



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

Date: 30 August 2018

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

Details on affected devices:

Zenith Alpha™ Thoracic Endovascular Graft

Table 1:

Product Brand Name	Catalogue Identifier*	Lot Number
Zenith Alpha™ Thoracic Endovascular Graft	All ZTA- devices (see attached list, Annex A)	All Lots

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.



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Transmission of this Field Safety Notice:

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.

Please kindly complete the acknowledgement of receipt attached and return to Cook Medical Sales Representative or the Regulatory Affairs Department. There will be another letter, a Dear Health Care Professional Letter (DHCPL) issued in consultation with Health Sciences Authority (HSA) shortly as well.

Reporting of Adverse Event:

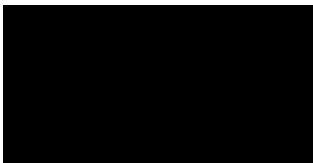
Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to;

COOK South East Asia, Regulatory Affairs Department
Attn: Yu Hosokai
Tel: +65 6812 7486
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.

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 medical questions or concerns, please contact Cook South East Asia at +65 6812 7400. We look forward to your response.

Yours Sincerely,



Regulatory Affairs Manager - SEA
Cook South East Asia Pte. Ltd.

CC: Chairman Medical Board
Relevant Head of Departments

Annex A

Product code	Description
ZTA-P-24-105	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-24-127	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-26-105	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-26-149	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-28-109	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-28-132	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-28-155	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-28-201	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-30-109	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-30-132	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-30-155	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-30-201	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-32-109	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-32-132	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-32-155	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-32-201	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-34-113	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-34-137	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-34-161	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-34-209	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-36-113	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-36-137	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-36-161	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-36-209	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-38-117	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-38-142	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-38-167	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-38-217	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-40-117	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-40-142	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-40-167	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-40-217	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-42-121	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-42-147	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-42-173	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-42-225	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component

Product code	Description
ZTA-P-44-125	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-44-152	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-44-179	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-44-233	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-46-125	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-46-152	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-46-179	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-P-46-233	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Component
ZTA-PT-30-26-108	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-32-28-178	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-32-28-201	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-34-30-161	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-34-30-209	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-36-32-161	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-36-32-209	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-38-34-167	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-38-34-217	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-40-36-167	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-40-36-217	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-42-38-173	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-42-38-225	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-44-40-179	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-44-40-233	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-46-42-179	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-PT-46-42-233	Zenith Alpha™ Thoracic Endovascular Graft – Proximal Tapered Component
ZTA-D-28-160	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-28-229	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-30-160	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-30-229	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-32-160	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-32-229	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-34-142	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-34-190	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-36-142	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-36-190	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-38-147	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-38-197	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-40-147	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component

Product code	Description
ZTA-D-40-197	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-42-152	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-42-204	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-44-157	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-44-211	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-46-157	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-D-46-211	Zenith Alpha™ Thoracic Endovascular Graft – Distal Component
ZTA-DE-24-104	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-24-148	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-26-104	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-26-148	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-28-108	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-28-154	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-30-108	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-30-154	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-32-108	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-32-154	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-34-112	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-34-160	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-36-112	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-36-160	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-38-91	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-38-141	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-40-91	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-40-141	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-42-94	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-42-146	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-44-97	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-44-151	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-46-97	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension
ZTA-DE-46-151	Zenith Alpha™ Thoracic Endovascular Graft – Distal Extension



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IMPORTANT: PLEASE RETURN THIS FORM

Acknowledgement of Receipt

I hereby acknowledge the receipt of the Urgent Field Safety Notice on Zenith Alpha™ Thoracic Endovascular Graft dated 30 August, 2018 with Cook Reference Number: 2018FA0009.

Signature _____

Date _____

Name:

Designation:

Organization: