Zenith® Iliac Branch

Instructions for use

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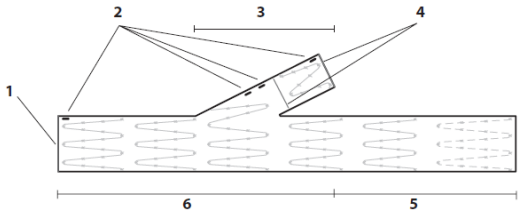

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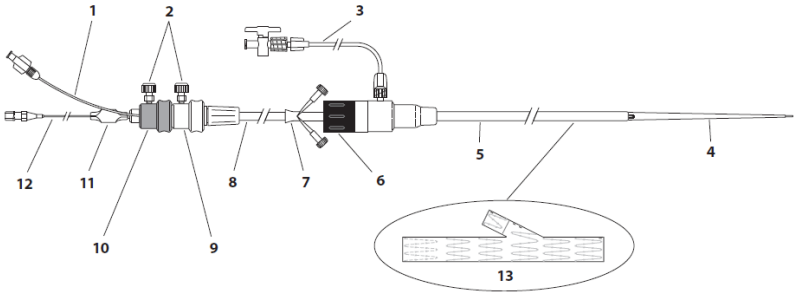

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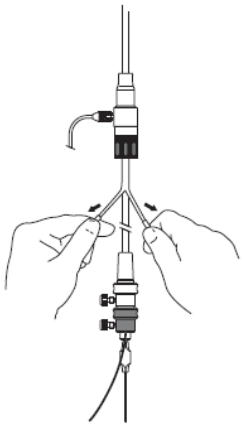

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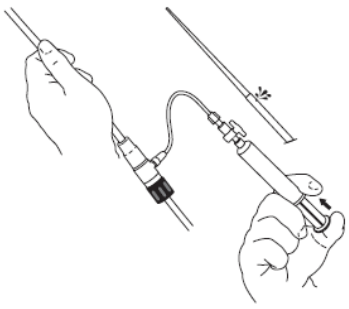

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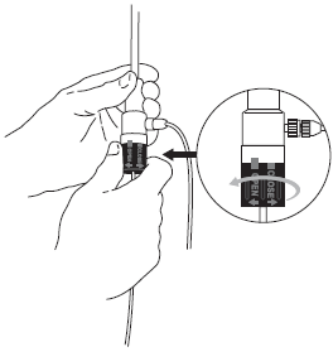

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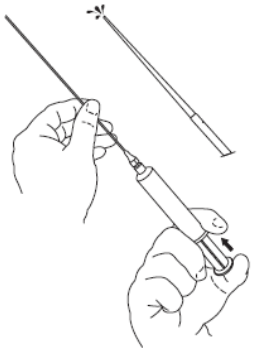

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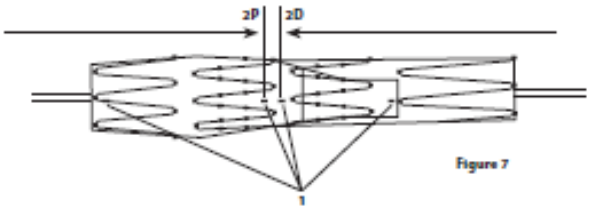
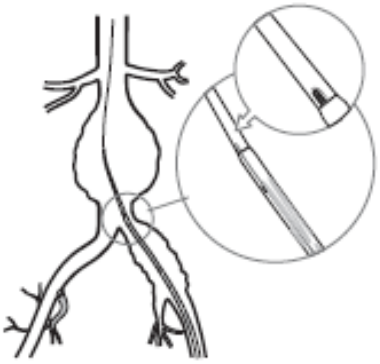


Figure 7

1. Gold Markers



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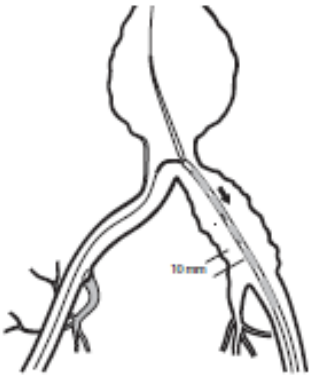

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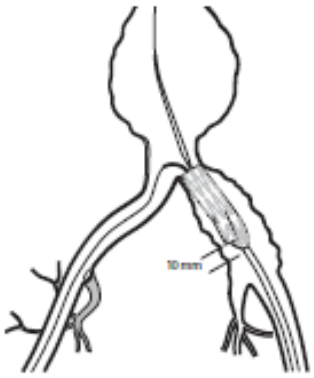

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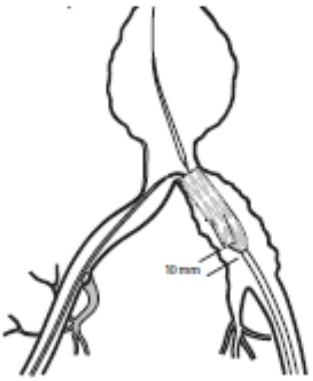

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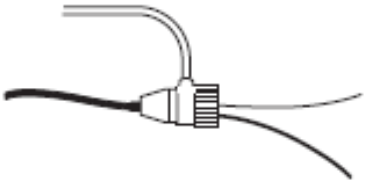

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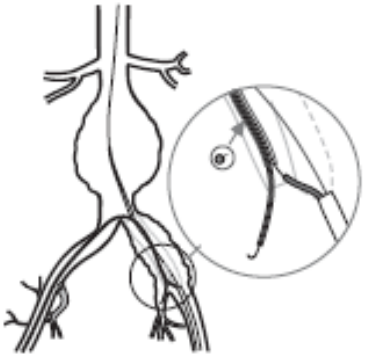

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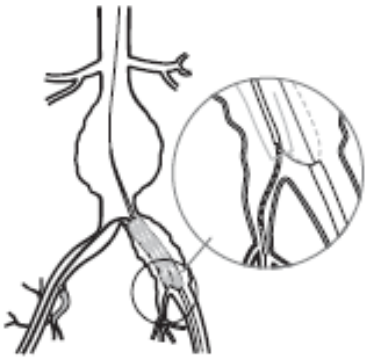

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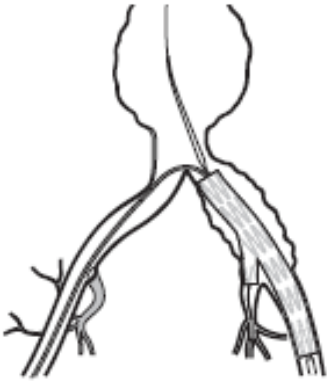

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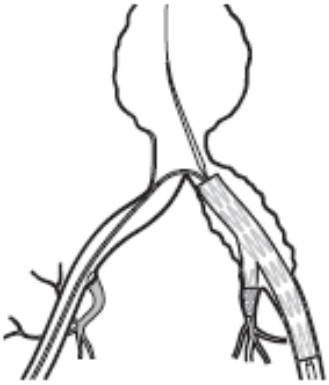

Figure 20

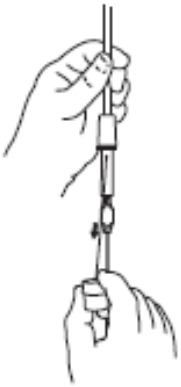

Figure 21

ZENITH® ILIAC BRANCH

CAUTION: U.S federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).
Read all instructions carefully. Failure to properly follow the information provided may lead to the device not performing as intended or injury to the patient.
For the Zenith® product line, there are several applicable Instructions for Use (IFU). This IFU applies to the Zenith® Iliac Branch. For information on other Zenith devices, please refer to the appropriate IFU.

1. DEVICE DESCRIPTION

The Zenith® Iliac Branch (ZBIS) is intended to be used in conjunction with the Zenith® Flex AAA Endovascular Graft (i.e., a Flex AAA main body and two iliac leg graft components) or Zenith® Fenestrated AAA Endovascular Graft (i.e., a fenestrated proximal body and a bifurcated distal body), Zenith® Spiral-Z AAA Iliac Leg (ZSLE) and a bridging stent.

1.1 Construction of device

The Zenith Iliac Branch is a bifurcated branch vessel graft with openings to connect the common iliac, internal iliac (sidebranch), and external iliac arteries. **(Figure 1)**

The graft is constructed of full-thickness, woven polyester fabric sewn to self-expanding stainless steel and nitinol Cook Z-Stents™ with braided polyester and monofilament polypropylene suture. Nitinol rings are positioned at the proximal end of the graft and within the internal iliac segment.

The Zenith Iliac Branch is shipped pre-loaded onto the H&L-B One-Shot™ Introduction System. **(Figure 2)**

The delivery system uses a 20 Fr (6.7 mm I.D.) H&L-B One-Shot Introduction System that includes both a pre-loaded catheter and wire guide.

1.2 Performance characteristics

1.2.1 Graft

The Zenith Iliac Branch is a bifurcated branch vessel graft with openings to connect the common iliac, internal iliac (sidebranch), and external iliac arteries.

The graft is constructed of full-thickness, woven polyester fabric sewn to self-expanding stainless steel and nitinol Cook Z-stents with braided polyester and monofilament polypropylene suture providing integrity and allowing exclusion of blood flow to the aneurysm and through the graft lumen. The graft is fully stented to provide stability and the expansile force necessary to open the lumen of the graft during deployment.

At the distal graft margin of the external iliac graft segment, the stainless steel Z-stent is attached to the inner lumen of the stent graft to achieve sealing with the vessel. Elsewhere, the Z-stents are sutured on the external surface. The nitinol reinforcement rings are sutured to the most proximal graft edge, to the sidebranch proximal to the nitinol Z-stent, and to the most distal aspect of the sidebranch. These rings help maintain lumen patency during access.

Additionally, the Cook Z-stents provide the necessary seal of the graft to the vessel wall **(Figure 1).**

To facilitate fluoroscopic visualization of the stent graft, four radiopaque gold markers are positioned along the internal iliac side of the proximal portion of the graft to indicate the position of the sidebranch segment. **(Figure 1)**

1.2.2 Delivery system

The Zenith Iliac Branch is shipped pre-loaded onto the H&L-B One-Shot Introduction System. It has a sequential deployment method with built-in features to provide continuous control of the endovascular graft throughout the deployment procedure.

The proximal end of the graft is attached to the delivery system by two nitinol trigger-wires. The distal end of the graft is also attached to the delivery system and held by an independent stainless steel trigger-wire. The H&L-B One-Shot Introduction System enables precise positioning and allows readjustment of the final graft position before full deployment.

The delivery system uses a 20 Fr (6.7 mm I.D.) H&L-B One-Shot Introduction System that includes both a pre-loaded catheter, used to facilitate cannulation of the side branch, and wire guide, used to ensure that the lumen of the catheter is preserved during loading and shipping. The pre-loaded catheter is curved in order to enhance the positioning capability of the wire guide during the snaring process. All systems are compatible with a 0.035-inch (0.89 mm) wire guide.

For added hemostasis, the Captor™ Hemostatic Valve can be loosened or tightened during introduction and/or the removal of ancillary devices into and out of the sheath. The Zenith Iliac Branch delivery system features a Flexor introducer sheath which resists kinking and is hydrophilically coated. Both features are intended to enhance trackability in the iliac arteries and abdominal aorta.

1.3 Device compatibility

1.3.1 Device sizing options

Cook recommends that the Zenith Iliac Branch component diameters be selected as described in **Table 1.1**. The length of the Zenith Iliac Branch is chosen to extend from the proximal portion of the common iliac artery to the external iliac artery. All lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters/lengths) are not certain. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes.

Table 1.1 below details the available lengths and diameters of the graft and the delivery system size:

Table 1.1 Zenith Iliac Branch

Reorder number[1]	Proximal diameter mm	Distal diameter mm	Sidebranch diameter[2] mm	Introduction sheath		Iliac segment length		Total graft length mm
				French size Fr	(I.D. / O.D.)mm	Common mm	External mm	
ZBIS-10-45-41-US	12	10	8	20	(6.7 / 7.7)	45	41	86
ZBIS-10-61-41-US	12	10	8	20	(6.7 / 7.7)	61	41	102
ZBIS-10-45-58-US	12	10	8	20	(6.7 / 7.7)	45	58	103
ZBIS-10-61-58-US	12	10	8	20	(6.7 / 7.7)	61	58	119
ZBIS-12-45-41-US	12	12	8	20	(6.7 / 7.7)	45	41	86
ZBIS-12-61-41-US	12	12	8	20	(6.7 / 7.7)	61	41	102
ZBIS-12-45-58-US	12	12	8	20	(6.7 / 7.7)	45	58	103
ZBIS-12-61-58-US	12	12	8	20	(6.7 / 7.7)	61	58	119

[1] ZBIS-XX-YY-ZZ-US is the Iliac Branch graft where XX is distal diameter, YY is the Common Iliac Segment Length (length from the proximal graft edge to the tip of the internal iliac segment), and ZZ is the External Iliac Segment Length (length from the tip of the internal iliac segment to distal edge of the graft).
[2] Internal iliac segment contains a 6 mm diameter nitinol z-stent, but should be expanded to at least 8 mm during bridging stent system deployment.

1.3.2 Device diameter sizing guidelines

The choice of diameter is determined from the outer wall to outer wall vessel diameter and not the lumen diameter. Undersizing or oversizing may result in incomplete sealing or compromised flow.

Table 1.2 Zenith Iliac Branch diameter sizing guide* (external iliac segment)

Intended external iliac vessel diameter[1,2] mm	Branch external iliac legdiameter[3] mm	Introduction Sheath	
		French size Fr	(I.D. / O.D.) mm
8	10	20	(6.7 / 7.7)
9	10	20	(6.7 / 7.7)
10	12	20	(6.7 / 7.7)
11	12	20	(6.7 / 7.7)

[1] Maximum diameter along the distal fixation site.
[2] Round measured iliac diameter to nearest mm.
[3] Additional considerations may affect choice of diameter.
*All dimensions are nominal.

1.3.3 Additional components

The Zenith Iliac Branch (ZBIS) must be used with an appropriate Zenith proximal device (i.e.: Zenith® Flex AAA Endovascular Graft (TFFB) or Zenith® Fenestrated AAA Endovascular Graft (ZFEN)), Zenith Spiral-Z AAA Iliac Leg (ZSLE) and appropriate bridging stent. Zenith Flex AAA Endovascular Graft (TFFB), Zenith Fenestrated AAA Endovascular Graft (ZFEN), and Zenith Spiral-Z AAA Iliac Leg (ZSLE) are collectively referred to as Zenith AAA devices.

The common iliac section of the Zenith Iliac Branch, positioned in the common iliac artery, will be connected to the short (contralateral) limb of a Zenith proximal device (TFFB) or ZFEN) by a ZSLE graft of suitable length and with a distal diameter of 16 mm (i.e.ZSLE-16-XX-ZT).

TFFB

Zenith Flex AAA Endovascular Graft is a modular system consisting of three components, a bifurcated aortic main body and two iliac leg grafts.

The graft modules are constructed of full-thickness woven polyester fabric sewn to self-expanding stainless steel Cook Z-stents with braided polyester and monofilament polypropylene suture. The modules are fully stented to provide stability and the expansile force necessary to open the lumen of the graft during deployment. Additionally, the Cook-Z stents provide the necessary attachment and seal of the graft to the vessel wall.

For the TFFB grafts and delivery systems, refer to the respective instructions for use for deployment instructions.

ZFEN

Zenith Fenestrated AAA Endovascular Graft is a modular system consisting of both a fenestrated proximal body and a bifurcated distal body and used in combination with an iliac leg graft.

The graft modules are constructed of full-thickness woven polyester fabric sewn to self-expanding stainless steel Cook-Z stents with braided polyester and monofilament polypropylene suture. The modules are fully stented to provide stability and the expansile force necessary to open the lumen of the graft during deployment. Additionally, the Cook Z-stents provide the necessary attachment and seal of the graft to the vessel wall.

For the ZFEN grafts and delivery systems, refer to the respective instructions for use for deployment instructions.

ZSLE

Zenith Spiral-Z AAA Iliac Leg is available and is constructed from the same materials used in the construction of the Zenith Iliac Branch. For the ZSLE graft and delivery system, refer to the respective instructions for use for deployment instructions.

The ZSLE grafts and delivery systems for use with the Zenith Iliac Branch are available in the following lengths and diameters:

Table 1.3 Iliac legs

Reorder Number[1]	Iliac leg diameter mm	Introduction Sheath		Iliac leg working length[2] mm
		French size Fr	(I.D. / O.D.) mm	
ZSLE-16-YY-ZT	16	14	(4.7 / 5.4)	39, 56, 74, 90

[1]Example: ZSLE-16-YY-ZT is the iliac leg where 16 refers to the iliac leg diameter and YY refers to the iliac leg working length

[2]Overall leg length = working length + 22 mm docking stent for ZSLE

Bridging Stent

The Zenith Iliac Branch has been studied with the Getinge iCast covered stent as the bridging stent – see Section 10 Summary of Clinical Studies for information on this device combination.

Bridging stent diameter is recommended to be between 8-10mm* and should be based on nominal internal iliac artery diameter and ZBIS branch diameter (8mm) to ensure adequate seal between the ZBIS and bridging stent. Bridging stent length should allow for 10-14mm of overlap between the ZBIS and bridging stent. Consult the bridging stent manufacturer's Instructions for Use for additional sizing guidelines.

*If using a 10mm device with a Cook introducer sheath, it is recommended to use an 8 Fr sheath to minimise potential for resistance

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1.3.4 Materials required

The device is required to be used in conjunction with the following.

For information on the use of these products, refer to the individual product's instructions for use.

(Not included)

- Fluoroscope with digital angiography capabilities (hybrid or fixed unit)
- Contrast media
- Syringe
- Heparinized saline solution
- Balloons of appropriate sizes
- Sterile gauze pads

1.3.5 Materials recommended

The device is recommended to be used in conjunction with the following (not included):

Wire guides

- 0.035 inch (0.89 mm) extra stiff wire guide, 260 cm; for example: Cook Medical's Lunderquist® Extra Stiff Wire Guides (LES)
  - Cook Medical's Amplatz Support Ultra Stiff Wire Guides (AUS2)
  - Cook Medical's soft-tipped Rosen Wire Guides
- 0.035 inch (0.89 mm) hydrophilic wire guide, 260 cm; for example:
  - Cook Medical's Roadrunner® PC Hydrophilic Wire Guide
  - Cook Medical's Roadrunner® UniGlide®

Molding balloons

- Cook Medical's CODA® Balloon Catheters (32 mm)

Introducer sets (7 Fr [2.3 mm I.D.], 8 Fr [2.7 mm I.D.], 10 Fr [3.3 mm I.D.] and 12 Fr [4.0 mm I.D.])

- Cook Medical's Check-Flo® Introducers-Flexor Introducers / Guiding Sheaths
- Cook Medical's Flexor Ansel Guiding Sheath
- Cook Medical's High-Flex Ansel Guiding Sheath

Catheters

- Sizing catheter; for example:
  - Cook Medical's Aurous™ Centimeter Sizing Catheters
  - Cook Medical's Beacon® Tip 5.0 Fr Angiographic Catheter (PIG)
  - Cook Medical's Slip-Cath® Beacon® Tip Hydrophilic Angiographic Catheter
  - Cook Medical's Royal Flush® Catheters

Entry needles

- 18 gauge or 19 ultra-thin gauge entry needles; for example:
  - Cook Medical's One-Part Percutaneous Needles

Snare

- Cook Medical's Indy OTW Vascular Retriever

1.4 Patient population

Adult patients with an aortoiliac or iliac aneurysm requiring preservation of internal iliac artery blood flow when the distal sealing site in the common iliac artery is, insufficient for the AAA device alone and the vessel morphology is suitable for endovascular repair.

1.5 Intended user

Physicians and teams trained in vascular interventional techniques and in the use of this device.

1.6 Contact with body tissue

The primary device will contact various healthy (non-dissected and non-aneurysmal) and diseased arterial tissues from the femoral to the common iliac artery. In some cases, contact could be made with a conduit used for vascular access.

During the procedure, accessory wire guides will extend into the abdominal aorta up to the level of visceral branch vessels.

1.7 Operating principles

The Zenith Iliac Branch is placed over a prepositioned wire guide and advanced to the target anatomy. The radiopaque tip of the sheath of the delivery system is used to visualize the deployment of the graft.

The H&LB One-shot Introduction System contains a preloaded catheter used to form a through-and-through wire guide to assist in the cannulation of the internal iliac segment. Four gold markers are aligned with the outer aspect of the internal iliac segment to ensure the graft is oriented correctly and positioned correctly in correlation with the internal iliac artery. Stent deployment is controlled by means of release mechanisms and by retraction of the sheath while stabilizing the delivery system.

Post deployment, the fully deployed graft imparts an outward radial force upon the lumen of the vessel, establishing patency in the stented region. Nitinol rings positioned at the proximal end of the graft and within the internal iliac segment maintain the lumen patency during access.

The Zenith Iliac Branch is used in combination with a Zenith proximal device an iliac leg graft and a bridging stent to provide an intravascular conduit that preserves flow to the internal iliac and excludes aortoiliac or iliac aneurysms from blood flow while maintaining distal perfusion.

1.8 Expected lifetime of device

The graft is not intended to be removed from the patient, therefore the expected lifetime of the device is permanent.

The delivery system is a single use device and has a shelf life of 2 years.

2. INTENDED USE

The Zenith Iliac Branch, when used with the necessary additional components (Zenith AAA devices and a covered bridging stent), is intended to provide an intravascular conduit that preserves flow to the internal iliac and excludes aortoiliac or iliac aneurysms from blood flow while maintaining distal perfusion.

3. INDICATIONS FOR USE

The Zenith Iliac Branch when used with the necessary additional components (Zenith AAA and a covered bridging stent), is indicated for endovascular treatment of aortoiliac or iliac aneurysms to preserve internal iliac arterial blood flow when the distal sealing site in the common iliac artery is insufficient for the AAA device alone and when the vessel morphology is suitable for repair, including:

- Common iliac artery diameter at the level of the internal iliac artery (luminal diameter) ≥16 mm
- Adequate iliac/femoral access compatible with a 20 Fr (7.7 mm O.D.) introduction system
- Non-aneurysmal external iliac artery fixation segment distal to the aneurysm:
  - With a length of at least 20 mm
  - With a diameter measured outer wall to outer wall of no greater than 11 mm and no less than 8 mm
- Non-aneurysmal internal iliac artery segment distal to the aneurysm:
  - With a length of at least 10 mm (with 20–30 mm being preferred)
  - With a diameter measured outer wall to outer wall no greater than 10 mm and no less than 7 mm.

4. CLINICAL BENEFITS

The intended clinical benefit of the Zenith Iliac Branch is to increase survivability of aneurysmal disease and prevent aneurysm rupture while preserving blood flow to the internal iliac artery.

5. CONTRAINDICATIONS

The Zenith Iliac Branch is contraindicated in:

- Patients with known sensitivities or allergies to stainless steel, polyester, solder (tin silver), nitinol (nickel, titanium), polypropylene, urethane, gold or ePTFE.
- Patients with a systemic infection who may be at increased risk of endovascular graft infection.
- Patients with uncorrected bleeding disorders.
- Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy.

6. WARNINGS

6.1 General

CAUTION: Safety and effectiveness of BILATERAL use of Zenith Iliac Branch has not been evaluated.

- Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.
- The Zenith Iliac Branch MUST only be used by physicians and teams trained in vascular interventional techniques and in the use of this device.
- Lack of non-contrast CT imaging may result in failure to appreciate iliac or aortic calcification, which may preclude access or reliable device fixation and seal.
- Pre-procedure imaging reconstruction thickness > 3 mm may result in suboptimal device sizing, or in failure to appreciate focal stenoses from CT.
- The safety and effectiveness of the Zenith Iliac Branch has been established through 5 years of follow-up. **However, the long-term safety and effectiveness of endovascular grafts has not yet been established**. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in **Section 16 Imaging guidelines and post-operative follow-up**.
- The Zenith Iliac Branch has not been fully evaluated to establish potential for chronic toxicity and carcinogenicity. Prolonged exposure to systemic or carcinogenic toxicants may lead to long-term tissue harm and long- term carcinogenic effects. The risks of these potential harms from the product have not been established clinically specifically for the ZBIS device. However, the available information from ZBIS clinical use and animal study data on devices with identical materials does not suggest chronic toxicity or carcinogenicity concerns.
- After endovascular graft placement, patients should be regularly monitored for endoleak, aneurysm growth or changes in the structure or position of the endovascular graft. At a minimum, annual imaging is required, including:
- 1) abdominal radiographs to examine device integrity (separation between components, stent fracture or barb separation) and
- 2) contrast and non-contrast CT to examine aneurysm changes, endoleak, patency, tortuosity and progressive disease.
- If renal complications or other factors preclude the use of image contrast media, abdominal radiographs and duplex ultrasound may provide similar information.
- The Zenith Iliac Branch is not recommended in patients unable to undergo, or who will not be compliant with the necessary preoperative and post-operative imaging and implantation studies as described in **Section 16 Imaging guidelines and post-operative follow-up**.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms, unacceptable decrease in fixation length (vessel and component overlap) and/or endoleak. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture.
- Patients experiencing reduced blood flow through the graft limb and/or leaks may be required to undergo secondary interventions or surgical procedures.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.
- Endovascular stent grafting is a surgical procedure, and blood loss from various causes may occur, infrequently requiring intervention (including transfusion) to prevent adverse outcomes. It is important to monitor blood loss from the hemostatic valve throughout the procedure, but is specifically relevant during and after manipulation of the gray positioner. After the gray positioner has been removed, if blood loss is excessive, consider placing an uninflated molding balloon or an introduction system dilator within the valve, restricting flow.

6.2 Sterile and single use

- This product is single use and shall not be reused.
- Do not reuse, reprocess or resterilize any part of this device.
- Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury, illness or death.
- Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- Contamination of the device may lead to injury, illness or death of the patient.

6.3 Patient selection, treatment and follow-up

- The Zenith Iliac Branch has not been evaluated in the following patient populations:
  - Pregnant or nursing females
  - Patients <18 years old
  - Occluded or > 50% stenosed internal iliac artery
- Access vessel diameter (measured inner wall to inner wall) and morphology (minimal tortuosity, occlusive disease, and/or calcification) should be compatible with vascular access techniques and delivery systems of the profile of a 20 Fr (7.7 mm O.D.) vascular introducer sheath. Vessels that are significantly calcified, occlusive, tortuous, or thrombus lined may preclude placement of the endovascular graft and/or may increase the risk of embolization.

- Key anatomic elements that may affect successful exclusion of the aneurysm include tortuosity of any or all of the vessels involved, undersized or oversized iliac arteries, circumferential thrombus, aneurysm of the internal and/or external iliac artery and/or calcification of the arterial implantation sites. Irregular calcification and/or plaque may compromise the fixation and sealing of the implantation sites and the ability to advance the introducer systems.
- The Zenith Iliac Branch is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and postoperative follow-up imaging.
- The Zenith Iliac Branch is not recommended in patients exceeding weight and/or size limits, which compromise or prevent the necessary imaging requirements.
- The Zenith Iliac Branch is not recommended in patients with known sensitivities or allergies to stainless steel, polyester, nitinol (nickel, titanium), polypropylene, gold, or ePTFE.
- The Zenith Iliac Branch is not recommended in patients who cannot tolerate radiation e.g., pregnancy.
- The Zenith Iliac Branch has not been evaluated for bilateral use.
- Patients with a systemic infection may be at increased risk of endovascular graft infection.
- Inability to maintain patency of at least one internal iliac artery may increase the risk of pelvic/bowel ischemia.
- Additional considerations for patient selection include but are not limited to:
  - Patient's age and life expectancy.
  - Co-morbidities (e.g., cardiac, pulmonary or renal insufficiency prior to surgery, morbid obesity).
  - Patient's suitability for open surgical repair.
  - Patient's anatomical suitability for endovascular repair.
  - The risk of aneurysm rupture compared to the risk of treatment with the Zenith Iliac Branch.
  - Ability to tolerate general, regional or local anesthesia.
  - Iliofemoral access vessel size and morphology (minimal thrombus, calcification and/or tortuosity) should be compatible with vascular access
  - Techniques and accessories of the delivery with vascular access techniques and accessories of the delivery profile of a 14 Fr (5.4 mm O.D.) to 20 Fr (7.7 mm O.D.) vascular introducer sheath.
  - Common iliac artery diameter at the level of the internal iliac artery (luminal diameter) ≥16mm
  - Non-aneurysmal external iliac artery fixation segment distal to the aneurysm:
    - With a length of at least 20 mm,
    - With a diameter measured outer wall to outer wall of no greater than 11 mm and no less than 8 mm.
  - Non-aneurysmal internal iliac artery segment distal to the aneurysm:
    - With a length of at least 10 mm (with 20–30 mm being preferred)
    - With a diameter measured outer wall to outer wall no greater than 10 mm and no less than 7 mm.
  - Freedom from significant femoral/iliac artery occlusive disease that would impede flow through the endovascular graft.
- The final treatment decision is at the discretion of the physician and patient.

6.4 Implant procedure

- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulation should be considered.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- To activate the hydrophilic coating on the outside of the Flexor introducer sheath, the surface must be wiped with gauze pads soaked in saline solution. Always keep the sheath hydrated for optimal performance.
- Maintain wire guide position during delivery system insertion.
- Do not bend or kink the delivery system. Doing so may cause damage to the delivery system and the Zenith Iliac Branch.
- Fluoroscopy should be used during introduction and deployment to confirm proper operation of the delivery system components, proper placement of the graft, and desired procedural outcome.
- The use of the Zenith Iliac Branch requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure post-operatively. Care should be taken to limit the amount of contrast media used during the procedure.
- To avoid any twist in the endovascular graft, during any rotation of the delivery system, be careful to rotate all of the components of the system together (from outer sheath to inner cannula).
- Inaccurate placement and/or incomplete sealing of the Zenith Iliac Branch within the vessel or with additional components may result in increased risk of endoleak, migration or inadvertent occlusion of internal iliac artery.
- Inadequate fixation of the Zenith Iliac Branch may result in increased risk of migration. Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
- Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the wire guide or delivery system. Stop and assess the cause of resistance. Vessel or catheter damage may occur. Exercise particular care in areas of stenosis, intravascular thrombosis or in calcified or tortuous vessels.
- Take care during manipulation of catheters, wires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus which can cause distal embolization.
- The bridging stent must be of adequate diameter to seal with both the internal iliac segment and the internal iliac artery, and of sufficient length to overlap 10–14 mm with the internal iliac segment and 10 mm (with 20–30 mm being preferred) with the distal fixation site in the internal iliac artery.
- Care should be taken not to damage any previously placed graft or disturb its position in the event reinstrumentation of the graft is necessary.

6.5 Molding balloon use

- Confirm complete deflation of balloon prior to repositioning.
- Do not inflate the balloon in vessel outside of graft.
- For added hemostasis, the Captor Hemostatic Valve can be opened or closed to accommodate the insertion and subsequent withdrawal of a molding balloon.

7. PRECAUTIONS

7.1 Training requirements for user

CAUTION: Always have a vascular surgery team available during implantation or re-intervention procedures in the event that conversion to open surgical repair is necessary.

CAUTION: The Zenith Iliac Branch MUST only be used by physicians and teams trained in vascular interventional techniques, general Zenith training, and training in the use of this device. The recommended skill/knowledge requirements for physicians using the Zenith Iliac Branch are outlined below:

Patient selection:

- Knowledge of the natural history of abdominal aortic aneurysms (AAA) and co-morbidities associated with AAA repair.
- Knowledge of radiographic image interpretation, device selection and sizing.

A multi-disciplinary team that has combined procedural experience with:

- Femoral cutdown, arteriotomy and repair
- Percutaneous access and closure techniques
- Non-selective and selective wire guide and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Appropriate use of radiographic contrast material
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

8. MRI SAFETY INFORMATION

MR Conditional	A patient with the Zenith Iliac Branch (ZBIS) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Item Name/Identification	Zenith Iliac Branch (ZBIS)
Normal Value(s) of Static Magnetic Field [T]	1.5 T or 3.0 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	7.2 T/m (720 Gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum whole body SAR [W/kg]	2.0 W/kg
Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
Image Artifact	The presence of this implant may produce an image artifact.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

It is recommended that patients register the conditions under which the implant can be safely scanned with the Medic Alert Foundation (medicalert.org) or an equivalent organization.

9. POTENTIAL ADVERSE EVENTS

Adverse events that may occur and/or require intervention include:

- Allergic reaction and/or anaphylactoid response to x-ray contrast dye, anti-platelet therapy, device materials
- Amputation
- Anesthetic complications and subsequent attendant problems (e.g., aspiration)
- Aneurysm enlargement
- Aneurysm rupture and death
- Aortic 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: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft material wear; dilatation; erosion; puncture; endoleak; barb separation 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)
- Multi-system organ failure
- Neurologic local or systemic complications and subsequent attendant problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, paralysis)
- Post-implant syndrome
- Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent attendant problems (e.g., artery occlusion, 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)

10. SUMMARY OF CLINICAL STUDIES

The ZBIS was the subject of an Investigational Device Exemption pivotal study that evaluated the safety and effectiveness of the ZBIS device in patients with aortoiliac or iliac aneurysms having morphology suitable for endovascular repair. The ZBIS was also evaluated in a continued access study, which provides supporting evidence regarding the safety and effectiveness of the ZBIS. Both studies are summarized herein.

10.1 Pivotal study – PRESERVE

The PRESERVE-Zenith Iliac Branch Clinical Study (conducted under the previous brand name PRESERVE-Zenith Branch Endovascular Graft-Iliac Bifurcation Clinical Study) was a prospective, non-randomized, single-arm, multi-center clinical study intended to assess the safety and effectiveness of endovascular treatment with the ZBIS in combination with the iCAST stent for the treatment of patients with aortoiliac or iliac aneurysms 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.

A total of 40 patients were treated with ZBIS and iCAST between 01 April 2014 and 06 May 2015.Study patients were enrolled across 18 investigational sites in the United States. This study evaluated safety and effectiveness through comparison to performance goals.

The primary endpoint was 6-month freedom from patency-related intervention, defined as a secondary intervention to treat a > 60% stenosis of the internal iliac artery (as identified through computed tomography (CT) scan, angiography, or duplex ultrasound and confirmed by core laboratory) associated with clinical symptoms. The performance goal for the primary endpoint was established through a review of data from reports on the complications rates associated with coil embolization and stent graft coverage of the IIA in endovascular repair of aortoiliac aneurysms. For the power calculation of the primary hypothesis, the true patency rate of the IIA following treatment with the ZBIS was assumed to be 83% based on clinical literature describing outcomes associated with sacrificing the IIA during endovascular repair available at the time of protocol development. A performance goal of 55% for freedom from patency-related intervention was determined and a simulation study indicated that a maximum sample size of 25 patients would provide a power of approximately 88.5%, at a type I error rate of 2.5%.

The analysis required that the performance goal of 55% be met (H_0: $\pi \leq 55\%$; H_a: $\pi > 55\%$). The study device was considered to have met the primary endpoint if the 2.5th percentile of the Bayesian posterior distribution of π was greater than the performance goal hypothesis testing.

The secondary safety endpoint for the study was 30-day freedom from morbidity (i.e., the morbidity index).The morbidity index is a measure of 33 elements in seven categories (i.e., cardiovascular, pulmonary, renal, bowel, wound, neurologic, and vascular).These included the same 31 prespecified elements measured as the morbidity index in the Zenith AAA Endovascular Graft Clinical Study and two additional elements (i.e., buttock claudication on the same side as the ZBIS and impotence) considered important for the PRESERVE-Zenith Iliac Branch System Clinical Study. The performance goal for the secondary safety endpoint was established through a review of safety data from the Zenith AAA Endovascular Graft Clinical Study (P020018). 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 IIA 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 [defined below] and hip/thigh/buttock claudication). With a performance goal of 46% for freedom from 30-day morbidity, the simulation study indicated that a maximum sample size of 29 patients would provide a power of 85.8%, at a type I error rate of 2.5%. The analysis required that the performance goal of 46% be met (H_0: $p \leq 46\%$; H_a: $p > 46\%$). The study device was considered to have met the secondary endpoint if the 2.5th percentile of the Bayesian posterior distribution of p was greater than the performance goal.

The secondary effectiveness endpoint for the study was branch vessel patency at 6 months. This endpoint was assessed for descriptive purposes only and therefore a performance goal for this endpoint was not established.

Additional endpoints for the study included assessments of aneurysm-related death, conversion, rupture, success measures (i.e., technical success during the implant procedure, procedural success within 30 days, and treatment success at 12-month follow-up), clinical utility measures (i.e., duration of intensive care unit (ICU) stay, days to ambulation, days to resumption of oral fluid intake, days to resumption of regular diet, days to first bowel function, days to hospital discharge, blood replacement requirements), adverse events related to the ZBIS or iCAST stent, distal Type I endoleaks [in the IIA and external iliac artery (EIA)], and Type III endoleaks involving the ZBIS and iCAST stent. Summary statistics for these endpoints will be provided, but no statistical inference or hypothesis testing will be performed.

An independent data safety monitoring board (DSMB) monitored the clinical trial according to an established safety monitoring plan. An independent clinical events committee (CEC) adjudicated predefined clinical events reported during the study in accordance with the CEC charter. An independent core laboratory analyzed all patient imaging.

Patients eligible to be enrolled in the study had an aortoiliac or iliac aneurysm and an unsuitable distal sealing site for a Zenith iliac leg graft within the common iliac artery on the intended side of ZBIS implantation (e.g., fixation/seal length <10 mm or diameter >20 mm). Key exclusion criteria included lack of distal seal zone for ZBIS in the external iliac artery (e.g., length <20 mm or diameter <8 mm), lack of distal seal zone for the bridging stent component in the internal iliac artery (e.g., length <10 mm or diameter >10 mm or <7 mm), occluded or >50% stenoses internal iliac artery (on side of ZBIS), and unsuitable anatomy for the use of the Zenith Flex AAA endograft component.

The study follow-up schedule **(Table 10.1)** consisted of both clinical and imaging assessments prior to the procedure and at post-procedure (pre-discharge), 30 days, 6 months, 12 months, and yearly thereafter through 5 years. The objective parameters measured during the study based on CT included assessment of endoleaks, migration, patency, and device integrity. Adverse events and complications were recorded at all visits.

Nearly all eligible patients (97.5%; 39/40) remained in the study at their 6-month follow-up visit which was the timepoint for the primary study endpoint. Moreover, through 5 years, 75% (30/40) of patients remained in the study. The percentage of eligible patients who completed the clinical exam and CT imaging was above 80% and above 75%, respectively, at each timepoint throughout the study **(Table 10.2)**.

Table 10.1. Follow-up Schedule

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

[1]Selective angiography may have been performed to provide more focused imaging in instances potential device integrity issues were identified but unable to be confirmed on 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]Pre-procedure angiography may be requested at discretion of film reviewer/proctor.
[4]Blood tests included creatinine.

Table 10.2. Follow-up Availability

Visit	Eligible for Follow-up	Percent of Data Available		Adequate Imaging for Core Laboratory to Assess Parameter					Events Occurring Before Next Interval			
		Clinical Exam	CT	Size Increase	Endoleak	Patency	Migration	Device Integrity	Death	Conversion	Lost to Follow-up (LTF)	Withdrawal
Procedure	40	N/A	N/A	N/A	92.5% (37/40)	92.5% (37/40)	N/A	N/A	0	0	0	0
Pre-discharge	40	100% (40/40)	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0
1-month	40	100% (40/40)	100% (40/40)	N/A	100% (40/40)	100.0% (40/40)	N/A	97.5% (39/40)	1	0	0	0
6-month	39	94.9% (37/39)	94.9% (37/39)	94.9% (37/39)	94.9% (37/39)	94.9% (37/39)	94.9% (37/39)	92.3% (36/39)	0	0	2	0
12-month	37	100% (37/37)	100% (37/37)	100.0% (37/37)	97.3% (36/37)	97.3% (36/37)	100% (37/37)	100% (37/37)	0	0	0	0
2-year	37	86.5% (32/37)	75.7% (28/37)	75.7% (28/37)	73.0% (27/37)	78.4% (29/37)	75.7% (28/37)	75.7% (28/37)	0	0	0	2
3-year	35	88.6% (31/35)	88.6% (31/35)	88.6% (31/35)	82.9% (29/35)	94.3% (33/35)	88.6% (31/35)	88.6% (31/35)	1	0	0	1
4-year	33	81.8% (27/33)	84.8% (28/33)	84.8% (28/33)	87.9% (29/33)	87.9% (29/33)	84.8% (28/33)	81.8% (27/33)	2	0	1	0
5-year	30	90.0% (27/30)	86.7% (26/30)	86.7% (26/30)	83.3% (25/30)	83.3% (25/30)	86.7% (26/30)	86.7% (26/30)	N/A	N/A	N/A	N/A

Note: In patients experiencing renal failure and unable to undergo contrast-enhanced CT scan, a duplex ultrasound may be used in conjunction with non-contrast CT scan. In these cases, the core laboratory may be able to adequately assess aneurysm size change, endoleak, and patency when an ultrasound is performed in combination with a non-contrast CT scan.
N/A = Not applicable.

10.2 Demographics and patient characteristics

The demographics and patient characteristics are presented in **Table 10.3**. The mean age was 67.8 ± 9.0 years, with most patients being male (95.0%, 38/40) and of white ethnicity (87.5%, 38/40).

Patient pre-existing comorbid medical conditions for the patient cohort are presented in **Table 10.4**. Common comorbidities in the population included hypertension (77.5%, 31/40) and past or current smoking (75%, 30/40).

Table 10.5 reports pre-procedure imaging to evaluate iliac morphology. Measurements provided are reported on the same side as the intended side for treatment (i.e., left or right) with ZBIS.

The extent of calcification was defined as either none (lack of calcification), mild (less than 40% circumferential calcification), moderate (between 40% and 70% circumferential calcification), or severe (greater than 70% circumferential calcification). The extent of occlusive disease was defined as either none (lack of occlusive disease), mild (some disease, focal with less than 30% narrowing), moderate (between 30-50% narrowing), or severe (greater than 50% narrowing). Tortuosity was defined as either none (no tortuosity), mild (minimal tortuosity with less than one turn involving either external or common iliac artery), moderate (single turn involving either external or common iliac artery), or severe (compound turns involving external and common iliac arteries). Per the site assessment, most patients had none or mild calcification and occlusive disease in the iliac arteries. Mild or moderate iliac tortuosity was reported in 75% of patients.

Table 10.3. Demographics and Patient Characteristics

Demographic		Mean ± SD (n, range) or Percent Patients (number/total number)
Age (years)		67.8 ± 9.0 (40, 48–86)
Sex	**Male**	95.0% (38/40)
	Female	5.0% (2/40)
Self-reported Race	**American Indian or Alaska Native**	0% (0/40)
	Asian	2.5% (1/40)
	Black or African American	7.5% (3/40)
	Hispanic or Latino	2.5% (1/40)

	Native Hawaiian or other Pacific Islander	0% (0/40)
	White	87.5% (35/40)
Height (in)		69.5 ± 2.7 (40, 64–76)
Weight (lbs)		198.4 ± 43.2 (40, 132.0–334.4)
BMI		28.8 ± 5.4 (40, 18.6–47.3)

Table 10.4. Pre-existing Comorbid Medical Conditions|

Medical History	**Percent Patients (number/total number)**
Cardiovascular	
Myocardial infarction (MI)	25.0% (10/40)
Percutaneous transluminal coronary angioplasty (PTCA)/stent	17.5% (7/40)
Coronary artery bypass graft surgery (CABG)	17.5% (7/40)
Symptomatic congestive heart failure (CHF)	5.0% (2/40)
Angina	12.5% (5/40)
Cardiac arrhythmia	17.5% (7/40)
Vascular	
Thromboembolic event	5.0% (2/40)
Peripheral vascular disease	5.0% (2/40)
Aneurysm (not subject of current study)	30.0% (12/40)
Dissection	0% (0/40)
Thoracic trauma	0% (0/40)
Stenting of iliac artery (not subject of current study)	0% (0/40)
Impotence	42.5% (17/40)
Buttock claudication	0% (0/40)
Uncorrectable coagulopathy	0% (0/40)
Endarterectomy	0% (0/40)
Hypertension	77.5% (31/40)
Pulmonary	
Chronic obstructive pulmonary disease (COPD)	25.0% (10/40)
Home oxygen	2.5% (1/40)
Renal	
Chronic renal failure	2.5% (1/40)
Dialysis	0% (0/40)
Renal insufficiency	10.0% (4/40)
Endocrine	
Diabetes	27.5% (11/40)
Infectious disease	
Systemic infection	10.0% (4/40)
Gastrointestinal	
Gastrointestinal disease	30.0% (12/40)
Hepatobiliary	
Liver disease	15.0% (6/40)
Neoplasms	
Cancer	15.0% (6/40)
Neurologic	
Stroke	12.5% (5/40)
Allergies	47.5% (19/40)
Smoking	
Current	27.5% (11/40)
Quit	47.5% (19/40)
Never	25.0% (10/40)

Table 10.5. Pre-procedure anatomical measurements in the iliac arteries per site

Measurement	**Mean ± SD (N, Range)**
At intended distal fixation site	
EIA outer diameter (mm)	10.2 ± 1.4 (40, 8.0-13.0)
EIA fixation length (mm)	44.7 ± 29.5 (40, 20.0-134.0)
IIA inner diameter (mm)	8.0 ± 0.9 (40, 6.9–10.0)
IIA outer diameter (mm)	8.8 ± 0.9 (40, 7.0–10.0)
IIA fixation length (mm)	20.5 ± 7.1 (40, 10.0-40.0)
Iliac artery diameters	
CIA maximum diameter (outer-wall; mm)	35.9 ± 10.1 (40, 20.0-62.9)

EIA minimum diameter (access) (inner-wall; mm)	10.6 ± 9.4 (40, 7.1-68.0)
EIA maximum diameter (outer-wall; mm)	10.4 ± 1.8 (40, 7.3-15.0)
CIA lumen diameter just proximal to IIA (mm)	21.4 ± 6.4 (40, 13.9-42.6)
IIA maximum diameter (outer-wall; mm)	9.7 ± 3.0 (40, 6.5-25.0)
IIA lumen diameter of ostia (mm)	8.1 ± 2.6 (40, 5.0-20.0)
Iliac artery lengths	
CIA length from aortic bifurcation to iliac bifurcation (mm)	70.9 ± 14.8 (40, 50.0-121.0)
IIA length from ostia to anterior-posterior division (mm)	33.8 ± 19.0 (40, 19.0-140.0)
Iliac artery angles and location	
Angle of IIA to EIA (degrees)	55.4 ± 31.5 (39, 15.0-153.0)
Angle of right CIA to left CIA (degrees)	54.4 ± 22.2 (39, 0-125.0)
Circumferential location of IIA (degrees)[1]	150.8 ± 50.2 (39.0, 23.0-270.0)

Note: CIA = common iliac artery; EIA = external iliac artery; IIA = internal iliac artery.

[1]Circumferential location of the IIA is measured from 0 to 360 degrees with 0 degrees being anterior, 90 degrees being left, 180 degrees being posterior, and 270 degrees being right.

10.3 Procedural information

The anesthesia and access methods used to support device placement is presented in **Table 10.6**. Most (90.0%) procedures were performed under general anesthesia. Vascular access was gained primarily via percutaneously (52.5%), or via femoral artery cutdown (45.0%) access technique during insertion of ZBIS.

Procedural measures are detailed in **Table 10.7**. The average procedure time was 210.5 ± 53.4 minutes with an average fluoroscopy time of 40.1 ± 15.7 minutes. The average total contrast volume used was 128.2 ± 63.5 cc with an average concentration of 310.0 ± 40.8 mgI/mL. Most patients (60%, 24/40) received non-ionic contrast agents. The average estimated blood loss was 275.6 ± 215.5 cc (maximum blood loss was 800 cc).

Table 10.8 reports the number and size of ZBIS devices placed at the index procedure. In total, 40 ZBIS devices were placed in 40 study patients. The Reference Part Number (RPN) for the ZBIS is presented in the following format according to the lengths and diameter of the ZBIS (mm): ZBIS-XX-YY-ZZ, where XX is distal diameter, YY is the Common Iliac Segment Length (length from the proximal graft edge to the tip of the sidebranch), and ZZ is the External Iliac Segment Length (length from the tip of the sidebranch to distal edge of the graft).All available ZBIS RPNs were used in the study with the most common being ZBIS-12-61-58 (27.5%, 11/40) and ZBIS-12-45-58 (22.5%, 9/40).

Table 10.9 has the number and size of iCAST stents implanted during the study procedures. In total, 47 iCAST stents were implanted in the 40 study patients. The most common iCAST stent sizes implanted were the 9 x 59 mm (29.8%, 14/47) and 9 x 38 mm (27.7%, 13/47) stents.Six patients received more than one iCAST stent deployed within the sidebranch of the ZBIS. Specifically, five patients received two iCAST stents and one patient received three iCAST stents. The use of multiple iCAST stents was to obtain either maximal seal distally within the internal iliac artery or to ensure optimal overlap within the ZBIS sidebranch.

The number and size of the Zenith Flex AAA endovascular graft and Zenith iliac leg grafts (ZSLE) components used in the study are shown in **Table 10.10**. In total, 40 Zenith Flex AAA Endovascular Grafts were implanted in the 40 patients. A ZSLE is deployed into the short (contralateral) leg of the Zenith Flex AAA Endovascular Graft, connecting the lumen of the main body graft to the ZBIS stent. An additional ZSLE is deployed into the long (ipsilateral) leg of the Zenith Flex AAA Endovascular Graft. More than one ZSLE may be deployed on either side according to physician discretion. In total, 44 ZSLE stents were implanted within the contralateral leg of the Zenith Flex AAA Endovascular Graft with 4 patients receiving more than one ZSLE stent (same side as ZBIS). In total, 41 ZSLE stents were implanted within the ipsilateral leg of the Zenith Flex AAA Endovascular Graft with 2 patients receiving more than one ZSLE stent (opposite side as ZBIS).

Table 10.11 reports the clinical utility measures. The average ICU stay was 17.1 ± 32.7 hours and the average length of time to hospital discharge was 2.0 ± 2.4 days.

Table 10.6. Primary anesthesia type and access method

Characteristic	Percent Patients (number/total number)
Anesthesia Method	
Local	5.0% (2/40)
Regional	5.0% (2/40)1
General	90.0% (36/40)
Access Method	
Percutaneous	52.5% (21/40)
Cutdown	45.0% (18/40)
Cutdown/Percutaneous	2.5% (1/40)
Iliac conduit	0% (0/40)
[1]One patient received both regional and monitored anesthesia care.	

Table 10.7. Procedural times, monitoring, and blood loss

Parameter	Mean ± SD (n, range) or Percent Patients (number/total number)
Procedure (min)	210.5 ± 53.4 (37, 123–331)
Fluoroscopy (min)	40.1 ± 15.7 (39, 12–93)
Total amount of contrast used (cc)	128.2 ± 63.5 (39, 35–328)
Concentration of contrast (mgI/mL)	310.0 ± 40.8 (40, 100–370)
Type of contrast agent[1]	
Ionic	25.0% (10/40)
Non-ionic	60.0% (24/40)
Iso-osmolar	17.5% (7/40)
Non-iso-osmolar	12.5% (5/40)
Estimated blood loss (cc)	275.6 ± 215.5 (40, 0–800)
Blood bank products received	
PRBC	5.0% (2/40)
FFP	0% (0/40)
Platelets	0% (0/40)

Cryoprecipitate	0% (0/40)
Cell saver	5.0% (2/40)
Amount of blood products received (cc)	
PRBC	350.0 ± 0 (2, 350–350)
FFP	N/A
Platelets	N/A
Cryoprecipitate	N/A
Cell saver	275.0 ± 14.1 (2, 265–285)
[1]Patients can receive multiple types of contrast agent and may appear on more than one row.	

Table 10.8. ZBIS sizes used in the PRESERVE clinical study

Distal Diameter (mm)	10	12	10	12	10	12	10	12	**Total # ZBIS**
Common Iliac Segment Length (CISL) (mm)	45	45	45	45	61	61	61	61	
External Iliac Segment Length (EISL) (mm)	41	41	58	58	41	41	58	58	
Total	2	5	2	9	2	4	5	11	40

Table 10.9. iCast covered stent sizes used in the PRESERVE clinical study

Diameter (mm)	**Length (mm)**		
	38	**59**	**Total**
8	7	5	12
9	13	14	27
10	8	N/A[1]	8
Total	28	19	47
[1]10 x 59 mm iCAST stents were not available in the United States during this study.			

Table 10.10 Zenith Flex AAA Endovascular Graft and ZSLE stents used

	Same side as ZBIS		**Opposite Side of ZBIS**	
Zenith Flex AAA Endovascular Graft	**ZSLE**	**Additional ZSLE**	**ZSLE**	**Additional ZSLE**
40	40	4	39[1]	2
[1] One patient did not receive a ZSLE on the opposite side as ZBIS				

Table 10.11. Clinical utility measures

Clinical utility	**Mean ± SD (range), Total**
Duration of ICU stay (hours)	17.1 ± 32.7 (38, 0 – 144)
Days to first ambulation	1.0 ± 0.8 (40, 0 – 5)
Days to resumption of oral fluid intake	0.4 ± 0.6 (40, 0 – 3)
Days to resumption of regular diet	0.8 ± 0.8 (40, 0 – 4)
Days to first bowel movement	2.1 ± 1.8 (30, 0 – 8)
Days to discharge	2.0 ± 2.4 (40, 0 – 14)

10.4 Safety and effectiveness results

The primary safety and effectiveness endpoint was prospectively defined as 6-month freedom from patency-related intervention, which is defined as a secondary intervention to treat a > 60% stenosis of the internal iliac artery (as identified through computed tomography (CT) scan, angiography, or duplex ultrasound and confirmed by core laboratory) associated with clinical symptoms. This endpoint definition includes patients with internal iliac artery stenosis following successful placement of the ZBIS and covered bridging stent, and 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. The results for 6-month freedom from patency-related intervention are presented in **Table 10.12**.

The success rate for the primary safety and effectiveness endpoint was 100% (39/39) of patients, and the 2.5th percentile of the Bayesian posterior distribution was 91.2%, surpassing the performance goal of 55%. Based on these results, the primary endpoint for the study was met.

Endpoint data were available for 39 patients due to the death of one patient prior to the 6-month follow-up visit; based on an intent-to-treat analysis, including this patient either as a success (40/40) or as a failure (39/40), the observed rate for the primary endpoint also met the established performance goal (posterior probability < 0.01).

The secondary safety endpoint for the study was 30-day freedom from morbidity (i.e., the morbidity index). The morbidity index is a measure of 33 elements in seven categories (i.e., cardiovascular, pulmonary, renal, bowel, wound, neurologic, and vascular). These included the same 31 prespecified events in the Zenith AAA Endovascular Graft Clinical Study morbidity index and hip/thigh/buttock claudication. The results for 30-day freedom from morbidity are presented in **Table 10.14**. Safety data through 30 days were available for all 40 patients. The success rate for the secondary safety endpoint was 85% (34/40) of patients, and the 2.5th percentile of the Bayesian posterior distribution is 70.8%, surpassing the performance goal of 46%. Based on these results, the secondary safety endpoint for the study was met.

Six patients experienced morbid events within 30 days of the procedure: distal embolization resulting in tissue loss or requiring reintervention (n = 1), inotropic support (n = 1), pneumonia requiring antibiotics (n = 1), paralytic ileus > 4 days (n = 1), impotence (n=1), and limb thrombosis on the same side as the ZBIS (n = 1).

Table 10.12. 6-month freedom from patency-related intervention

6-month freedom from patency-related reintervention	Performance goal	Lower bound[1]	Posterior probability	Performance goal met
100% (39/39)	55%	91.2%	< 0.01	Yes
[1]The lower bound, per the protocol, is the 2.5th percentile of the Bayesian posterior distribution				

Table 10.13. 30-day freedom from morbidity

30-day freedom from morbidity	Performance goal	Lower Bound[1]	Posterior probability	Performance goal met
85% (34/40)	46%	70.8%	< 0.01	Yes
[1]The lower bound, per the protocol, is the 2.5th percentile of the Bayesian posterior distribution.				

