Field Safety Notice – Updated Instructions for Use
Reference: 2015FA0001

Affected Products: Zenith Alpha™ Thoracic Endovascular Graft

January 2015

Dear Health Care Provider:

Cook Medical is sending you this important safety communication to inform you that additional warnings and precautions are being implemented in the Instructions for Use (IFU) for the Zenith Alpha™ Thoracic Endovascular Graft. This Field Safety Notice is only for information purpose and no devices need to be returned. All future devices will include the updated Instructions for Use.

Reason for this Field Action

The updates to the IFU are being made to emphasize best practices in response to a few recent findings of distal Type I endoleak, migration and aneurysm growth during on-going longer-term follow-up of patients enrolled in the multi-national clinical investigation of the device. To date, no similar events have been reported from markets in which the device is commercially available. These findings from the clinical investigation were found to be associated with thoracic aneurysms (not ulcers) treated with a single proximal component that resulted in a short distal seal length (i.e., less than 20 mm) and likely inadequate (i.e., less than 10%) distal oversizing for the device.

It is essential to ensure that a minimum seal length of 20 mm is achieved and maintained both proximally and distally for all patients. This can be best assured through careful planning and sizing of the device based on the length of greater curve of the aneurysm, as well as careful device placement and evaluation of completion imaging during the procedure. Additionally, a two-component treatment (proximal and distal component repair) is recommended for aneurysms, whereas use of a single proximal component may be appropriate for ulcers. In aneurysm cases where a two-component treatment is unable to be achieved, it is essential that a minimum of 20 mm distal seal length is planned and maintained to ensure long term success. Additional warnings and precautions related to these considerations are being implemented in the IFU in order to ensure long term success is achieved for all patients treated with the Zenith Alpha™ Thoracic Endovascular Graft.

Advice on action to be taken by the customer/user

Patients **already treated** with a single proximal component who have a short distal sealing length, graft length inadequate to maintain distal seal when settled into the greater curve of the aneurysm, inadequate oversizing, or any other complications (e.g., Type I endoleak, aneurysm/ulcer enlargement, migration) should receive additional surveillance, and treatment if necessary.

Adherence to the additional recommendations in the IFU (see below) is necessary for the planning, sizing, placement, and evaluation of the procedural result in **future patients** receiving the Zenith Alpha™ Thoracic Endovascular Graft.

Section 1.1 Zenith Alpha Thoracic Endovascular Graft

- *The proximal component can be either tapered or non-tapered and may be used independently (for ulcers/saccular aneurysms), or in combination with a distal component.*

Section 4.2 Patient Selection, Treatment and Follow-up

- *Graft length should be selected to cover the lesion as measured along the greater curve of the aneurysm, plus a minimum of 20 mm of seal zone on the proximal and distal ends.*

Section 4.3 Pre-Procedure Measurements Techniques and Imaging

- *Length measurements should be taken along the greater curvature of the aorta, including the aneurysm if present.*

  NOTE: The greater curvature is the longest measurement following the curve of the aneurysm and may be on the outer or inner curvature of the aorta depending on the location of the aneurysm.

  NOTE: Large aneurysms and difficult anatomy may require extra care in planning.

Section 4.4 Device Selection

- *Graft length should be selected to cover the lesion as measured along the greater curve of the aneurysm, plus a minimum of 20 mm of seal zone on the proximal and distal ends.*
- *In aneurysms the graft may settle into the greater curve of the aneurysm over time. Accordingly, extra graft length needs to be planned.*
  - *A two component repair (proximal and distal component) is recommended, as it provides ability to adapt to the length change over time. A two component repair (proximal and distal component) also provides active fixation at both the proximal and distal seal sites.*
  - *If an acceptable two-component (proximal and distal component) treatment plan cannot be achieved (e.g., excessive aortic coverage, even with maximal overlap of shortest components), the proximal component must be selected with enough length to achieve and maintain the minimum 20 mm sealing zones at both ends even when positioned in the greater curve of the aneurysm.*

Section 4.5 Implant Procedure & 10.2.4 Final Angiogram

- *In the final angiogram confirm that there are no endoleaks or kinks, that the proximal and distal gold radiopaque markers are positioned to provide adequate overlap between components, and that there is sufficient graft length to maintain over time a minimum of 20 mm in proximal and distal seal.*

  NOTE: If endoleaks or other problems are observed, (e.g., inadequate seal length or overlap length) refer to Section 10.2 Ancillary Devices.

Please share this notice with others in your organization who may be affected by this action. Please also note that Cook Medical has informed the relevant Competent Authorities about this Field Safety Notice and the updated Instructions for Use.

We apologize for any inconvenience this may cause, however we find it important to assure that you are aware of these recommendations for optimal care of patients in your practice. If you need any further information or support concerning this information, please contact your local Cook Medical Sales Representative.

Sincerely,

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