PRESERVE-Zenith® Iliac Branch Clinical Study

Clinical Study to Evaluate the Safety and Effectiveness of the Zenith® Branch Endovascular Graft-Iliac Bifurcation

Global Clinical Number # 05-625

May 09, 2018

Sponsor: Cook Research Incorporated
1 Geddes Way
West Lafayette, IN 47906
USA

CLINICAL INVESTIGATION PLAN SIGNATURE PAGE

This clinical trial will be conducted in compliance with the clinical investigation plan, GCP, and other applicable requirements as appropriate.

Signatures:

Sponsor Contact

Signature	DD/MM/YYYY
Printed Name	Title

CLINICAL INVESTIGATION PLAN SIGNATURE PAGE, CON'T.

National Principal Investigator

I hereby confirm that I approve of this Clinical Investigation Plan and agree to comply with its terms as laid out in this document.

Signature	DD/MM/YYYY
Printed Name	Title

CLINICAL INVESTIGATION PLAN SIGNATURE PAGE, CON'T.

Principal Clinical Investigator

I hereby confirm that I approve of this Clinical Investigation Plan and agree to comply with its terms as laid out in this document.

Signature	DD/MM/YYYY
Printed Name	Title

CONFIDENTIALITY STATEMENT

This document shall be treated as a confidential document for the sole information and use of the clinical investigation team and the Ethics Committee / IRB.

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1.0. General Information

1.1. Sponsor and Manufacturer

Sponsor

Cook Research Incorporated
1 Geddes Way
West Lafayette, IN 47906
USA

Manufacturer

William A. Cook Australia Pty. Ltd.
95 Brandl Street
Eight Mile Plains
Brisbane, QLD 4113, Australia
Establishment Registration #9680654

1.2. Data Coordinating Center

Cook Research Incorporated
1 Geddes Way
West Lafayette, IN 47906
USA

1.3. Trial Administration

The trial will be conducted in compliance with applicable regulations and standards (e.g., 21 CFR 50, 54, 56, and 812).

1.4. Investigators and Investigative Sites

Contact information of the coordinating clinical investigator, principal clinical investigators, clinical investigators, and core laboratory will be updated and maintained by the Data Coordinating Center and updates will be sent to sites periodically.

1.5. Monitoring Arrangements

The study will be monitored in accordance with written standard operating procedures consistent with 21 CFR 812 and other applicable regulations. Written procedures for monitoring the investigation are maintained by the monitors.

Name and address of the monitor:

Cook Research Incorporated
1 Geddes Way
West Lafayette, IN 47906
USA

Phone: 765-463-7537
Fax: 765-497-0641

1.6. Data Management and Quality Assurance

A dedicated study coordinator and physician team will complete standardized, data collection forms (see section 17). The completed data forms will be reviewed, processed, and stored in electronic databases according to standard operating procedures maintained by Cook Research Incorporated.

Pertinent imaging (pre-procedure, procedural, and follow-up) will be sent to Cook Research Incorporated, who will coordinate shipment of imaging to the core lab for independent analysis.

2.0. Approval and Agreement of Clinical Investigation Plan

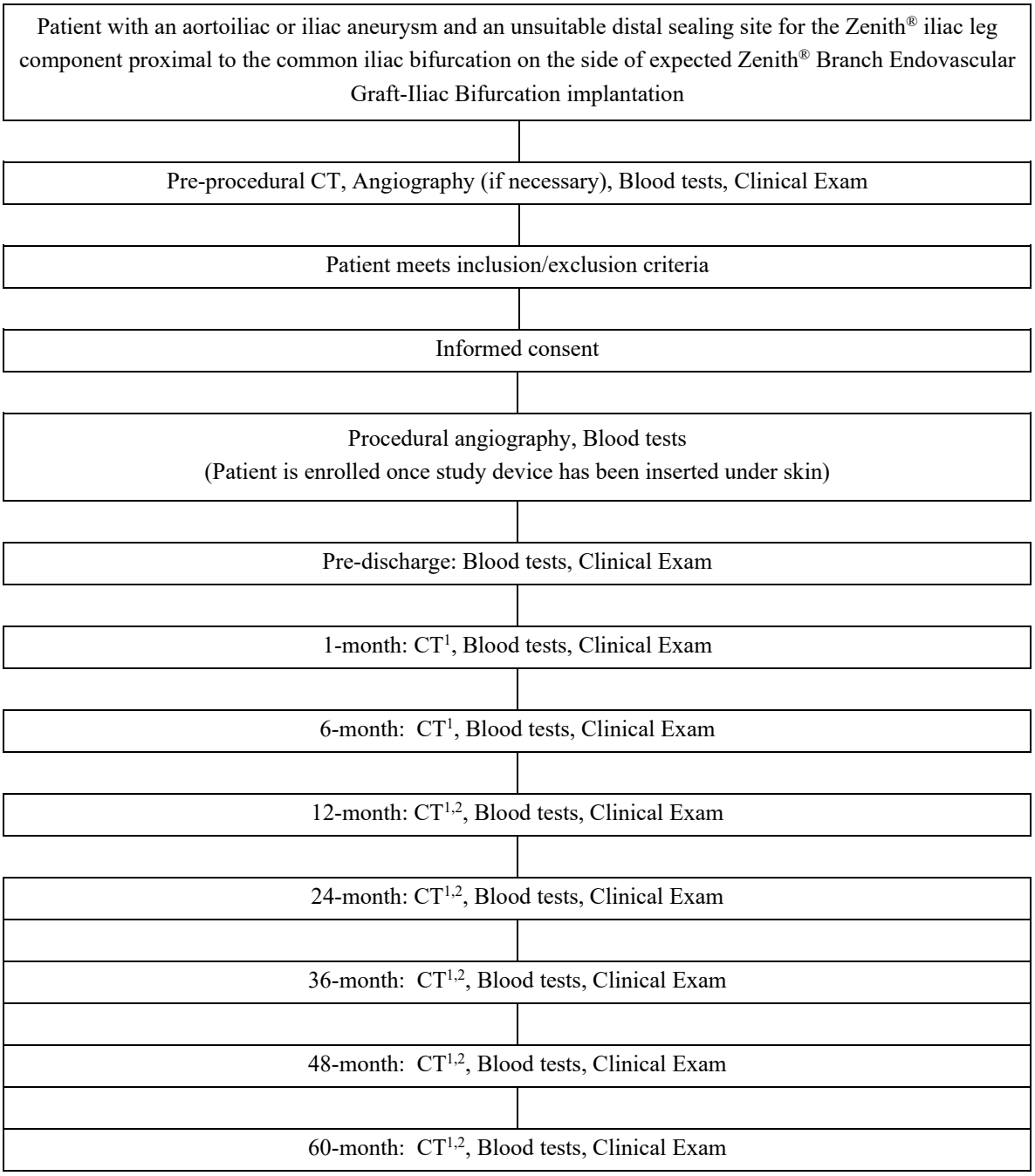
The Sponsor, coordinating clinical investigator, and principal clinical investigators for each site shall agree to this document and any modifications approved by the FDA prior to implementation. A justification for any modification will be documented. Approval and agreement will be indicated by signing and dating the extended clinical investigation plan.

