

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/46

Issued: 25 August 2004

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	



NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE

	Section
Medical Device/Equipment: Endomed Inc: Endofit™ Thoracic Endoluminal Stent Graft	▶ ①
Problem: New contraindications regarding device placement.	▶ ②
Action by: All Interventional Radiologists and Vascular Surgeons who implant endoluminal stent grafts	▶ ③
Action: <ul style="list-style-type: none"> Do not implant the Endofit™ Thoracic Endoluminal Stent Graft in the aortic arch or ascending aorta. It is indicated for use in the descending thoracic aorta only. Do not implant the Endofit™ Thoracic Endoluminal Stent Graft or extender Cuff with external fixation (i.e. proximal uncovered stent ring) in the presence of a dissection of the thoracic aorta. The versions without external fixation should be used under these circumstances. Pay special attention to the product diagrams recently added to the device pouch labels, together with the product codes, to ensure correct device selection. 	▶ ④
Distributed by NIAIC to: <ul style="list-style-type: none"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers 	▶ ⑤
Contacts Details of manufacturer/supplier contacts, NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC Report any stent graft implantation complications to NIAIC and the manufacturer	▶ ⑦

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

1. DEVICE/EQUIPMENT:

The Endofit™ stent-graft, which comprises a tube of PTFE enclosing a nitinol stent, is used to treat abdominal aortic aneurysms. It is available both without and with an uncovered stent ring extending from the proximal end (external fixation) to aid anchorage against the aorta. In addition to the main stent-grafts, accessory occluders, extenders and cuffs are available. It was first provided only cartridge-loaded, but since November 2003 has also been sold as a single pre-loaded stent-graft delivery system.

The manufacturer estimates that approximately 600 thoracic Endofit™ stent-grafts have been implanted worldwide since the product was first introduced to clinical use in June 2001. It was first implanted in the UK in June 2002 and to date has been used at only eight UK hospitals.

2. PROBLEM:

Due to insufficient evidence over the safety of the device when placed high up in the aortic arch, the manufacturer amended the Endofit™ instructions in January 2004, to restrict use of the device to the **descending** thoracic aorta only.

Furthermore, investigation of adverse incidents involving placement of thoracic Endofit™ with external fixation in the presence of a Type B dissection (dissection of the descending aorta) identified that the uncovered stent can cause the dissection to progress and ultimately result in aortic rupture. The manufacturer therefore modified the device instructions to contraindicate use of this version of the product with aortic dissections. A lack of clear information on the product labelling had also resulted in confusion over selection of grafts and cuffs with/without external fixation, and hence Endomed has now added diagrams to the pouch labels to aid correct product identification.

Endomed additionally took the following actions to improve safety during deployment of the Endofit™ stent-graft:

- radiopaque marker tabs were added to the proximal end of the stent-graft to improve visualisation under fluoroscopy.
- additional advice regarding the angiographic procedure, particularly involving exchanging guidewires, was added to the instructions for use.

3. ACTION BY:

All Interventional Radiologists and Vascular Surgeons who implant endoluminal stent grafts

4. ACTION:

- Do not implant the Endofit™ Thoracic Endoluminal Stent Graft in the aortic arch or ascending aorta. It is indicated for use in the **descending** thoracic aorta only.
- Do not implant the Endofit™ Thoracic Endoluminal Stent Graft or extender Cuff with external fixation (i.e. proximal uncovered stent ring) in the presence of a dissection of the thoracic aorta. The versions **without external fixation** should be used under these circumstances.
- Pay special attention to the product diagrams recently added to the device pouch labels, together with the product codes, to ensure correct device selection.

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
- Clinical Governance Leads
- Medical Directors
- Catheter Laboratory Managers
- Interventional Radiologists
- Radiology Department Managers
- Vascular Managers
- Paediatric Units
- Independent Health Care Providers – Private Clinics through HSS Board R&I Units

6. CONTACTS:

Enquiries to the Supplier should be addressed to
Mr Patrick Hegarty – Managing Director
PyraMed Ltd
Units 5&6
Sundial Court
Tolworth Rise South
Surbiton
Surrey KT5 9NN

Tel: 020 8335 5900
Fax: 020 8330 6432

Enquiries to the Manufacturer's Authorised
Representative should be addressed to:
Mr Barry Pearce – VP Europe
Shottwell and Carr Inc
25 Barker Close,
Fishbourne
Chichester,
West Sussex, PO18 8BJ

Tel: 01243 779550
Fax: 01243 781 563

Enquires to NIAIC should quote reference number MDEA(NI)2004/46 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 any stent graft implantation complications to NIAIC and the 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