COOK®

Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441

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

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Date: June 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-/-	

**Please refer to the complete product listing for further information.*

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.

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:
   Cook Medical EUDC
   Robert-Koch-Straße, 2
   52499 Baesweiler
   GERMANY

   Credit will be provided for the returned devices where applicable.

3. Send the Customer Response Form via email to European.FieldAction@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61 334441). **Do not enclose the response form with the returned product.**

4. Please report any adverse event to Cook Medical Customer Relations by contacting our Customer Services Department.

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:
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 action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

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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.

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