3.0. Clinical Investigation Plan Overview

The purpose of this extended study is to evaluate the safety and effectiveness of the Zenith® Branch Endovascular Graft-Iliac Bifurcation in combination with the commercially available Atrium iCAST™ covered stent in patients with an unsuitable distal sealing site for a Zenith® iliac leg component proximal to the common iliac bifurcation to maintain internal iliac artery patency during endovascular aneurysm repair.

This extended study is designed as a prospective, non-randomized study enrolling up to 60 additional patients to receive the Zenith® Branch Endovascular Graft-Iliac Bifurcation at up to 30 clinical sites. This additional enrollment will include a cohort of 40 patients who will be treated with the Zenith® Branch Endovascular Graft-Iliac Bifurcation in combination with the Atrium iCAST™ covered stent, which is replacing the alternate covered stents used in a portion of the additional patients already enrolled in the extended study (18 patients) as well as the initial cohort of 40 patients accrued prior to the extended study. Patients with anatomy amenable to endovascular repair, who meet other enrollment criteria (see section 8.6), will be included in this extended study, which will be complete with respect to enrollment upon accrual of 40 patients treated with the Zenith® Branch Endovascular Graft-Iliac Bifurcation in combination with the Atrium iCAST™ covered stent. Patients who do not meet the criteria will be excluded. A patient will be considered enrolled in the study once the delivery system of the study device has been inserted under the skin.

As depicted by Figure 1, all patients will be evaluated clinically and radiographically (when applicable) at pre-procedure, procedure, pre-discharge, 1, 6, 12, 24, 36, 48, and 60 months. Additionally, it is recommended that all previously enrolled patients who received the ConnectSX™ undergo CT follow-up to assess stent integrity every six months unless the stent has been relined to treat an observed or threatened Type III endoleak.



[1] Selective angiography may be requested to provide more focused imaging if potential device integrity issues are identified, but are unable to be confirmed, using CT.

[2] It is recommended that all previously enrolled patients who received the ConnectSX™ undergo CT follow-up to assess stent integrity every six months unless the stent has been relined to treat an observed or threatened Type III endoleak.

Figure 1. Extended study flow diagram

4.0. Objectives of the Clinical Investigation

The objectives of this extended study are to evaluate the safety and effectiveness of the Zenith® Branch Endovascular Graft-Iliac Bifurcation with the Atrium iCAST™ stent.

4.1. Primary Objectives

Primary Endpoint: The primary assessment will be based on 6-month freedom from patency-related intervention since the Zenith® Branch Endovascular Graft-Iliac Bifurcation is intended to maintain blood flow to the internal iliac artery and minimize the risk of associated clinical symptoms with the need for reintervention.

4.2. Secondary Objectives

Secondary Safety Endpoint: The secondary safety endpoint will be based on freedom from 30-day morbidity (i.e., the morbidity index).
[The information in this section has been redacted due to confidential content.]

4.3. Specific Hypothesis to be Accepted or Rejected by Statistical Data

4.3.1. Primary Hypothesis

The primary hypothesis will assess the rate of freedom from patency-related intervention evaluated at 6 months and will be based on results from the cohort of patients treated with the Zenith® Branch Endovascular Graft-Iliac Bifurcation in combination with the Atrium iCAST™ covered stent as part of the extended study. The analysis requires that, using a Bayesian beta-binomial model, a specified performance goal described in the following sentences be met. The Zenith® Branch Endovascular Graft-Iliac Bifurcation (Branch Graft) is intended to preserve flow to the internal iliac artery (IIA), providing an alternative treatment option for patients who would otherwise require sacrifice of the IIA through coil embolization and stent-graft coverage of the IIA as part of endovascular aneurysm repair of aortoiliac or iliac aneurysms. In order to provide the most meaningful labeling for clinical decision making on whether to sacrifice or preserve the IIA, it was determined appropriate to base the performance goal for the Branch Graft on outcomes associated with sacrificing the IIA, which represents the only endovascular treatment option currently available for the intended patient population. Specifically, unilateral coil embolization and stent-graft coverage of the IIA results in pelvic ischemic symptoms/complications in approximately 45% of patients with no good option for alleviating the symptoms through endovascular means.[1-12] Based on this, a performance goal of 55% for freedom from patency-related intervention was established.

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1. Cynamon J, Lerer D, Veith FJ, et al. Hypogastric artery coil embolization prior to endoluminal repair of aneurysms and fistulas: buttock claudication, a recognized but possibly preventable complication. J Vasc Interv Radiol 2008;11:573-577.
2. Criado FJ, Wilson EP, Velazquez OC, et al. Safety of coil embolization of the internal iliac artery in endovascular grafting of abdominal aortic aneurysms. J Vasc Surg 2000;32:684-688.
3. Wolpert LM, Dittrich KP, Hallisey MJ, et al. Hypogastric artery embolization in endovascular abdominal aortic aneurysm repair. J Vasc Surg 2001;33:1193-1198.
4. Lyden SP, Sternbach Y, Waldman DL, et al. Clinical implications of internal iliac artery embolization in endovascular aneurysm repair of aortoiliac aneurysms. Ann Vasc Surg 2001;15:539-543.
5. Schoder M, Zaunbauer L, Holzenbein T, et al. Internal iliac artery embolization before endovascular repair of abdominal aortic aneurysms: frequency, efficacy, and clinical results. Am J Roentgenol 2001;117:599-605.
6. Lin PH, Bush RL, Chaikof EL, et al. A prospective evaluation of hypogastric artery embolization in endovascular aortoiliac aneurysm repair. J Vasc Surg 2002;36:500-506.
7. Wyers MC, Schermerhorn ML, Fillinger MF, et al. Internal iliac occlusion without coil embolization during endovascular abdominal aortic aneurysm repair. J Vasc Surg 2002;36:1138-1145.
8. Kritpracha B, Pigott JP, Price CI, et al. Distal internal iliac artery embolization: a procedure to avoid. J Vasc Surg 2003;37:943-948.

The null (H_0) and alternate (H_A) hypotheses are expressed as follows:

Null Hypothesis: The 6-month rate of freedom from patency-related intervention in patients treated with the Zenith® Branch Endovascular Graft-Iliac Bifurcation does not meet the performance goal (55%).