10.5 Death, rupture, and conversion

Table 10.14 provides the results from Kaplan-Meier analysis for freedom from death (all-cause and aneurysm-related), rupture, conversion and MAEs through 5 years. Among the 40 study patients, there was one death through 1 year; the freedom from all-cause mortality was 97.5%. In total, there were four deaths during the study; the 5-year freedom from all-cause mortality was 88.5%. There were no aneurysm-related deaths in the study. Likewise, there were no ruptures or conversions to open surgical repair during the study.

Table 10.14. Kaplan-Meier estimates (freedom from death, rupture, and conversion)

Serious Adverse Event	Parameter	30 Days	180 Days	365 Days	730 Days	1095 Days	1460 Days	1825 Days
All-cause mortality	Number at risk	40	39	37	37	35	33	18
	Cumulative events	0	1[1]	1	1	1	2[1,2]	4[1-4]
	Cumulative censored	0	0	2	2	4	5	18
	Kaplan-Meier estimate	100%	97.5%	97.5%	97.5%	97.5%	94.6%	88.5%
	Standard error	0%	2.5%	2.5%	2.5%	2.5%	3.8%	5.7%
Aneurysm-related mortality	Number at risk	40	39	37	37	35	33	18
	Cumulative events	0	0	0	0	0	0	0
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	100%	100%	100%	100%	100%	100%
	Standard error	0%	0%	0%	0%	0%	0%	0%
Rupture	Number at risk	40	39	37	37	35	33	18
	Cumulative events	0	0	0	0	0	0	0
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	100%	100%	100%	100%	100%	100%
	Standard error	0%	0%	0%	0%	0%	0%	0%
Conversion	Number at risk	40	39	37	37	35	33	18
	Cumulative events	0	0	0	0	0	0	0
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	100%	100%	100%	100%	100%	100%
	Standard error	0%	0%	0%	0%	0%	0%	0%

[1]Respiratory failure from CHF on POD 167; CEC adjudication was not related; related to pre-existing condition
[2]Malignant neoplasm of bladder with metastasis to liver and spine on POD 1383; CEC adjudication was not related; related to pre-existing condition
[3]Multi-factorial acute hypoxic respiratory failure on POD 1570; CEC adjudication was not related; related to fall, rib fractures, respiratory failure
[4]Unknown cause of death on POD 1723; CEC was unable to adjudicate

10.6 All adverse events

A total of 29 patients (72.5%) had a total of 141 adverse events. **Table 10.15** reports the Kaplan-Meier estimates for all adverse events according to category.

In particular, several types of vascular adverse events were reported during study follow-up.

- Additional aneurysms (5 events) were reported in four patients. Three of these aneurysms occurred in the iliac arteries on the side opposite the ZBIS and were all successfully treated with either stent placement (n=2) or bypass (n=1). The remaining two aneurysms occurred in the thoracic aorta, one requiring surgical replacement of the aortic root and ascending aorta and the other occurring in the ascending aorta and was not treated.
- Thrombosis events were reported in three patients. Two of which had thrombosis of the external iliac segment of the ZBIS resulting in an occlusion. Both were treated with a secondary intervention involving thrombectomy and stent placement and were reported to have successfully restored patency. The third patient had thrombosis and occlusion of the iCAST stent in the IIA, on which no treatment was performed.
- Embolization with ischemia or infarction of the left gluteal area was reported in one patient on same day as the index procedure. Four surgical treatments were performed involving surgical exploration, drainage, and debridement of the left gluteal area and left buttock after which the event was considered to have resolved.
- Vascular injury was reported in 2 patients. One vascular injury was reported to be a stenosis of the external iliac artery at the distal edge of the ZBIS resulting in a secondary intervention which included balloon angioplasty and stent placement. The second vascular injury was reported to be an occlusion of the IIA (same side as ZBIS) that did not require treatment.

Table 10.15. Kaplan-Meier estimates (freedom from morbidity)

Category	Parameter	30 Days	180 Days	365 Days	730 Days	1095 Days	1460 Days	1825 Days
Access site/incision	Number at risk	40	39	37	37	35	33	18
	Cumulative events	0	0	0	0	0	0	0
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	100%	100%	100%	100%	100%	100%
	Standard error	0%	0%	0%	0%	0%	0%	0%
Cardiovascular	Number at risk	39	38	36	33	30	28	16
	Cumulative events	1	1	1	4	5	5	5
	Cumulative censored	0	1	3	3	5	7	19
	Kaplan-Meier estimate	97.5%	97.5%	97.5%	89.4%	86.5%	86.5%	86.5%
	Standard error	2.5%	2.5%	2.5%	5.1%	5.8%	5.8%	5.8%
Cardiac arrhythmia	Number at risk	39	38	36	35	32	30	17
	Cumulative events	1	1	1	2	3	3	3
	Cumulative censored	0	1	3	3	5	7	20
	Kaplan-Meier estimate	97.5%	97.5%	97.5%	94.8%	91.9%	91.9%	91.9%
	Standard error	2.5%	2.5%	2.5%	3.7%	4.6%	4.6%	4.6%
Congestive heart failure (CHF)	Number at risk	40	39	37	36	33	31	17
	Cumulative events	0	0	0	1	2	2	2
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	100%	100%	100%	97.3%	94.4%	94.4%	94.4%
	Standard error	0%	0%	0%	2.7%	3.9%	3.9%	3.9%
Myocardial Infarction (MI)	Number at risk	40	39	37	36	34	32	17
	Cumulative events	0	0	0	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	100%	100%	97.3%	97.3%	97.3%	97.3%
	Standard error	0%	0%	0%	2.7%	2.7%	2.7%	2.7%
Cerebrovascular/ neurologic	Number at risk	40	39	36	36	33	31	17
	Cumulative events	0	0	2	2	3	3	3
	Cumulative censored	0	1	2	2	4	6	20
	Kaplan-Meier estimate	100%	100%	94.8%	94.8%	92.0%	92.0%	92.0%
	Standard error	0%	0%	3.6%	3.6%	4.5%	4.5%	4.5%

Transient ischemic attack	Number at risk	40	39	36	36	34	32	18
	Cumulative events	0	0	1	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	100%	100%	97.3%	97.3%	97.3%	97.3%	97.3%
	Standard error	0%	0%	2.7%	2.7%	2.7%	2.7%	2.7%
Stroke	Number at risk	40	39	37	37	34	32	17
	Cumulative events	0	0	1	1	2	2	2
	Cumulative censored	0	1	2	2	4	6	21
	Kaplan-Meier estimate	100%	100%	97.4%	97.4%	94.7%	94.7%	94.7%
	Standard error	0%	0%	2.5%	2.5%	3.8%	3.8%	3.8%
Gastrointestinal	Number at risk	39	38	36	36	34	32	18
	Cumulative events	1	1	1	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%
	Standard error	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
Bleeding requiring intervention	Number at risk	40	39	37	37	34	32	18
	Cumulative events	0	0	0	0	1	1	1
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	100%	100%	100%	100%	97.2%	97.2%	97.2%
	Standard error	0%	0%	0%	0%	2.7%	2.7%	2.7%
Infection	Number at risk	40	39	37	37	34	32	18
	Cumulative events	0	0	0	0	1	1	1
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	100%	100%	100%	100%	97.2%	97.2%	97.2%
	Standard error	0%	0%	0%	0%	2.7%	2.7%	2.7%
Ileus	Number at risk	39	38	36	36	34	32	18
	Cumulative events	1	1	1	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%
	Standard error	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
Hepatic	Number at risk	40	39	37	37	35	33	18
	Cumulative events	0	0	0	0	0	0	0
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	100%	100%	100%	100%	100%	100%
	Standard error	0%	0%	0%	0%	0%	0%	0%
Pulmonary	Number at risk	38	36	34	33	27	25	13
	Cumulative events	2	3	3	4	8	8	8

	Cumulative censored	0	1	3	3	5	7	19
	Kaplan-Meier estimate	95.0%	92.5%	92.5%	89.8%	78.5%	78.5%	78.5%
	Standard error	3.4%	4.2%	4.2%	5.0%	7.0%	7.0%	7.0%

Chronic obstructive pulmonary disease (COPD)	Number at risk	40	39	37	37	32	30	15
	Cumulative events	0	0	0	0	3	3	4
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	100%	100%	100%	100%	91.6%	91.6%	88.3%
	Standard error	0%	0%	0%	0%	4.7%	4.7%	5.8%
Pneumothorax	Number at risk	40	38	36	36	34	32	17
	Cumulative events	0	1	1	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%
	Standard error	0%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
Pulmonary embolism	Number at risk	39	38	36	36	33	31	17
	Cumulative events	1	1	1	1	2	2	2
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	97.5%	97.5%	97.5%	97.5%	94.6%	94.6%	94.6%
	Standard error	2.5%	2.5%	2.5%	2.5%	3.8%	3.8%	3.8%
Pneumonia	Number at risk	39	38	36	35	32	30	16
	Cumulative events	1	1	1	2	3	3	3
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	97.5%	97.5%	97.5%	94.8%	92.0%	92.0%	92.0%
	Standard error	2.5%	2.5%	2.5%	3.7%	4.5%	4.5%	4.5%
Renal/urologic	Number at risk	39	37	35	33	30	30	16
	Cumulative events	1	2	2	4	5	5	6
	Cumulative censored	0	1	3	3	5	5	18
	Kaplan-Meier estimate	97.5%	95.0%	95.0%	89.6%	86.8%	86.8%	83.9%
	Standard error	2.5%	3.4%	3.4%	5.0%	5.7%	5.7%	6.3%
Renal failure requiring dialysis	Number at risk	40	39	37	37	35	33	18
	Cumulative events	0	0	0	0	0	0	1
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	100%	100%	100%	100%	100%	100%	97.0%
	Standard error	0%	0%	0%	0%	0%	0%	3.0%
Urinary Tract Infection (UTI)	Number at risk	39	37	35	34	32	31	16
	Cumulative events	1	2	2	3	3	4	4
	Cumulative censored	0	1	3	3	5	5	20
	Kaplan-Meier estimate	97.5%	95.0%	95.0%	92.3%	92.3%	89.4%	89.4%
	Standard error	2.5%	3.4%	3.4%	4.4%	4.4%	5.2%	5.2%
Serum creatinine rise > 30% above baseline resulting	Number at risk	40	39	37	36	33	31	17
	Cumulative events	0	0	0	1	2	2	2

