



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: 2017FA0011
Type of action: Removal of specific Device Sizes from the market and IFU Correction

June 28, 2017

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	ZTA-D-/-	All Lots
	ZTA-DE-/-	
	ZTA-P-/-	
	ZTA-PT-/-	

Description of the Problem:

As described in the recent Field Safety Notice 2017FA0001 of March 2017 regarding the Zenith Alpha™ Thoracic Endovascular Graft, there were complaints involving thrombosis/occlusion of the product when used to treat blunt thoracic aortic injury (BTAI). Since that time, Cook Medical has received additional complaints for the same problem. Although the complaints were from patients treated prior to issuance of the above noted Field Safety Notice, Cook Medical is initiating a voluntary correction of the Instructions for Use (IFU) and is also voluntarily removing specific sizes of the Zenith Alpha Thoracic Endovascular Graft from the market.

Description of the Correction:

The correction to the IFU for this device removes the indication for use in BTAI. The following paragraph is the indications for use as stated in section 2 in the IFU (corrections shown in **bold**):

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**.

Additionally, the following warning has been added in section 4.2 in the IFU to describe the thrombus risk that has been observed when the device is used to treat BTAI:

- Risk of in-graft thrombus has been observed when the Zenith Alpha Thoracic Endovascular Graft has been used to treat BTAI.



Patients already treated with the Zenith Alpha Thoracic Endovascular Graft for the BTAI indication should be followed according to the current IFU and with considerations outlined in Cook Medical's recent Field Safety Notice 2017FA0001 of March 2017.

Description of the Removal:

Because of the IFU correction to remove BTAI from the indication, it is necessary to remove specific sizes of this device (grafts with a proximal or distal diameter 18-22 mm) that would likely be used only for BTAI. The following table lists the specific catalogue numbers for the product sizes that are being removed:

Table 2:

Product Brand Name	Catalogue Identifier	Global Product Number	Lot Number
Zenith Alpha™ Thoracic Endovascular Graft	ZTA-P-18-105	G34671	All Lots
	ZTA-P-18-127	G34672	
	ZTA-P-20-105	G34673	
	ZTA-P-20-127	G34674	
	ZTA-P-22-105	G34675	
	ZTA-P-22-127	G34676	
	ZTA-PT-22-18-105	G44447	
	ZTA-PT-26-22-105	G44448	
	ZTA-DE-18-104	G34603	
	ZTA-DE-18-148	G34623	
	ZTA-DE-20-104	G34604	
	ZTA-DE-20-148	G34624	
	ZTA-DE-22-104	G34605	
	ZTA-DE-22-148	G34625	

Potential adverse events that may occur if these devices were used for BTAI include death, paraplegia, and/or surgical intervention.

Please refer to Annex A attached for exhaustive list of affected products.

Advise on action to be taken by the user:

1. Immediately collect all remaining affected products of the grafts with a proximal or distal diameter 18 - 22 mm, as shown in Table 2 above, from your inventory.
2. Please complete the enclosed Customer Response Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Customer Response form.

Product should be addressed to:
 DKSH Singapore Pte Ltd
 24 Penjuru Road, #07-03
 Singapore 609128

Credit will be provided for the returned devices where applicable.

3. Upon completing this Acknowledgement and Receipt Form, please email to SNG-RegulatoryAffairs@CookMedical.com or return to a Cook South East Asia Pte. Ltd. representative. **Do not enclose the response form with the returned product.**
4. Please report any adverse event 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.

5. Upon availability of the corrected IFU, your Cook Medical Sales Representative will personally follow-up and provide corrected IFUs for your inventory for the remaining sizes of the Zenith Alpha Thoracic Endovascular Graft (grafts with a proximal or distal diameter above 22 mm).

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.

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
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.