H_0: $\pi \leqq 55\%$

Alternate Hypothesis: The 6-month rate of freedom from patency-related intervention in patients treated with the Zenith® Branch Endovascular Graft-Iliac Bifurcation meets the performance goal (55%).

H_A: $\pi > 55\%$

where π is the proportion of all patients treated with the Branch Graft who have freedom from patency-related intervention at 6 months. The hypothesis will be assessed by comparing the 2.5^{th} percentile of the Bayesian posterior distribution of π to the performance goal. The null hypothesis will be rejected if the 2.5^{th} percentile of the Bayesian posterior distribution of π is greater than the performance goal.

4.3.2. Secondary Safety Hypothesis

The secondary safety hypothesis will assess the freedom from 30-morbidity and will be based on results from the cohort of patients treated with the Zenith® Branch Endovascular Graft-Iliac Bifurcation in combination with the Atrium iCAST™ covered stent as part of the extended study. For the secondary safety endpoint performance goal, patients with occluded internal iliac arteries in the Zenith® AAA Endovascular Graft Clinical Study were evaluated to identify the rate of 30-day morbidity based on a composite endpoint of

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9. Tefera G, Turnipseed WD, Carr SC, et al. Is coil embolization of hypogastric artery necessary during endovascular treatment of aortoiliac aneurysms? Ann Vasc Surg 2004;18:143-146.
10. Arko FR, Lee WA, Hill BB, et al. Hypogastric artery bypass to preserve pelvic circulation: improved outcome after endovascular abdominal aortic aneurysm repair. J Vasc Surg 2004;39:404-408.
11. Farahmand P, Becquemin JP, Desgranges P, et al. Is hypogastric artery embolization during endovascular aortoiliac aneurysm repair (EVAR) innocuous and useful? Eur J Vasc Endovasc Surg 2008;35:429-435.
12. Rayt HS, Bown MJ, Lambert KV, et al. Buttock claudication and erectile dysfunction after internal iliac artery embolization in patients prior to endovascular aortic aneurysm repair. Cardiovasc Intervent Radiol 2008;31:728-734.

31 pre-specified measured elements in seven categories (i.e., cardiovascular, pulmonary, renal, bowel, wound, neurologic, and vascular) which comprised the morbidity index for the Zenith® AAA Endovascular Graft Clinical Study. Approximately 44% of the patients had experienced morbidity within 30 days, with a margin of 10%, a performance goal of 46% was established. [The information in this section has been redacted due to confidential content.]

The null (H_0) and alternate (H_A) hypotheses are expressed as follows:

Null Hypothesis: The rate of freedom from 30-day morbidity following treatment with the Zenith® Branch Endovascular Graft-Iliac Bifurcation does not meet the performance goal (46%).

H_0: $p \leq 46\%$

Alternate Hypothesis: The rate of 30-day morbidity following treatment with the Zenith® Branch Endovascular Graft-Iliac Bifurcation meets the performance goal (46%).

H_A: $p > 46\%$

where p is the proportion of all patients treated with the Branch Graft who have freedom from morbidity at 30 days. The hypothesis will be assessed by comparing the 2.5^{th} percentile of the Bayesian posterior distribution of p to the performance goal. The null hypothesis will be rejected if the 2.5^{th} percentile of the Bayesian posterior distribution of p is greater than the performance goal.

5.0. Device Description and Intended Purpose

5.1. Device Identification

The Zenith® Branch Endovascular Graft-Iliac Bifurcation and the commercially available Atrium iCAST™ stents available for the extended clinical study are outlined in the Clinical Investigator Brochure.

Each device will have traceability throughout the course of the extended study through the use of a product log, which includes information such as lot numbers, quantity, and disposition of devices. Additionally, information such as the quantity, size(s), and lot number(s) of devices used in patients will be recorded on Case Report Forms (CRFs).

5.2. Intended Purpose

The Zenith® Branch Endovascular Graft-Iliac Bifurcation with the H&L-B One-Shot™ Introduction System is indicated for the endovascular treatment of patients with an aortoiliac or iliac aneurysm, an insufficient distal sealing site within the common iliac artery, and having morphology suitable for endovascular repair. [The information in this section has been redacted due to confidential content.]

5.3. General Device Description

A general device description, including any materials that will be in contact with tissues or body fluids can be located in the Clinical Investigator Brochure. The device does not contain medicinal products, human and/or animal tissues or their derivatives, or other biologically active substances.

5.4. Device Sizes

5.4.1. Zenith® Branch Endovascular Graft-Iliac Bifurcation

[The information in this section has been redacted due to confidential content.]

5.4.2. Atrium iCAST™ Stent

Commercially available Atrium iCAST™ stents will be used in conjunction with the Branch Graft. The Atrium iCAST™ covered stent is a balloon-expandable endoluminal device consisting of a laser cut 316L stainless steel stent with an encapsulated cover made of expanded PTFE. The sizes listed in Table 5.4.2-1 reflect the subset of commercially available sizes that are recommended for use in combination with the Branch Graft as part of the study.

Table 5.4.2-1. Atrium iCAST™ Covered Stent Availability

Delivery System Lengths (cm)	Nominal Stent Outer Diameter (mm)	Nominal Length (mm)	Delivery System Size (Fr)
80	8	38	7
80	9	38	7
80	10	38	7
80	8	59	7
80	9	59	7

5.5. Instructions for Use and Implantation

Please reference the corresponding manufacturer's Instructions for Use for complete instructions for each device, including implantation, storage and handling requirements,

preparation for use, pre-use checks for safety and performance, and precautions to be taken after use. [The information in this section has been redacted due to confidential content.]

5.6. Summary of Necessary Training and Experience

See the Instructions for Use of each device for a complete summary of necessary training and experience. Briefly, in addition to training on and review of this protocol, review of the indications, contraindications, adverse events, warnings, precautions, and Instructions for Use (including patient selection, device planning and sizing, patient follow-up, and post-procedure care) for the Zenith® Branch Endovascular Graft-Iliac Bifurcation and Atrium iCAST™ stent is required. In addition, the investigator must have practical experience deploying these devices.

5.7. Endovascular Graft and Bridging Stent Deployment

Refer to the Instructions for Use for complete details regarding use of the Zenith® Branch Endovascular Graft-Iliac Bifurcation, Atrium iCAST™ stent, and Zenith Flex® AAA Endovascular Graft and iliac legs. Fluoroscopic guidance and angiography should be used throughout the procedure to verify positioning of the device with respect to the patient's anatomy. [The information in this section has been redacted due to confidential content.]

5.8. Description of Necessary Medical or Surgical Procedures

Please reference the manufacturer's Instructions for Use for a complete description of the procedures involved in the use of this device.

6.0. Summary of Preliminary Investigations

Refer to the Manufacturer's Instructions for Use and for a complete description of the procedures involved in the use of this product and Clinical Investigator Brochure for a comprehensive literature review and evaluation.

