COOK®

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Urgent Field Safety Notice

Commercial name of the affected product: Zenith Alpha™ Thoracic Endovascular Graft

Manufacturer: William Cook Europe Aps, Sandet 6, 4632 Bjaeverskov, Denmark

Cook Reference Number: 2018FA0009

Type of action: Field Safety Corrective Action – Field Safety Notice

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Date: 21 August 2018

Attention: Health Care Provider / Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Catalogue Identifier
Zenith Alpha™ Thoracic Endovascular Graft	All ZTA- devices (See attached list)

Description of the problem:

William Cook Europe (WCE) has become aware that the Zenith Alpha™ Thoracic Endovascular Graft has been used to treat patients with thoracic aortic dissections.

As per the Instructions For Use (IFU), the Zenith Alpha Thoracic Endovascular Graft is indicated for the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta having vascular morphology suitable for endovascular repair, including:

- Iliac/femoral anatomy that is suitable for access with the required introduction systems
- Nonaneurysmal aortic segments (fixation sites) proximal and distal to the thoracic aneurysm or ulcer:
    - with a length of at least 20 mm, and
    - with a diameter measured outer-wall-to-outer-wall of no greater than 42 mm and no less than 20 mm.

To emphasize best practices, WCE would like to reiterate that the Zenith Alpha Thoracic Endovascular Graft and ancillary components should be used as specified in the IFU. The IFU section 4.2 "Patient Selection, Treatment and Follow Up" states that the safety and effectiveness of the Zenith Alpha Thoracic Endovascular Graft and ancillary components have not been evaluated in the patient populations for dissection.

Refer to IFU section 5 for potential adverse events associated with either Zenith Alpha Thoracic Endovascular Graft or the implantation procedure that may occur and/or require intervention.

Advise on action to be taken by the user:

No devices need to be returned and patients **already treated** for a dissection should receive standard follow up procedures.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this information has an impact.

Please maintain awareness on this notice for an appropriate period to ensure effectiveness of the information.

Contact reference person:

Thomas Hessner Kirk
Team Lead, Regulatory Reporting
Regulatory Affairs
William Cook Europe
Bjaeverskov, DENMARK

Or

Annemarie Beglin
Quality Systems Manager
COOK Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

We recognize this situation is a disruption to your normal operations and we sincerely apologize. Thank you again for your immediate assistance in this matter. Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@cookmedical.com, phone +353 61 334440).

We confirm that this notice has been notified to the appropriate Regulatory Agency.