COOK SOUTH EAST ASIA PTE. LTD.
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COVER LETTER

March 27, 2017

Please kindly note that a field safety notice as attached has been provided by the manufacturer for the following product.

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

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

Please share this notice with others in your organization who either use this device or follow patients treated with the device. If you need any further information or support concerning this notice, please contact your local Cook Medical Sales Representative.

Kindly note that this safety communication is to call your attention to several aspects of a new version of Instructions for Use (IFU) for Zenith Alpha™ Thoracic Endovascular Graft. These updates are of key importance when using the device to treat blunt thoracic aortic injury (BTAI). However, this indication for isolated lesions of the descending aorta is still not approved in Singapore (please refer to table 1 below).

Table 1: Major Differences in IFU received with product and IFU attached to this field safety notice

IFU: I-ALPHA-TAA-436-04 (Currently approved in Singapore)	IFU: I-ALPHA-THORACIC-440-01 **(Not approved in Singapore yet)**
Intended Use The Zenith Alpha Thoracic Endovascular Graft is indicated for the endovascular treatment of patients with aneurysms/ulcers of the descending thoracic aorta having vascular morphology suitable for endovascular repair, (Fig. 3) including: • Iliac/femoral anatomy that is suitable for access with the required introduction systems, • Nonaneurysmal aortic segments (fixation sites) proximal and distal to the 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 15 mm	Indications for Use The Zenith Alpha Thoracic Endovascular Graft is indicated for the endovascular treatment of patients with isolated lesions of the descending thoracic aorta (not including dissections) having vascular anatomy suitable for endovascular repair (Fig. 3 and 4), 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 lesion: • 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 15 mm

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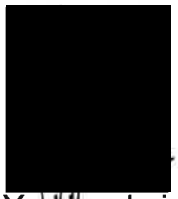
Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to;

COOK South East Asia, Regulatory Affairs Department
Yu Hosokai Tel:+65 6812 7486
Jennifer Chin Tel:+65 6812 7461
Email: SNG-RegulatoryAffairs@CookMedical.com
Fax: +65 6812 7401

Alternatively, healthcare professionals may report the adverse events to the Vigilance and Compliance Branch, Health Products Regulation Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae_online. Events that are reported to COOK South East Asia will be investigated and subsequently reported to HSA.

Yours Sincerely,



Yu Hosokai
Regulatory Affairs Specialist
COOK South East Asia Pte. Ltd.

CC: Chairman Medical Board
Relevant Head of Departments