7.0. Risk Analysis and Risk Assessment

Please reference the Clinical Investigator Brochure for a complete risk analysis.

7.1. Risks and Foreseeable Adverse Device Effects

Events known to be related to pre-existing conditions or existing at admission are not considered adverse events (e.g., prior medically-treated cardiac arrhythmia with no

change in status during the endovascular procedure). Additionally, common standard of care practices are not considered adverse events (e.g., centers located at high geographical altitudes that discharge all patients on home oxygen therapy regardless of procedure).

Adverse events that may occur and/or require intervention include, but are not limited to:

- Allergic or hypersensitivity reaction to stainless steel, polyester, polytetrafluoroethylene, gold, or nitinol
- Amputation
- Anesthetic complications and subsequent attendant problems (e.g., aspiration)
- Aneurysm enlargement
- Aneurysm rupture and death
- Arterial damage, including perforation, dissection, bleeding, rupture, and death
- Arterial or venous thrombosis and/or pseudoaneurysm
- Arteriovenous fistula
- Bleeding, hematoma, or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock, lower limb)
- Death
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Endoprosthesis/stent: improper component placement, incomplete component deployment, component migration, suture break, occlusion, infection, stent fracture, graft material wear, dilatation, erosion, puncture, perigraft flow, and corrosion
- Fever and localized inflammation
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- Graft or native vessel occlusion
- Hepatic failure
- Impotence
- Infection of the aneurysm, device, or access site, including abscess formation, transient fever, and pain

- Lymphatic complications and subsequent attendant problems (e.g., lymph fistula)
- Neurologic or systemic complications and subsequent attendant problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, paralysis)
- Pulmonary/respirator complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent attendant problems (e.g., contrast toxicity, insufficiency, failure)
- Surgical conversion to open repair
- Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula
- Vessel damage
- Wound complications and subsequent attendant problems (e.g., dehiscence, infection)
- Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death)

7.2. Methods to Minimize Risks

As described previously, the device design, extended clinical study design, and the instructions for use are intended to minimize the risks associated with endovascular procedures.

It is anticipated that, guided by experience, continued efforts such as this study will make the endovascular treatment of aortoiliac and iliac aneurysms safer and more effective than open surgical repair.

8.0. Design of the Clinical Investigation

8.1. Type of Investigation

The design will be a prospective, non-randomized, extended study enrolling up to 60 additional patients to receive the Zenith® Branch Endovascular Graft-Iliac Bifurcation, including a cohort of 40 patients treated in combination with the Atrium iCAST™ covered stent. It will be conducted at up to 30 investigative sites. The results from the cohort of patients treated with the Zenith® Branch Endovascular Graft-Iliac Bifurcation in combination with the Atrium iCAST™ covered stent will be the subject of the hypothesis testing described in Section 4.5.

8.2. Measures to be Taken to Avoid or Minimize Bias

This extended study is not randomized or blinded. It is intended to prospectively collect safety and effectiveness data to support the marketing application for the Zenith® Branch Endovascular Graft-Iliac Bifurcation and Atrium iCAST™ stent in conjunction with the Zenith Flex® AAA Endovascular Graft.

8.3. Limitations of the Study

The study is inherently limited by the number of patients who will be excluded due to general, medical, and anatomical exclusion criteria. Additional challenges to the study include the anticipated comorbidities likely to be found in patients with aortoiliac, or iliac aneurysms, which may confound data analysis. Additional confounding elements of the study might include difficulty adjudicating device-related events to a specific endovascular graft (i.e., Zenith® Branch Endovascular Graft-Iliac Bifurcation, Atrium iCAST™ stent, Zenith Flex® AAA Endovascular Graft, and iliac leg component) and the lower incidence of AAA in women, with the anticipation of fewer women than men being enrolled in the study.

8.4. Duration of the Investigation

Patient recruitment (pivotal patients receiving the Atrium iCAST™ stent; n=40) is expected to be completed within 12 months of restarting the extended study. Follow-up data will continue to be collected for five years after graft deployment for each patient in the extended study, making the study duration approximately 60 months for each patient.

8.5. Assessing Outcome/Rationale

The primary endpoint will be based on 6-month freedom from patency-related intervention since the Zenith® Branch Endovascular Graft-Iliac Bifurcation is intended to maintain blood flow to the internal iliac artery and minimize the risk of associated clinical symptoms with the need for reintervention.

The secondary safety endpoint will be based on 30-day morbidity. The secondary effectiveness endpoint (for descriptive purposes only) will be based on branch vessel patency at 6 months. For the secondary effectiveness endpoint, the 95% confidence interval will be reported.

All endpoints and assessments will be based on the results from the cohort of patients treated with the Zenith® Branch Endovascular Graft-Iliac Bifurcation in combination with the Atrium iCAST™ covered stent. [The information in this section has been redacted due to confidential content.]

8.6. Inclusion and Exclusion Criteria

All patients eligible for aneurysm repair will be evaluated for enrollment in this study according to the inclusion/exclusion criteria. All patients eligible for entry into the study will have the potential risks and benefits of the procedures and the overall clinical investigation plan explained to them. Each patient who wishes to participate in this study will provide written informed consent prior to his or her enrollment into the study.
All patients must meet the general inclusion criteria to be enrolled in the study. **No** patients may be enrolled if any of the general or medical exclusion criteria are true. **No** patients may be enrolled in the study if any of the anatomical exclusion criteria are true. The general and medical exclusion criteria will be assessed during the initial patient evaluation by conducting a history and physical examination. Anatomical exclusion criteria will be assessed using a variety of imaging techniques that are routinely performed during the evaluation of abdominal aortic and/or iliac aneurysms.

Assessment of inclusion and exclusion criteria will be based upon data available pre-operatively. Data obtained peri-operatively and post-operatively may contradict pre-operative assessment, and such is anticipated in several cases. However, such contradiction should not be construed as evidence of inadequate or inaccurate pre-operative assessment with respect to the enrollment criteria or evidence of inappropriate enrollment. Enrollment is to be based upon the best available pre-operative data. Therefore, some criteria relate to subjective assessment while other criteria are considered absolute and able to be determined definitively. Variability in assessment between centers, investigators and observers is expected with several criteria. [This information has been redacted due to confidential content.]

General Inclusion Criteria:

Patients can be considered for entry into the Zenith® Branch Endovascular Graft-Iliac Bifurcation extended study if treatment is clinically indicated. Specifically, the patient must have the following:

1) An aortoiliac or iliac aneurysm
2) An unsuitable distal sealing site for a Zenith® iliac leg graft within the common iliac artery on the intended side of Branch Graft implantation

General Exclusion Criteria:

Patients are excluded from enrollment into the Zenith® Branch Endovascular Graft-Iliac Bifurcation extended study if any of the following are true:

1) Age < 18 years
2) Pregnant, breast-feeding, or planning on becoming pregnant prior to completion of the study
3) Unwilling or unable to comply with the follow-up schedule
4) Unable or unwilling to give informed consent
5) Simultaneously participating in another investigative device or drug study

8.7. Registration/Point of Enrollment

Point of enrollment will be based on the intent-to-treat population, and is defined to include any patient for which the treatment procedure is initiated. More specifically, once the delivery system of the study device (Zenith® Branch Endovascular Graft-Iliac Bifurcation) has been inserted under the patient's skin, this patient would be included in the intent-to-treat population. Primary statistical analyses will be based on this set of patients.

8.8. Measurements and Data Collection/Variables

Please reference the case report forms for a complete list of data points collected during the extended study.

Patients meeting the selection criteria who have provided informed consent will undergo a detailed pre-procedural examination. Data will be collected and stored in a database. Data points include patient demographics, risk assessment (e.g., SVS-ISCV risk score), blood tests, a clinical evaluation, and a CT (with angiography if necessary).

To evaluate deployment characteristics and procedural outcome, the following data points will be collected intra-operatively:

1) Assessment of system performance including: deployment issues (difficulty visualizing, deploying, or removing the devices

2) Complications (if any), will be captured on Event form
3) Adjunctive maneuvers including: balloon dilation of iliac arteries, additional stents/ancillary components required, and additional surgical procedures
4) Findings of completion assessment: device patency, endoleak, and kinks

In addition, the results of the endovascular repair (including internal iliac artery patency) will be assessed by clinical and/or imaging evaluation at the time of graft insertion, within 7 days post-procedure, at 30 days (± 10 days), 6 months (180 ± 30 days), 12 months (365 ± 45 days), 2 years (730 ± 60 days), 3 years (1095 ± 60 days), 4 years (1460 ± 90 days), and 5 years (1825 ± 90 days) according to the post-operative study schedule below (Table 8.8-1). The ranges listed above are considered guidelines for the investigative sites when scheduling visits.

It is recommended that all previously enrolled patients who received the ConnectSX™ undergo CT follow-up to assess stent integrity every six months unless the stent has been relined to treat an observed or threatened Type III endoleak.

Table 8.8-1. Extended study exam schedule

				Month						
	Pre-op	Intra-op	Pre-discharge	1	6	12	24	36	48	60
CT Scan[1]	X			X[2,3]	X[2,3]	X[2,3]	X[2,3]	X[2,3]	X[2,3]	X[2,3]
Angiography	X[4]	X								
Blood tests[5]	X		X	X	X	X	X	X	X	X
Clinical Exam	X		X	X	X	X	X	X	X	X

[1] Selective angiography may be requested to provide more focused imaging if potential device integrity issues are identified, but are unable to be confirmed, using CT.
[2] In patients experiencing renal failure during follow-up, selective angiography (preferred) or duplex ultrasound may be used in conjunction with non-contrast CT.
[3] It is recommended that all previously enrolled patients who received the ConnectSX™ undergo CT follow-up to assess stent integrity every six months unless the stent has been relined to treat an observed or threatened Type III endoleak.
[4] Pre-procedure angiography may be requested at discretion of film reviewer/proctor.
[5] Blood tests include creatinine.

8.9. Criteria and Procedures for Extended Study Termination

A patient's follow-up in the extended study will end after:

1) Failure to deploy the device + 30 days
2) Conversion to open surgical technique + 30 days
3) Patient withdrawal
4) Patient death

5) Closure of the investigation
6) Completion of all scheduled clinical and imaging visits, up to 5 year follow-up

8.10. Statistical Considerations

8.10.1 Sample Size

Bayesian simulation studies were performed to determine the sample size required to test the study hypotheses with sufficient statistical power (in the frequentist context).
For the power calculation of the primary hypothesis, the true patency rate of the IIA following treatment with the Branch Graft was assumed to be 83% based on the literature.[13-19] With a performance goal of 55% for freedom from patency-related intervention (derived as described in section 4.3.1), the simulation study indicates that a maximum sample size of 25 patients will provide a power of approximately 88.5%, at a type I error rate of 2.5%.

For the secondary safety hypothesis, the true rate of freedom from 30-day morbidity was assumed to be 72.5%, which was derived from patients with patent internal iliac arteries in the Zenith® AAA Endovascular Graft Clinical Study who were free from 30-day morbidity (i.e., free from all 31 events in the Zenith® AAA Endovascular Graft Clinical Study morbidity index and hip/thigh/buttock claudication). With a performance goal of 46% for freedom from 30-day morbidity (derived as described in section 4.3.2), the simulation study indicates that a maximum sample size of 29 patients will provide a power of 85.8%, at a type I error rate of 2.5%.

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13. Ziegler P, Avgerinos ED, Umscheid T, et al. Branched iliac bifurcation: 6 years experience with endovascular preservation of internal iliac artery flow. J Vasc Surg 2007;46:204-210.
14. Serracino-Inglott F, Bray AE, Myers P. Endovascular abdominal aortic aneurysm repair in patients with common iliac artery aneurysms – initial experience with the Zenith bifurcated iliac side branch device. J Vasc Surg 2007;46:211-217.
15. Dias NV, Resch TA, Sonesson B, et al. EVAR of aortoiliac aneurysms with branched stent-grafts. Eur J Vasc Endovasc Surg 2008;35:677-684.
16. Verzini F, Parlani G, Romano L, et al. Endovascular treatment of iliac aneurysm: concurrent comparison of side branch endograft versus hypogastric exclusion. J Vasc Surg 2009;49:1154-1161.
17. Huigol RL, Denton MJ, Cohen T. The iliac bifurcation device for endovascular iliac aneurysm repair: indications, deployment options and results at 1-year follow-up of 25 cases. ANZ J Surg 2009;79:844-849.
18. Tielliu I, Bos W, Zeebregts C, et al. The role of branched endografts in preserving internal iliac arteries. J Cardiovasc Surg 2009;50:213-218.
19. Ferreira M, Monteiro M, Lanziotti L. Technical aspects and midterm patency of iliac branched devices. J Vasc Surg 2010;51:545-550.

Cook intends to enroll 40 patients with the Zenith® Branch Endovascular Graft-Iliac Bifurcation and Atrium iCAST™ covered stent, allowing for those who may withdraw or be lost to follow-up, in the study at up to 30 institutions.

8.10.2 General Statistical Analyses

Statistical analysis will be performed only on the cohort of patients treated with the Zenith® Branch Endovascular Graft-Iliac Bifurcation in combination with the Atrium iCAST™ covered stent as part of the extended study. SAS® for Windows® (release 9.3 or higher) or other widely accepted statistical software will be used to perform the analysis. Continuous variables will be reported as means and standard deviations unless otherwise noted. Categorical variables will be reported as percent. Techniques such as logistic regression, Kaplan-Meier, or Cox Proportional Hazards may be used for additional analysis.

8.10.3 Missing Data

The primary and secondary hypotheses will be assessed using the intent-to-treat patient population. Any patient that is considered missing for this endpoint analysis will first be examined to determine if best-available data can be used to assess the endpoint. Previous clinical trial experience suggests that some portion of the imaging data may not meet the criteria for accurate review by the core laboratory; however, it is recognized that the investigator uses this information to provide the best possible care for the patient. Therefore, it is reasonable to substitute any missing core laboratory measurements with the corresponding measurements made by the investigator or institutional staff. Otherwise, missing responses will be imputed from the empirical distribution of responses. Additional analyses may also be performed to address missing data, including tipping point analysis.

8.11. Methods

8.11.1. Medication

The hospital's standard protocol should be followed with respect to medication pre-procedure and during the procedure.

8.11.2. Pre-procedure

Zenith® Branch Endovascular Graft-Iliac Bifurcation Sizing

The Zenith® Branch Endovascular Graft-Iliac Bifurcation is sized based on the findings from pre-operative radiographic studies, including computerized tomography (CT) and

conventional angiography. Zenith® Branch Endovascular Graft-Iliac Bifurcation component selection should be based on the recommended sizing guidelines in the Instructions for Use of this device.

Atrium iCAST™ Sizing

The Atrium iCAST™ stent is sized based on the findings from pre-operative radiographic studies, including computerized tomography (CT) and conventional angiography, if needed. Final sizing is based on findings from intra-operative angiography.

Additional Component Sizing

Since the patient will undergo concomitant AAA endovascular repair with a standard Zenith Flex® AAA Endovascular Graft (main body and iliac legs), all proximal aortic measurements should be assessed and sized according to Zenith Flex® AAA Endovascular Graft Instructions for Use (IFU).

8.11.3. Procedure

Standard techniques for placement of arterial access sheaths, guiding catheters, angiographic catheters, and wire guides should be employed during use of the Zenith® Branch Endovascular Graft-Iliac Bifurcation, Atrium iCAST™, and Zenith Flex® AAA Endovascular Graft and iliac legs. All components are compatible with 0.035 inch diameter wire guides.

Refer to institutional protocols relating to anesthesia, anticoagulation and monitoring of vital signs. Position the patient on an imaging table allowing fluoroscopic visualization from the aortic arch to the femoral bifurcations. Expose both common femoral arteries using standard surgical technique and establish adequate proximal and distal vascular control of both femoral vessels.

Refer to the Instructions for Use for complete details regarding use of the Zenith® Branch Endovascular Graft-Iliac Bifurcation, the Zenith Flex® AAA Endovascular Graft, and iliac legs. A commercially available balloon-expandable covered stent (Atrium iCAST™ stent) will be placed to preserve blood flow to the internal iliac artery; likewise, the Manufacturers' Instructions for Use should be referred to for additional information. Fluoroscopic guidance and angiography should be used throughout the procedure to verify positioning of the device with respect to the patient's anatomy.

8.11.4. Post-operative Treatment of Endoleaks

The presence of contrast media in the aneurysm sac is indicative of an endoleak. Type I or type III endoleaks may warrant treatment at the time of implantation. To classify an endoleak as type II, imaging documentation must clearly show the source. Due to the anatomy of the iliac bifurcation area, the presence of a type II endoleak is unlikely; however, should one occur, the patient should be treated at the physician's discretion. Type IV endoleaks are generally associated with grafts with a high porosity and are unlikely with this graft.

8.12. Period of Use for the Device or its Control

The follow-up period for the clinical investigation should permit the demonstration of performance over a period of time sufficient to represent a realistic test of the performance of the device and allow identification and risk assessment of any associated adverse device effects over that period.

8.13. Safety Monitoring

A Data Safety Monitoring Board (DSMB), consisting of independent physicians who are not investigators in the extended study and do not have a perceived conflict of interest with the conduct and administration of the extended study, will be convened on a regular basis to evaluate the extended study progress and review adverse events.

An independent Clinical Events Committee (CEC) will be established. Any adjudication of clinical events will be performed according to standard operating procedures to assess whether the events were due to a pre-existing condition, procedure-related, technique-related, and/or device-related. In addition, a core laboratory will be established to independently review available imaging.

Regularly scheduled monitoring, including on-site visits, will be conducted, in part, for identification of adverse events and assurance that they are correctly reported to the DSMB and CEC.

9.0. Emergency Situations

Patients will not be treated with the Zenith® Branch Endovascular Graft-Iliac Bifurcation in emergency situations where prior consent of the patient (or legally authorized representative) is not possible. Since the Zenith Flex® AAA Endovascular Graft is

approved for commercial use, the physician may use the Zenith Flex® AAA Endovascular Graft to treat a patient in an emergency situation; however, that patient would not be enrolled in the current study and no data would be collected under this investigational plan. The Zenith® Branch Endovascular Graft-Iliac Bifurcation and Atrium iCAST™ may not be used to treat a patient in an emergency situation.

10.0. Deviations from the Clinical Investigation

Deviations or non-compliances will be recorded together with an explanation. Deviations shall be reported to the Sponsor, regulatory authorities, and local IRB/ethics committee as required.

When available, the reasons for withdrawal and discontinuation of any patient from the investigation shall be recorded. If such discontinuation is because of problems with safety or lack of effectiveness, that patient shall still be followed-up in the investigation, if possible.

If appropriate, corrective and preventive actions will be discussed by the sponsor, investigator, and/or IRB to determine a suitable course of action.

11.0. Amendments to the Clinical Investigation

If necessary, changes to the clinical investigation plan, which affect the validity of the data; relationship of likely patient risk to benefit; scientific soundness; or rights, safety, or welfare of human subjects, will be approved by the regulatory authority and local institutional review board/ethics committee prior to implementation.

12.0. Informed Consent

A written informed consent must be obtained from all study patients (or their legally authorized representative), in accordance with applicable regulatory requirements, prior to enrollment in the trial. If new information is obtained after a patient receives treatment with the device, any patient who has not exited the study will be informed about the new information, and will be reconsented at the discretion of the investigator and/or the site's IRB.

13.0. Procedure for Reporting Adverse Events and Adverse Device Effects

Events known to be related to pre-existing conditions or existing at enrollment are not considered adverse events (e.g., new treatment for congestive heart failure diagnosed prior to the procedure). Additionally, common standard of care practices are not considered adverse events (e.g., supplemental oxygen provided for all patients discharged from institutions at high altitudes).

