
Urgent Field Safety Notice

Commercial name of the affected product: Zenith TX2 TAA Endovascular Graft with Pro-Form Proximal Component

FSCA-identifier: FSCA-2014-03-31

Type of action: Recall

Date: March 31, 2014

Attention: Chief Executive

Details on affected devices:

Product name: Zenith TX2 TAA Endovascular Graft Proximal Component

Catalogue number: ZTEG-2P-34-202-PF

Lot number: E3128285 and E3130420

Description of the problem:

Cook Medical has become aware of a labeling issue involving two (2) Zenith TX2 TAA Endovascular Graft with Pro-Form (ZTEG-) devices supplied to Japan and Australia, respectively. The devices are likely labeled with a wrong label indicating wrong length and diameter.

Cook Medical has received one complaint from Korea (PR# 97620) where a device was labeled as a five segment stent graft (length 127 mm) but the stent graft was in fact an eight segment stent graft with a length of 202 mm. This was discovered after deployment in the patient. This resulted in open surgery to excise three distal segments of the stent graft.

Use of the product may cause one or more of following complications: Covering of vital arteries, endoleak, migration and aorta damage. These complications may all result in life threatening injury; conversion to open surgery or death.

There is reason to believe that a mix up has taken place with the complaint device and one of the above mentioned Lot numbers. Therefore Cook Medical is conducting a recall on these two devices.

Advise on action to be taken by the user:

1. Please review the attached customer list and quarantine any affected product that remains in your stock.

2. Please complete the attached Customer Response Form, which lists the product and lot numbers affected and return by fax to Cook Medical marked for the contact person listed below as soon as possible to +45 5686 8696 or alternatively via e-mail to WCE-Complaints@CookMedical.com. **This must be done by April 07, 2014 at the latest**.
3. Immediately collect all remaining unused products. The remaining unused products should be returned as soon as possible via DHL quoting Cook Medical's account number: 960 009 561 to arrange pick up.

Send the unused devices to:

Wiliam Cook Europe Aps
Att: Lissi Walmann
Sandet 6
DK-4632 Bjaeverskov
DENMARK

Please reference RA # FSCA-2014-03-31 on the outside of the shipping carton.
Please be advised that the manufacturer will issue credit for all devices returned.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. We have informed the relevant competent authorities.

Contact reference persons:

Lissi Walmann
William Cook Europe
Sandet 6
DK-4632 Bjaeverskov
DENMARK
Tel: +45 5686 8686
Fax: +45 5686 8696

Annette Lüneborg
William Cook Europe
Sandet 6
DK-4632 Bjaeverskov
DENMARK

Should you have any questions, please feel free to contact us for more information. We regret the inconvenience this may cause you. Thank you again for your immediate assistance in this matter. We look forward to receiving your response.

Best regards,

Lissi Walmann
Bjaeverskov, March 31, 2014