***Cook – Zenith® Fenestrated AAA Endovascular Graft***

***Annual Clinical Update – 2024***

I. Overview:

This annual clinical update provides a review of ongoing experience with the Zenith Fenestrated AAA Endovascular Graft for the treatment of abdominal aortic or aorto-iliac aneurysms having short infrarenal aortic necks (≥ 4 mm and < 15 mm). In this update, 5 years of pre-market study and post-approval study data as well as 10 years of worldwide commercial experience are presented. The post-approval study requirements for this device consisted of ongoing follow-up (through 5 years) of the 67 patients enrolled in the pre-market study combined with 21 additional patients enrolled in the post-market study (88 patients total).

The device was originally approved in 2012. The only design change since the time of initial approval was a modification to the introduction system (also in 2012). Links to the original approval order and Summary of Safety and Effectiveness Data can be accessed here:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020018S040

The IFU for the Zenith Fenestrated AAA Endovascular Graft can be accessed here:

https://ifu.cookmedical.com/data/IFU_PDF/IFU-FU-V005.PDF

II. Worldwide Device Distribution:

There have been over 35,109 devices distributed worldwide. Specifically, devices as part of the IDE [67 proximal fenestrated components, 66 distal bifurcated components], post approval studies [20 proximal fenestrated components, 20 distal bifurcated components] and commercially [18,678 proximal fenestrated components, 16,431 distal bifurcated components].

III. Clinical Evaluations:

A description of the original IDE study and results at the time of PMA approval as well as a description of the post-approval study with final 5-year follow-up results (IDE study subjects and post-approval study subjects combined) can be found in the corresponding summary of clinical studies sections of the IFU, which can be accessed using the link provided in Section I.

IV. Worldwide Recalls, Safety Communications and Field Safety Notices:

There have been no recalls, safety communications, or field safety notices.

V. Worldwide Commercial Experience:

There have been no reported adverse reactions, side effects, or injuries attributable to the device that are not addressed in the labeling for the device or that occurred with unexpected frequency.

VI. Explant Analysis:

There has been one explant analyzed (from noncommercial experiences outside the multicenter study). The implantation time was approximately 170 days. The explant was taken at the time of autopsy from a patient who died following a myocardial infarction. The explant analysis identified barb separations, suture break (green), and cuts in the graft material – there was no evidence of stent fracture or graft material wear. While damage from surgical instruments during

explantation was sometimes obvious, it was not always possible to determine if observations occurred before explantation or if the explantation process contributed to, or caused, the observations.

VII. Literature Review:

In total, 68 publications involving use of Zenith Fenestrated AAA Endovascular Grafts for any reason have been identified since 2012. There were no notable publications during this reporting period. Adverse events reported in publications are treated as complaints by the manufacturer and may similarly result in filing of a Medical Device Report (MDR) to FDA, if applicable. As noted in Section V, there have been no reported adverse reactions, side effects, or injuries attributable to the device that are not addressed in the labeling for the device or that occurred with unexpected frequency.

VIII. Conclusion:

Based on available clinical study data and world-wide clinical experience to date, endovascular therapy with the Zenith® Fenestrated AAA Endovascular Graft continues to be a viable treatment option for patients with short neck abdominal aortic or aorto-iliac aneurysms.

Adverse Event Reporting:

Accurate and timely reporting of adverse events to Cook and FDA is critical for monitoring device performance and detection of potential device-related safety issues. Adverse events should be reported to Cook via email to CustomerRelationsNA@CookMedical.com or via phone at 1-800-457-4500, ext. 152146 (7:30 am-5:00 pm EST) and to FDA via MedWatch FDA Form 3500, a copy of which is available at: https://www.fda.gov/media/135528/download.

Patient Follow-Up and Selection:

Regular follow-up of all patients treated with the Zenith® Fenestrated AAA Endovascular Graft is required. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient. Please refer to the IFU for additional information regarding recommended follow-up. In particular, and consistent with the recommendations provided in the IFU, it is important to ensure an adequate overlap length between the proximal fenestrated component and distal bifurcation component not only at the time of procedure, but also during follow-up, with consideration for reintervention in the setting of a decrease in the length of overlap between components, particularly when the length of overlap is less than the 2-stent minimum.

Please refer also to FDA's Letter to Health Care Providers that summarizes the Circulatory System Devices Advisory Panel recommendations on lifelong surveillance and long-term postmarket data collection for patients with AAA endovascular aortic repair, a copy of which is available at:

https://www.fda.gov/medical-devices/letters-health-care-providers/fda-advisory-panel-recommendations-lifelong-surveillance-and-long-term-postmarket-data-collection