Adverse events are reported using the appropriate case report form (Adverse and Other Event form). Each completed form is to be submitted to the data coordinating center, who will inform the Sponsor accordingly. In cases of adverse device effects (typically reported on appropriate imaging form rather than Event form) or serious adverse events, completed forms should be submitted to the data coordinating center immediately after the site learns of the event.

The data coordinating center will notify the Sponsor accordingly. In accordance with applicable requirements, the investigator will notify the local institutional review board/ethics committee, while the Sponsor will notify the regulatory authority. The DSMB and CEC will also review applicable adverse events.

14.0. Ethical Considerations

The investigator is responsible for obtaining approval of this clinical investigation plan by the relevant IRB. The Sponsor must be provided with a copy of this approval before delivery of any study devices. Furthermore, the investigator will ensure that local regulations concerning data protection are followed.

15.0. Early Termination or Suspension of the Investigation

The Sponsor reserves the right to terminate/suspend the extended study at any point should they believe that important harmful events might result from its continuation. Study patients may withdraw from the extended study at any time without penalty or loss of benefits. The investigator may also decide to withdraw a patient from the extended study at any time on the basis of medical judgement. In any case, the reasons for withdrawal will be documented.

16.0. Publication Policy

Publication policy, rights and obligations for this Investigation have been negotiated, detailed and defined in the Investigation Contractual Documents and Agreements with the Investigation Site and Investigators.

17.0. Data Collection

All data will be recorded on standardized, preprinted, data collection forms (CRF) suitable for electronic data capture. Data will be entered by qualified personnel (i.e., the clinical investigator or a person designated by him/her).

18.0. Data Reporting

Progress reports and a final report at the conclusion of the clinical investigation will be submitted by the investigators and Sponsor to the regulatory bodies and local IRB/ethics committees as required by local regulations.

ATTACHMENT A
Written Procedures for Monitoring Investigations

Written Procedures for Monitoring Investigations

A. Selection of the monitor.

Designated by the sponsor to oversee the extended investigation, the monitor must be an employee of the sponsor or an independent contractor or consultant. The monitor shall be qualified by training and experience to monitor the investigational study in accordance with all applicable regulations and standards for conducting clinical investigations.

B. General duties of the monitor.

The monitor must ensure that the extended investigation is conducted in accordance with:

1. The signed investigator agreement.
2. The clinical investigational plan (CIP)/protocol.
3. Any conditions imposed by the IRB/EC or regulatory authority.
4. The requirements of the applicable regulations and standards.

C. Reports by the monitor to the sponsor.

1. Any noncompliance with the items listed above. In the event that the investigator is not complying with the requirements outlined above, it is the sponsor's responsibility to secure compliance.
2. Any adverse events/effects that are potentially reportable to a regulatory authority.

D. Initiating the study.

Prior to initiating any clinical use of the device, the monitor must conduct a pre-investigation or initiation visit with each investigator to ensure that:

1. The investigator understands the investigational status of the device.

2. The investigator understands and accepts his/her obligation in conducting the extended clinical investigation.
3. The investigator and his/her staff have sufficient time and access to an adequate number of subjects to conduct the extended clinical investigation.
4. The investigator has a signed Investigator Agreement on file.
5. Each IRB/EC approval is on file, and all conditions of the IRB/EC approval have been met.
6. The clinical use of the device does not begin until regulatory authority and IRB/EC approval has been received.

E. During the course of the extended investigation.

1. Conduct periodic discussions with the investigator or his/her staff to ensure that the study is being conducted in accordance with the protocol or Clinical Investigational Plan, any conditions of the IRB/EC, and the requirements of the applicable regulations.
2. Review study data sheets (i.e., paper or electronic case report forms, data collection forms) and records to ensure that they are complete, accurate, and legible.
3. Review study data sheets (i.e., paper or electronic case report forms, data collection forms) and records for any adverse events/effects that are potentially reportable to a regulatory authority.
4. Ensure that the investigator has properly disposed of or returned all devices to the sponsor, unless this action would jeopardize the rights, safety, or welfare of the subject.

F. Records of the monitor.

The monitor shall prepare and maintain records of each initiation visit and each periodic visit, general site contact, or discussion. These will include:

1. Date, name and address of the investigator, and names of other staff members present at each meeting.
2. A summary of the findings of the visit.
3. A statement of any action taken by the monitor or investigator to correct any deficiencies noted.
4. The monitor shall immediately notify the sponsor of any conditions of non-compliance with the protocol, Clinical Investigational Plan,

conditions of IRB/EC or regulatory authority approval, or the applicable regulations.

ATTACHMENT B
Definitions

Definitions

Aneurysm (common iliac artery): > 20 mm in diameter (outer wall to outer wall).

Aneurysm (internal iliac artery): > 20 mm in diameter (outer wall to outer wall).

Buttock Claudication: Pain in the buttock or posterior thigh, which is initiated by activity and resolves with rest.

Calcification: Calcification will be graded based upon the following:

None:	Lack of calcification.
Mild:	Less than 40% circumferential calcification.
Moderate:	40-70% circumferential calcification.
Severe:	Greater than 70% circumferential.

Embolization: Clinical evidence of ischemic tissue remote from the operative field, presumably caused by thrombus dislodged from the aneurysmal sac, aortic neck, or adjacent vessels, including ischemia of the kidneys, pelvis (IIA), or lower limbs. This is, of course, distinct from pre-operative, operative or post-operative intentional embolization procedures.

Endoleak: Contrast-enhanced blood entering the aneurysm sac from around the proximal or distal end of the graft (type I), between joints of the graft and extension (if applicable) or through defects in the graft material (type III), via collateral vessels (type II), or graft fabric porosity (type IV).

Endoleak Type Classification:

Type I endoleak: A peri-prosthetic leak occurring at the proximal and/or distal attachment zones of the endovascular system.

Type II endoleak: A leak caused by retrograde flow from patent vessels. (Requires imaging documentation of Type II source). To classify an endoleak as

Type II, documentation with a CT-enhanced and/or selective angiogram clearly showing the source is required.
Type III endoleak: A leak caused by a defect in the graft fabric, inadequate seal (between graft components only), or disconnection of additional or ancillary graft components.
Type IV endoleak: A leak caused by graft fabric porosity, often resulting in a generalized blush of contrast within the aneurysm sac.
Unknown endoleak: Continuing blood flow into the aneurysmal sac with undefined origin.

Endoleak (early): Any endoleak observed by core laboratory within 30 days of device deployment.

Endoleak (late): Any endoleak observed by core laboratory later than 30 days after device deployment, which was not documented during the first 30 days post-deployment.

Ileus: Absence (or lack) of intestinal peristalsis lasting more than 4 days.

Limb Occlusion (Branch Graft): Core laboratory determination of the presence of thrombus within any aspect Zenith® Branch Endovascular Graft-Iliac Bifurcation (i.e., common iliac segment, external iliac segment, or sidebranch segment), creating occlusion.

