Cook – Zenith® Dissection Endovascular System
Annual Clinical Update – 2023

I. Overview:

This simplified annual clinical update provides a review of the ongoing experience with the Zenith® Dissection Endovascular System used in the treatment of patients with acute, complicated Type B aortic dissection. In this update, 5 years of pivotal study data, ongoing continued access study data, and post-approval study (PAS) data, as well as 5 years of worldwide commercial experience are presented.

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=P180001

The IFU (that addressed the updates according to S002 and S005) for the Zenith Dissection Endovascular System can be accessed here:
I-DISSECT-SYSTEM-441-02EN.PDF.

II. Worldwide Device Distribution:

There have been nearly 20,000 devices distributed worldwide to date, which include the pivotal study (101 stent-grafts, 78 bare stents), the continued access study (15 stent-grafts and 13 bare stents), for premarket emergency use (5 stent-grafts, 12 bare stents), and for commercial use (11,719 stent-grafts and 8,032 bare stents).

III. Clinical Evaluations:

The overview of the clinical evaluations of the Zenith® Dissection Endovascular System that have been performed through IDE (pivotal) study, continued access study, and PAS are as follows.

Pivotal Study

A description of the pivotal study and the results from completed 5-year follow-up can be found in the corresponding summary of the IFU, which can be assessed using the link provided in **Section I**.

Continued Access Study

The continued access study was conducted to provide continued (extended) physician access to the Zenith Dissection Endovascular System, allowing to collect confirmatory safety and effectiveness data during the PMA process. The continued access study patients followed the same study inclusion/exclusion criteria as for the pivotal study (i.e., enrolling patients with acute, complicated Type B dissection) and were evaluated using the same endpoints, but not for the purpose of statistical inference. The continued access study enrolled 11 patients from 2 sites in the US (2 patients treated with only the graft component, 9 patients treated with both the graft and bare stent components). Enrolled patients were to be followed for 5 years (within 7 days post-procedure, at 30 days, 6 months, 12 months, and yearly thereafter). The last follow-up for continued access study patients was completed on 16 November 2021.

The summary of the final data has been reported in the 2022 Annual report (P180001/R011); there have been no changes to the final data since then.

PAS (SVS VQI post-market surveillance)

As a condition of PMA approval, Cook agreed to participate in the SVS VQI post-market surveillance project, accruing 120 patients with acute dissection (treated with the complete Zenith Dissection Endovascular System) and 60 chronic patients (treated with any component of the Zenith Dissection Endovascular System) with device technical success. The study endpoints include false lumen characteristics and freedom from dissection-related mortality, which will be assessed through 5 years. Enrollment and follow-up are ongoing.

As of 02 September 2023, a total of 124 patients (63 acute patients and 61 chronic patients) have been enrolled, among whom, a total of 20 patients (i.e., 12 acute patients and 8 chronic patients) appeared to have not achieved the device technical success. Although enrollment and follow-up are limited, there do not appear to be any unique events thus far in the post-market study that were not also observed in either the premarket study for this device (and likewise are already accounted for in the device labeling) or the post-market study involving other devices approved for the same indication. Further details of the annual progress of the SVS VQI post-market surveillance are to be reported in a separate annual report under P180001/PAS002.

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:
No explants have been received for analysis.

VII. Literature Review:
In total 26 publications involving use of the Zenith Dissection Endovascular System for any reason have been identified since 2018. 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 the above **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 Dissection Endovascular System continues to be a viable treatment option for patients with Type B aortic dissection.

Adverse Event Reporting:
Accurate and timely reporting of adverse events to Cook and FDA is critical for monitoring device performance and detecting 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 Dissection Endovascular System (stent-graft and/or stent) is required. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient.