Medical Device Alert

Action

Ref: MDA/2009/023 Issued: 02 April 2009 at 15:00

Device

Zenith® abdominal aortic aneurysm (AAA) endovascular grafts and associated H&L-B One-Shot™ Introduction Systems. Manufactured by Cook Medical Incorporated.

Problem

Potential for serious injury or death of the patient due to difficulty releasing or inability to release the suprarenal stent during graft deployment.

Action by

Vascular surgeons
Interventional radiologists
Theatre managers

CAS deadlines

Action underway: 14 April 2009

Action complete: 23 April 2009

Action

- Review previous guidance on resolving trigger wire release problems in the manufacturer's 'Important Patient Safety Information', (published November 2008) and in the device 'Physicians Manual'.
- Obtain the manufacturer's recent guidance (issued February 2009) on a new troubleshooting technique.
- Consider the need for additional training being offered by the manufacturer to ensure proficiency with the new technique.
- Ensure fluoroscopy equipment used during endovascular graft implantation has adequate resolution to aid deployment and, if necessary, troubleshooting.

Contact

European representative:
William Cook Europe (Denmark)
Mr Arne Mølgaard-Nielsen

E-mail: a.moelgaard@cook-wce.com

Tel: +45 5686 8686

Link to full Medical Device Alert

Problem

Potential for serious injury or death of the patient due to difficulty releasing or inability to release the suprarenal stent during graft deployment.

The MHRA has received reports relating to complications experienced during attempts to release the top-cap and deploy the suprarenal stent (top-stent) in a number of Cook Zenith AAA endograft procedures. These have involved difficulties releasing or inability to remove the proximal black trigger-wire, delaying or preventing the release of the top-cap and the associated deployment of the enclosed top-stent.

Cook Zenith endovascular grafts have unique proximal and distal trigger-wire release mechanisms. The purpose of the proximal black trigger-wire is to prevent the premature release of the barbed top-stent held within the top-cap of the H&L-B One-Shot Introduction System. The trigger-wire passes through a single hole in the top-cap and through one of the top-stent 'stent eyelets' constrained within it. Once deployed, the top-stent is designed to provide physical radial pressure on the aortic wall and stability for the AAA endograft device, minimising the risk of distal migration.

Deployment of this device is a multistage procedure. When the proximal trigger-wire is about to be removed, the endograft is already in a partially deployed condition and it is no longer possible to re-sheath or remove the device from the patient.

Although the worldwide incidence of trigger-wire or top-cap release problems with this introduction system since 2003 remains low (below 0.1%) these have included serious patient complications such as conversion to open surgery, permanent injury or subsequent patient death.

The following factors appear to give rise to difficulty in removing the proximal trigger-wire:

1) inadvertent upward movement of the top-cap in relation to the top-stent during insertion and manipulation of the introduction system may raise tension on the trigger-wire, thereby temporarily entrapping it and increasing the potential for wire deformation;
2) the tension between the entrapped trigger-wire and the top-cap may be amplified further if an operator pulls downwards on this trigger-wire in an effort to free it, possibly leading to added deformation of the trigger-wire. Similarly, undue tension will be applied to the entrapped trigger-wire if the top-cap is pushed forward in an attempt to free the top-stent.

Excessive downward force on a deformed, entrapped trigger-wire may also irreversibly alter the shape and position of the proximal end of the inner cannula and dilator tip, causing it to bow. It is important to ensure that the manufacturer's recommended model and length of stiff guide wire is used and advanced beyond the end of the dilator tip (to the thoracic aorta) to provide maximum support for the inner cannula.

Techniques that may help resolve an entrapped trigger wire are described in the 'Physicians Reference Manual' (see Chapter 8, pages 126-127). If these techniques are unsuccessful, an alternative deployment sequence is available to resolve the situation (see trigger wire release instructions).

Well maintained and high resolution fluoroscopy equipment is essential for troubleshooting during implantation of these complex devices. Good fluoroscopy will also assist in accurately confirming the position of the top-cap in relation to the top-stent.

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- Health Protection Agency (HPA) (Directors)
- HSC Trusts in Northern Ireland (Chief Executives)
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- Regional directors
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- Safety officers

Change of address or removal from address list for Care Quality Commission:

National Contact Centre
Care Quality Commission
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 03000 61 61 61

E-mail: enquiries@cqc.org.uk

Contacts

Manufacturer
Cook Incorporated
750 N Daniels Way
Bloomington, IN 47404
USA

Tel: +1 (812) 339 2235
Fax: +1 (812) 355 6213

European Representative
Mr Arne Mølgaard-Nielsen
William Cook Europe
Sandet 6, DK 4632
Bjaeverskov,
Denmark

Tel: +45 5686 8686

Email: a.moelgaard@cook-wce.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/023** or **2008/008/007/061/009**.

Technical aspects
Alexander McLaren or Samantha Baxter
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Tel: 020 7084 3292/3242
Fax: 020 7084 3106

E-mail: alexander.mclaren@mhra.gsi.gov.uk
sam.baxter@mhra.gsi.gov.uk

Clinical aspects
Dr Christopher Brittain
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Tel: 020 7084 3126
Fax: 020 7084 3111

E-mail: christopher.brittain@mhra.gsi.gov.uk

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Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

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Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523 704
Fax: 02890 523 900

E-mail: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at https://sabs.dhsspsni.gov.uk

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

E-mail: iric@shs.csa.scot.nhs.uk

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

National Assembly for Wales
HIMTE 3 Division
NHS Directorate
Cathays Park
Cardiff
CF10 3NQ

Tel: 029 2082 3373
Fax: 029 2082 5479

E-mail: Haz-Aic@wales.gsi.gov.uk