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,



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

CC: Chairman Medical Board
Relevant Head of Departments

Annex A



ZENITH ALPHA™ THORACIC ENDOVASCULAR GRAFT

- All lots affected
- RPNs to remain on the market
- IFU to be replaced

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
ZTA-D-28-160	G34602	ZTA-DE-38-91	G34616	ZTA-P-38-167	G34704
ZTA-D-28-229	G34609	ZTA-DE-40-141	G34634	ZTA-P-38-217	G34705
ZTA-D-30-160	G34610	ZTA-DE-40-91	G34617	ZTA-P-40-117	G34706
ZTA-D-30-229	G34614	ZTA-DE-42-146	G34635	ZTA-P-40-142	G34707
ZTA-D-32-160	G34619	ZTA-DE-42-94	G34618	ZTA-P-40-167	G34708
ZTA-D-32-229	G34621	ZTA-DE-44-151	G34636	ZTA-P-40-217	G34709
ZTA-D-34-142	G34641	ZTA-DE-44-97	G34620	ZTA-P-42-121	G34710
ZTA-D-34-190	G34647	ZTA-DE-46-151	G34637	ZTA-P-42-147	G34712
ZTA-D-36-142	G34649	ZTA-DE-46-97	G34622	ZTA-P-42-173	G34713
ZTA-D-36-190	G34651	ZTA-P-24-105	G34677	ZTA-P-42-225	G34714
ZTA-D-38-147	G34654	ZTA-P-24-127	G34678	ZTA-P-44-125	G34715
ZTA-D-38-197	G34658	ZTA-P-26-105	G34679	ZTA-P-44-152	G34716
ZTA-D-40-147	G34660	ZTA-P-26-149	G34680	ZTA-P-44-179	G34717
ZTA-D-40-197	G34662	ZTA-P-28-109	G34682	ZTA-P-44-233	G34718
ZTA-D-42-152	G34663	ZTA-P-28-132	G34681	ZTA-P-46-125	G34719
ZTA-D-42-204	G34664	ZTA-P-28-155	G34683	ZTA-P-46-152	G34720
ZTA-D-44-157	G34665	ZTA-P-28-201	G34684	ZTA-P-46-179	G34721
ZTA-D-44-211	G34667	ZTA-P-30-109	G34685	ZTA-P-46-233	G34722
ZTA-D-46-157	G34668	ZTA-P-30-132	G34686	ZTA-PT-30-26-108	G44446
ZTA-D-46-211	G34670	ZTA-P-30-155	G34687	ZTA-PT-32-28-178	G34638
ZTA-DE-24-104	G34606	ZTA-P-30-201	G34688	ZTA-PT-34-30-161	G34640
ZTA-DE-24-148	G34626	ZTA-P-32-109	G34689	ZTA-PT-34-30-209	G34642
ZTA-DE-26-104	G34607	ZTA-P-32-132	G34690	ZTA-PT-36-32-161	G34643
ZTA-DE-26-148	G34627	ZTA-P-32-155	G34691	ZTA-PT-36-32-209	G34645
ZTA-DE-28-108	G34608	ZTA-P-32-201	G34692	ZTA-PT-38-34-167	G34646
ZTA-DE-28-154	G34628	ZTA-P-34-113	G34694	ZTA-PT-38-34-217	G34648
ZTA-DE-30-108	G34611	ZTA-P-34-137	G34695	ZTA-PT-40-36-167	G34650
ZTA-DE-30-154	G34629	ZTA-P-34-161	G34696	ZTA-PT-40-36-217	G34652
ZTA-DE-32-108	G34612	ZTA-P-34-209	G34697	ZTA-PT-42-38-173	G34653
ZTA-DE-32-154	G34630	ZTA-P-36-113	G34698	ZTA-PT-42-38-225	G34655
ZTA-DE-34-112	G34613	ZTA-P-36-137	G34699	ZTA-PT-44-40-179	G34656
ZTA-DE-34-160	G34631	ZTA-P-36-161	G34700	ZTA-PT-44-40-233	G34657
ZTA-DE-36-112	G34615	ZTA-P-36-209	G34701	ZTA-PT-46-42-179	G34659
ZTA-DE-36-160	G34632	ZTA-P-38-117	G34702	ZTA-PT-46-42-233	G34661
ZTA-DE-38-141	G34633	ZTA-P-38-142	G34703	ZTA-PT-32-28-201	G34639



ZENITH ALPHA™ THORACIC ENDOVASCULAR GRAFT

- All lots affected
- RPNs to be removed from the market

Reference Part Number	Global Product Number	Reference Part Number	Global Product Number	Reference Part Number	Global Product Number
ZTA-P-18-105	G34671	ZTA-P-22-127	G34676	ZTA-DE-20-104	G34604
ZTA-P-18-127	G34672	ZTA-PT-22-18-105	G44447	ZTA-DE-20-148	G34624
ZTA-P-20-105	G34673	ZTA-PT-26-22-105	G44448	ZTA-DE-22-104	G34605
ZTA-P-20-127	G34674	ZTA-DE-18-104	G34603	ZTA-DE-22-148	G34625
ZTA-P-22-105	G34675	ZTA-DE-18-148	G34623		



COOK SOUTH EAST ASIA PTE. LTD.
238A THOMSON ROAD, #12-08 NOVENA SQUARE
OFFICE TOWER A, SINGAPORE 307684
PHONE: +65 6812 7400, FAX: +65 6812 7401
CO. REGN: 198602196G
WWW.COOKMEDICAL.COM

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 June 28, 2017 with Cook Reference Number: 2017FA0011.

Signature _____

Date _____

Name:

Designation:

Organization:

