express<sup>2™</sup> Coronary Stents.</p>	▶ ③
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>• Do not implant any Taxus™ Express<sup>2™</sup> or Express<sup>2™</sup> coronary stents until you have received and acted upon the recall notification from Boston Scientific.</li> <li>• Upon receipt of the recall notification: <ul style="list-style-type: none"> <li>➢ Review your stocks of coronary stents and identify those included in the recall</li> <li>➢ Immediately segregate all coronary stents included in the recall and return them to Boston Scientific in accordance with their instructions</li> <li>➢ Only implant coronary stents <b>not included</b> in the recall.</li> </ul> </li> <li>• If you hold stocks of Taxus™ Express<sup>2™</sup> or Express<sup>2™</sup> coronary stents and you have not received a recall notification from Boston Scientific by <b>29 July 2004</b>, return all products to the manufacturer.</li> </ul>	▶ ④
<p><b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers <b>For onward distribution see Section 5</b></p>	▶ ⑤
<p><b>Contacts</b> Contacts for manufacturer/supplier, clinical and technical information and advice.</p>	▶ ⑥
<p><b>Feedback Requirements to NIAIC</b> 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™ Express<sup>2™</sup> Paclitaxel-Eluting Coronary Stent Systems Express<sup>2™</sup> Coronary Stent Systems

## 2. PROBLEM:

Boston Scientific has initiated a world-wide recall of certain batches of its Taxus™ Express<sup>2™</sup> Paclitaxel-Eluting Coronary Stent Systems and Express<sup>2™</sup> Coronary Stent Systems because of balloon deflation problems during coronary stent deployment. Both devices use the same delivery catheter systems. 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 inhibit balloon deflation and may necessitate surgical conversion or lead to patient death. The MHRA is continuing to investigate.

### Taxus™ Express<sup>2™</sup> Paclitaxel-Eluting Coronary Stent Systems

To date Boston Scientific has distributed more than 500,000 Taxus™ Express<sup>2™</sup> stent systems world-wide and has received reports of one death and 18 serious injuries related to balloon deflation problems. In the UK the company has distributed these products to 75 hospitals and received reports of one incident with no deaths. The UK recall involves approximately 26,000 products.

### Express<sup>2™</sup> Coronary Stent Systems

To date Boston Scientific has distributed more than 600,000 Express<sup>2™</sup> stent systems world-wide and has received reports of two deaths and 25 serious injuries related to balloon deflation problems. In the UK the company has distributed these products to 62 hospitals and received reports of two incidents with no deaths. The UK recall involves approximately 15,000 products.

Some 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.

## 3. ACTION BY:

All cardiologists, interventional radiologists and cardiothoracic surgeons who implant Taxus™ Express<sup>2™</sup> Paclitaxel-Eluting Coronary Stents and Express<sup>2™</sup> Coronary Stents.

## 4. ACTION:

Due to the number of products involved, it is not possible to include a full list of products in this alert.

A comprehensive list of all Taxus™ Express<sup>2™</sup> Paclitaxel-Eluting Coronary Stent System and Express<sup>2™</sup> Coronary Stent System batches subject to this recall can be found on the MHRA website at <http://www.mhra.gov.uk>

Batches not included on the list are not affected by the recall.

## 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:

- Cardiologists
- Cardiothoracic surgeons
- Catheter laboratory managers
- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Interventional radiologists
- Radiology department managers
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Medical, Nursing and Care Staff
- Supplies Staff (RSS)
- Independent Health and Social Care Providers
- Operating Theatre Staff
- Coronary Care

## 6. CONTACTS:

Enquiries to the manufacturer/supplier 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 831666

Fax: 01727 797675

Clinical aspects - enquiries to the MHRA should quote reference number **2004/007/020/291/007** and be addressed to:

Dr Susanne Ludgate  
Medicines & Healthcare products Regulatory Agency  
Hannibal House  
Elephant and Castle  
London SE1 6TQ

Tel: 020 7972 8123

Fax: 020 7972 8111

E-mail: [susanne.ludgate@mhra.gsi.gov.uk](mailto:susanne.ludgate@mhra.gsi.gov.uk)

Enquires to NIAIC should quote reference number MDEA(NI)2004/37 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](mailto: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](http://www.dhsspsni.gov.uk/niaic)

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