

Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/24

Issued: 3 September 2003



NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE

For:

IMMEDIATE ACTION	
ACTION	
UPDATE	
INFORMATION REQUEST	✓

	Section
Medical Device/Equipment: CYPHER™ Sirolimus-eluting Coronary Stent.	▶ ①
Problem: Reports of in-stent thrombosis.	▶ ②
Action by: All cardiologists and radiologists performing coronary angioplasty procedures and stenting.	▶ ③
Action: Report all adverse incidents related to this device and in particular instances of in-stent thrombosis. Be aware of the precautions and contraindications documented in the manufacturer's instructions for use.	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤
Contacts Manufacturer and NIAIC contact details	▶ ⑥
Feedback Requirements to NIAIC Clinicians who become aware of adverse events associated with in-stent thrombosis in patients implanted with CYPHER™ Sirolimus-eluting Coronary Stents, should inform NIAIC and the manufacturer as soon as possible. NIAIC will be liaising with the Medicines and Healthcare products Regulatory Agency (MHRA) on a UK wide basis concerning this issue.	▶ ⑦

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

1. DEVICE/EQUIPMENT:

CYPHER™ Sirolimus-eluting Coronary Stent manufactured by Cordis/Johnson & Johnson.

2. PROBLEM:

Cordis has received a number of reports from clinicians of probable in-stent thrombosis for the CYPHER™ Sirolimus-eluting Coronary Stent.

The stent is a pre-mounted balloon expandable stainless steel stent. It is coated with a polymer containing Sirolimus, an anti-proliferate drug aimed at reducing the incidence of neointimal hyperplasia and restenosis.

In the USA, approximately 100,000 of these devices have been implanted since US approval was granted in April 2003. To date there have been 92 reports involving 117 devices of probable in-stent thrombotic events in the USA. The manufacturer has recently issued a letter to clinicians in the USA indicating that, while the specific reasons for reported in-stent thrombosis remain unclear, use of the devices without following the manufacturer's instructions for use, may be a contributory factor in some instances. The Cordis letter has also reminded clinicians in the USA of the indications and contraindications for the use of this product, as summarised in 'Action' below.

The CYPHER™ stent was approved for free sale in Europe in April 2002. The rate of reported in-stent thrombosis in Europe is lower than in the USA (see table below).

Number of thrombotic events received by Cordis as at 22 July 2003:

	Number of thrombosed stents	Approximate number of stents implanted	Approximate rate of incidence per 1,000
UK	3	9,000	0.30
Europe (excluding UK)	3	35,000	0.09
USA	117	100,000	1.17
Rest of the world (excluding USA, UK and Europe)	19	82,000	0.23
Total	142	226,000	0.63

The factors contributing to the occurrence of in-stent thrombosis in the USA and the significance of these findings to UK clinical practice are unclear.

3. ACTION BY:

All clinicians who implant coronary stents, particularly the CYPHER™ Sirolimus-eluting Coronary Stent.

4. ACTION:

Report all adverse incidents observed with the CYPHER™ stent (e.g. thrombosis and deployment problems etc.) as directed in the 'Feedback' section of this Medical Device/Equipment Alert (see below).

Clinicians using the CYPHER™ stent should be aware of the following indications, precautions and contraindications recommended by the manufacturer:

Patient selection	The CYPHER™ stent is indicated for improving coronary luminal diameter in previously untreated vessels and is not indicated for the treatment of in-stent restenosis, or in the setting of acute myocardial infarction.
Size selection	The size of stent used must closely match the reference vessel diameter. Do not use stents of incorrect size for the intended anatomy or under-expand the stent.
Deployment technique	The stent must be fully deployed and in contact with the target vessel wall. Do not directly stent the target vessel, but predilate the lesion with a balloon catheter. Limit the length of the balloon to keep the region of vessel wall injury caused by the balloon to within the stent deployment area.
Antiplatelet regimen	To reduce the risk of thrombosis, comply strictly with recommended pre and post procedure antiplatelet regimens (two months antiplatelet therapy is recommended in the instructions for use, extension beyond this may be considered in higher risk cases).

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
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Cardiologists
- Interventional radiologists
- Radiology department managers
- Medical directors
- Catheter laboratory managers
- Adult & paediatric intensive care units

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Lisa Kingham
Business Co-ordinator
Cordis, Johnson and Johnson
Coronation Road
Ascot
Berkshire, SL5 9EY

Tel: 01344 871 193

Fax: 01344 871 160

Enquires to NIAIC should quote reference number MDEA(NI)2003/24 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:

NIAIC in conjunction with MHRA is seeking to gain a wider understanding of the incidence and significance of any problems experienced with the Cordis CYPHER™ stent and is keen to hear from NI clinicians about any incident where in-stent thrombosis is confirmed.

Whilst information is sought about postoperative experience, any perioperative issues relating to stent deployment should also be reported.

A report form specific to the Cordis CYPHER™ stent is appended to this Medical Device/Equipment Alert.

Reports may be submitted to NIAIC as indicated in 'HOW TO REPORT ADVERSE INCIDENTS'.

The MHRA is also working closely with other regulatory authorities and the manufacturer, to identify any issues of significance that may relate to the use of this device.

NIAIC and MHRA would also like to receive reports from clinicians that become aware of adverse incidents with stents in general.



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) 2003/01. 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

NIAIC Information Request Form
Cordis - CYPHER™ Sirolimus-eluting Coronary Stent

Origin of report:
Reporting Body.....
Address.....
Reporter.....
Position.....
Telephone Number.....
Consultant in charge (if known).....

Which of the following have you observed to date?
(Please tick appropriate boxes):

- In-stent thrombosis Number of cases (if known).....
- Other (please give details below) Number of cases (If known).....
- No known problems

Please indicate the number of CYPHER™ stents that have been implanted at your centre []

Further details:

Please send completed form by post to: NIAIC, Health Estates, Stoney Road, Dundonald, BT16 1US
or by fax to: **028 9052 3900**