



TITLE:
ENDOFIT ENDOLUMINAL AORTIC STENT GRAFT

MANUFACTURER/SUPPLIER

PyraMed Ltd

PROBLEM

Risk of complications during stent-graft deployment, associated with loading the cartridge into the introducer sheath and/or graft misplacement

DISTRIBUTED BY NIAIC TO:

Chief Executive of each HSS Board, Trust and Agency.

NIAIC Liaison Officers.

For onward distribution as appropriate to:

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	Medical Directors
Risk Managers	Vascular Surgeons
Health & Safety Officers/Advisors	Directors of Radiology
Clinical Governance Leads	Interventional Radiologists
	Catheter Laboratory Managers
	Interventional Cardiologists

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.

ACTION

Users of this product should be aware of the precautions outlined during the implantation procedure.

- The tip of the introducer sheath must be positioned at, or ideally proximal to, the appropriate landing zone before the stent graft is loaded
- When using the Cook Keller-Timmermans Introducer, the cartridge must be loaded the correct distance into the introducer's silicone sleeve.
- The proximal end of the stent-graft must be maintained in the correct position when the sheath is withdrawn during deployment
- Do not risk inadvertent placement of the proximal uncovered stent into a side-branch vessel

BACKGROUND

The Endofit endoluminal aortic stent graft consists of a single piece PTFE graft, encapsulating circumferential Z-shaped nitinol rings along its length. There is no longitudinal support along the length of the graft, as the Z-rings are not linked together. There is an uncovered Z-stent extending from the proximal end of the stent-graft to achieve fixation against the aorta, which is attached to the first Z-ring of the covered stent at only two crowns. The Endofit is supplied within a cartridge and not as a single pre-loaded stent-graft delivery system. The device instructions currently recommend using the Cook Keller-Timmermans Introducer Set. The stent-graft is available in thoracic and aortomonoiliac configurations (including custom-made devices) with accessory

occluders, extenders and cuffs.

The manufacturer estimates that some 475 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 4 UK hospitals.

NIAIC has been informed that the Medical Devices Agency (MDA) has been notified of the death of a UK patient following complications during the deployment of an Endofit thoracic stent-graft. During the procedure the tip of the introducer was withdrawn beyond the intended landing zone, and the proximal uncovered stent was deployed within a subclavian artery. Due to the sharp angulation of this bare stent to the body of the graft, and masking by the Trans Oesophageal Echo (TOE) probe, the implant was difficult to view on fluoroscopy. The proximal end of the graft was thus prevented from opening adequately, despite attempted correction by ballooning, and ultimately caused occlusion of the patient's aorta.

MDA is also aware of two further fatal incidents, both of which occurred outside the UK. In the first case a thoracic Endofit stent-graft cartridge was deliberately loaded into the introducer the wrong way around. The consequent inadequate proximal fixation of the stent-graft caused it to buckle and migrate. In the second, excessive stress was required to push a thoracic graft through the introducer, which led to only partial graft deployment.

The manufacturer has received reports of an additional 8 deployment-related incidents worldwide associated with the Endofit stent-graft, 4 involving thoracic, and 4 involving aortomonoiliac versions. Many of these deployment-related complications were linked to difficulties in loading the stent-graft cartridge through the Cook Keller-Timmermans Introducer Set. In particular, failure to advance the cartridge far enough into the silicone sleeve of the introducer has led to partial deployment of the graft in the silicone area. Similarly, advancing the cartridge too far into the silicone sleeve has compressed it, making further delivery of the stent-graft into the introducer extremely difficult. In light of these complications, Endomed is currently redesigning the product as a single pre-loaded system, which they plan to make available for clinical use in 2003.

Users of this product should be aware of the following precautions during the implantation procedure:

- The tip of the introducer sheath must be positioned at, or ideally proximal to, the appropriate landing zone before the stent graft is loaded, as subsequent advancement is not possible.
- When using the Cook Keller-Timmermans Introducer, the cartridge must be loaded the correct distance into the introducer's silicone sleeve. Insufficient advancement carries the risk of partial stent deployment within the silicone area, while advancing it too far, or "pinching" the silicone sleeve, can cause compression of the cartridge and difficulties in further advancing the graft through the introducer.
- The proximal end of the stent-graft must be maintained in the correct position when the sheath is withdrawn during deployment, and not pulled back with the introducer sheath. This is particularly important when withdrawing the introducer through narrow or tortuous arteries.
- Do not risk inadvertent placement of the proximal uncovered stent into a side-branch vessel as the acute angle may lead to kinking of the graft, with consequent occlusion of the aorta, which can not be corrected without open surgical repair.



HEALTH ESTATES
ESTATE POLICY

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SAFETY

NOTICE

ENQUIRIES

Enquires to the supplier should be addressed to:
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Surbiton
Surrey KT10 OYT

Tel: 020 8339 6125
Fax: 020 8339 6161

Enquires to the NIAIC should quote the reference number SN(NI) 2003/06 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



HEALTH ESTATES
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SAFETY

NOTICE

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
Áisíneacht Feidhmeannach don Roinn Sláinte. Serbhísí Sóisialta agus Sábháilteacht Phoiblí*