Lower Extremity Ischemia: New tissue loss or rest pain.

Major Complications: Conversion to open surgical repair, aneurysm rupture, death, any cardiac events requiring percutaneous or surgical intervention, renal failure requiring dialysis where not previously needed, bowel ischemia, new onset of impotence or buttock claudication on the same side as Branch Graft implantation, ileus, lower extremity ischemia, ischemic neuropathy, paralysis, and stroke.

Medically Intractable Hypertension: Systolic arterial pressure >160 mmHg despite receiving medication.

MI (Non-Q-Wave): Investigator identified patients having clinical evidence of a myocardial infarction with elevated peak CK values greater than or equal to three times the upper limit of normal with elevated CK-MB (above the institution's upper limit of

normal) in the absence of new pathological Q-waves or clinical evidence of a myocardial infarction with troponin greater than three times the upper limit of normal, as determined by the investigator.

MI (Q-Wave): Post-procedure presence of new Q-waves greater than 0.04 seconds in at least two EKG leads.

Migration-Radiographic (Branch Graft): Core laboratory determination, and CEC confirmation, of caudal or cranial movement of the Branch Graft ≥10 mm relative to the overlap with the iliac leg graft (TFLE/ZSLE) as compared to the position on the first post-operative CT scan.

Migration-Clinical (Branch Graft): Antegrade or retrograde movement of the Branch Graft requiring surgical or endovascular intervention.

Morbidity Index:

Category	Measured Element	
Cardiovascular	1)	Q-wave myocardial infarction
	2)	non-Q-wave myocardial infarction
	3)	congestive heart failure (CHF)
	4)	arrhythmias which require new medication or treatment
	5)	cardiac ischemia requiring intervention
	6)	inotropic support
	7)	medically intractable hypertension
Pulmonary	8)	reintubation or ventilation >24 hours
	9)	pneumonia requiring antibiotics
	10)	patient receiving supplemental oxygen at discharge
Renal	11)	dialysis in patients with normal pre-operative renal function
	12)	creatinine rise >30% from baseline on two or more follow-up tests
Bowel	13)	bowel obstruction
	14)	bowel ischemia
	15)	paralytic ileus > 4 days
Access Site/Incision	16)	infection requiring antibiotic treatment
	17)	hernia
	18)	lymph fistula
	19)	dehiscence
	20)	necrosis requiring debridement
Neurologic	21)	stroke
	22)	TIA
	23)	spinal cord ischemia/paralysis
Vascular	24)	buttock claudication on the same side as Branch Graft implantation
	25)	limb thrombosis on the same side as Branch Graft implantation
	26)	distal embolization resulting in tissue loss or requiring intervention
	27)	transfusion post procedure (resulting from pseudoaneurysm, vascular injury, aneurysm leak or other procedure related causes)
	28)	pseudoaneurysm

Category	Measured Element
	29) aorto-enteric fistula 30) vascular injury (such as inadvertent occlusion, dissection or other procedure related causes) 31) aneurysm leak or rupture 32) increase in aneurysm size by more than 0.5 cm relative to the smallest of any prior measurement.
Miscellaneous	33) impotence

New York Heart Association Classification:

1 Patient with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea.

2 Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest; ordinary physical activity results in fatigue, palpitation or dyspnea.

3 Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest; less than ordinary physical activity causes fatigue, palpitation or dyspnea.

4 Patients with cardiac disease resulting in inability to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Occlusive Disease of Iliacs: Occlusive disease will be graded based upon the following:

None:	Lack of occlusive disease.
Mild:	Some disease, focal with less than 30% narrowing.
Moderate:	Between 30-50% narrowing not requiring interventional techniques to meet inclusion criteria.
Severe:	Greater than 50% or any patient requiring angioplasty prior to endograft delivery.
100% Occluded:	No blood flow past site of occlusion.

Patency-Related Intervention:

- Secondary intervention to treat a > 60% stenosis of the internal iliac artery (as identified through CT, angiography, or duplex ultrasound and confirmed by core laboratory) associated with clinical symptoms. Of note, this not only includes patients with internal iliac artery stenosis following successful placement of the Zenith® Branch Endovascular Graft-Iliac Bifurcation and covered bridging stent, but also any cases of technical failure resulting in occlusion of the internal iliac

artery during the initial implant procedure that require secondary intervention for associated clinical symptoms.

Renal Failure: Acute or progressive renal insufficiency leading to the need for dialysis or hemofiltration.

Renal Insufficiency: A rise in serum creatinine of more than 30% above the pre-procedure level, resulting in a serum creatinine level > 2.0 mg/dl that does not spontaneously resolve (does not include those patients with a pre-procedure serum creatinine > 2.0 mg/dl).

Serious Adverse Event: An adverse event that led to death, led to a serious deterioration in the health of the subject that resulted in a life-threatening illness or injury, resulted in a permanent impairment of a body structure or a body function, required in-patient hospitalization or prolongation of existing hospitalization, resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function, led to fetal distress, fetal death, a congenital abnormality or birth defect.

Stent/attachment system fracture/break: Fracture or breakage of any portion of the Zenith® Branch Endovascular Graft-Iliac Bifurcation or covered bridging stent or attachment system including metallic fracture or breakage of any suture material used to construct the stent or secure the stent or attachment system to the graft material as determined by the core laboratory and confirmed by CEC.

Success Measures

- *Technical Success:* The ability to deliver and deploy the Zenith® Branch Endovascular Graft-Iliac Bifurcation and covered bridging stent in the desired location; graft patency and internal iliac artery patency following deployment, as evidenced by intraoperative angiography; and successful removal of the delivery system.
- *Procedural Success:* Technical success with no type I, type III, or type IV endoleaks (see endoleak definition) at 30 days; no procedure-related major complications through 30 days; freedom from patency-related intervention through 30 days; and endovascular graft patency through 30 days, as evidenced by CT scan, angiography, or by duplex ultrasound in those patients experiencing renal failure and unable to undergo contrast-enhanced CT scan.

- *Treatment Success:* Technical success with no type I, type III, or type IV endoleaks at 12 months, no aneurysm-related major complications through 12 months, freedom from patency-related intervention through 12 months, no aneurysm enlargement greater than 0.5 cm through 12 months, and endovascular graft patency through 12 months as evidenced by CT scan, angiography or by duplex ultrasound in those patients experiencing renal failure and unable to undergo contrast-enhanced CT scan.

Tortuosity of iliac arteries: Tortuosity will be graded based upon the following:

None:	No tortuosity.
Mild:	Minimal tortuosity (less than one turn involving either external or common iliac artery).
Moderate:	Single turn involving either external or common iliac artery.
Severe:	Compound turns involving external and common iliac arteries.