in a persistent value > 2 mg/dL	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	100%	100%	100%	97.3%	94.5%	94.5%	94.5%
	Standard error	0%	0%	0%	2.7%	3.8%	3.8%	3.8%
Vascular	Number at risk	36	34	32	30	27	25	13
	Cumulative events	4	5	5	7	8	8	9
	Cumulative censored	0	1	3	3	5	7	18
	Kaplan-Meier estimate	90.0%	87.5%	87.5%	82.0%	79.1%	79.1%	75.9%
	Standard error	4.7%	5.2%	5.2%	6.3%	7.0%	7.0%	7.6%
Aneurysm	Number at risk	40	39	37	36	32	30	17
	Cumulative events	0	0	0	1	3	3	4
	Cumulative censored	0	1	3	3	5	7	19
	Kaplan-Meier estimate	100%	100%	100%	97.3%	91.6%	91.6%	88.5%
	Standard error	0%	0%	0%	2.7%	4.7%	4.7%	5.6%
Thrombosis	Number at risk	39	37	35	34	32	30	16
	Cumulative events	1	2	2	3	3	3	3
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	97.5%	95.0%	95.0%	92.3%	92.3%	92.3%	92.3%
	Standard error	2.5%	3.4%	3.4%	4.4%	4.4%	4.4%	4.4%
Embolization with ischemia or infarction	Number at risk	39	38	36	36	34	32	18
	Cumulative events	1	1	1	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	21
	Kaplan-Meier estimate	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%
	Standard error	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
Buttock claudication (total)	Number at risk	40	39	37	36	34	32	17
	Cumulative events	0	0	0	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	100%	100%	97.3%	97.3%	97.3%	97.3%
	Standard error	0%	0%	0%	2.7%	2.7%	2.7%	2.7%
Same side as investigational devices	Number at risk	40	39	37	36	34	32	17
	Cumulative events	0	0	0	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	100%	100%	97.3%	97.3%	97.3%	97.3%
	Standard error	0%	0%	0%	2.7%	2.7%	2.7%	2.7%
Opposite side from investigational devices	Number at risk	40	39	37	36	34	32	17
	Cumulative events	0	0	0	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	100%	100%	97.3%	97.3%	97.3%	97.3%

	Standard error	0%	0%	0%	2.7%	2.7%	2.7%	2.7%
Vascular injury	Number at risk	40	39	36	36	34	32	16
	Cumulative events	0	0	1	1	1	1	2
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	100%	97.3%	97.3%	97.3%	97.3%	94.3%
	Standard error	0%	0%	2.7%	2.7%	2.7%	2.7%	4.1%
Leg claudication	Number at risk	39	38	36	36	34	32	17
	Cumulative events	1	1	1	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%
	Standard error	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
Deep vein thrombosis (DVT)	Number at risk	40	39	37	36	34	32	17
	Cumulative events	0	0	0	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	100%	100%	100%	97.3%	97.3%	97.3%	97.3%
	Standard error	0%	0%	0%	2.7%	2.7%	2.7%	2.7%
Lower extremity ischemia	Number at risk	39	38	36	36	34	32	17
	Cumulative events	1	1	1	1	1	1	1
	Cumulative censored	0	1	3	3	5	7	22
	Kaplan-Meier estimate	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%
	Standard error	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
Miscellaneous	Number at risk	32	26	19	15	13	11	4
	Cumulative events	8	13	18	22	23	24	25
	Cumulative censored	0	1	3	3	4	5	11
	Kaplan-Meier estimate	80.0%	67.3%	53.8%	42.5%	39.4%	36.4%	32.8%
	Standard error	6.0%	7.0%	7.6%	7.2%	7.2%	7.0%	7.2%
Impotence	Number at risk	39	37	34	33	31	29	15
	Cumulative events	1	2	3	4	4	4	5
	Cumulative censored	0	1	3	3	5	7	20
	Kaplan-Meier estimate	97.5%	95.0%	92.4%	89.7%	89.7%	89.7%	86.4%
	Standard error	2.5%	3.4%	4.2%	5.0%	5.0%	5.0%	6.3%
Sepsis	Number at risk	39	38	36	36	33	31	15
	Cumulative events	1	1	1	1	2	3	4
	Cumulative censored	0	1	3	3	5	6	21
	Kaplan-Meier estimate	97.5%	97.5%	97.5%	97.5%	94.7%	91.8%	88.5%
	Standard error	2.5%	2.5%	2.5%	2.5%	3.7%	4.7%	5.8%
Other	Number at risk	33	27	20	16	14	12	5

Cumulative events	7	12	17	21	22	23	24
Cumulative censored	0	1	3	3	4	5	11
Kaplan-Meier estimate	82.5%	69.8%	56.3%	45.0%	42.0%	39.0%	35.5%
Standard error	5.7%	6.9%	7.6%	7.3%	7.3%	7.2%	7.4%

10.7 Additional effectiveness results

Table 10.16 reports the 6-month branch vessel (i.e., internal iliac artery) patency (reported for descriptive purposes only), the secondary effectiveness endpoint for the study. The success rate for the secondary effectiveness endpoint was 100% (37/37) of patients based on available imaging analyzed by the core laboratory at 6 months.

Table 10.17 reports technical success, which was defined as the ability to deliver and deploy the ZBIS 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. Overall, all 40 patients were reported to have had successful deployment of the ZBIS System (i.e., AAA graft, iliac leg grafts, ZBIS, and iCAST stent).This resulted in a technical success rate of 100% (40/40) for the ZBIS and iCAST stent.

Table 10.18 reports procedural success, which was defined as technical success with no Type I, Type III, or Type IV endoleaks 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 duplex ultrasound in those patients experiencing renal failure and unable to undergo contrast-enhanced CT scan. Overall, the rate of procedural success was 87.5% (35/40).Of the five patients who failed to meet procedural success, three were due to major complications (impotence, ileus, and lower extremity ischemia) and two were due to occlusion of the ZBIS.

Changes in the treated common iliac aneurysm size are reported in **Table 10.19**. Aneurysm shrinkage was defined as a decrease in aneurysm maximum diameter of > 5 mm from the first post-procedure measurement (i.e., 1-month exam). Aneurysm growth was defined as an increase in maximum aneurysm diameter of > 5 mm from the first post-procedure measurement. Lastly, no change was defined as an increase or decrease in maximum aneurysm diameter ≤ 5 mm as compared to the first post-procedure measurement. Only one patient (2.5%, 1/40) experienced an increase in common iliac aneurysm size on the ZBIS side during the study. The patient had a reported increase in size of 5.5 mm as measured by the core laboratory on the 4-year CT scan. The site reported a similar growth of 7 mm on the same 4-year CT. This patient was also noted by the core laboratory to have had a distal Type I endoleak involving the iCAST stent persisting from 12-months to the 5-year imaging exam and a Type II endoleak persisting from 4-year to 5-year imaging exam; notably, the site only reported presence of a Type II endoleak. The aneurysm growth was not treated with a secondary intervention. Despite this, growth was not identified by the core laboratory at 5 years.

Table 10.16. Results for 6-month branch vessel patency based on core lab analysis

6-month branch vessel patency	95% Confidence interval
100% (37/37)[1]	88.8%, 100%

[1]Three patients who did not complete 6-month CT imaging were excluded from the analysis of branch vessel patency at 6 months.

Table 10.17. Technical Success

Success Measure	Percent Patients (n/N)
Technical success	100% (40/40)

Table 10.18. Procedural Success

Success Measure	Percent Patients (n/N)
Procedural success	87.5% (35/40)

Table 10.19. Change in common iliac artery aneurysm size based on results from core laboratory analysis

Status	% Patient (number/total number)					
	6-month	12-month	2-year	3-year	4-year	5-year
Increase (> 5 mm)	0% (0/37)	0% (0/37)	0% (0/38)	0% (0/31)	3.6% (1/28)[1]	0% (0/26)
Decrease (> 5 mm)	10.8% (4/37)	16.2% (6/37)	21.4% (6/28)	29.0% (9/31)	25.0% (7/28)	26.9% (7/26)
No change (≤ 5 mm)	89.2% (33/37)	83.8% (31/37)	78.6% (22/28)	71.0% (22/31)	71.4% (20/28)	73.1% (19/26)

[1]One patient had aneurysm growth reported at 4 years, but no growth at 5 years. The patient also had an associated distal Type I endoleak involving the iCAST stent reported consistently from 12-months through 5-years and a Type II endoleak reported at 4-years and 5-years. No reintervention to treat the aneurysm growth was performed.

Table 10.20 reports endoleak events by type, as assessed by the core laboratory at each follow-up exam period. In total, one patient (2.5%, 1/40) had a reported Distal Type I endoleak which was first identified on the 12-month CT exam and persisted through the 5-year CT exam. This Distal Type I endoleak was on the same side as the ZBIS and involved the iCAST stent. Of note, the site did not report a Distal Type I endoleak, but rather a Type II endoleak at 12 months through 5 years. This patient experienced growth of the CIA aneurysm at 4 years and no secondary intervention was performed for the endoleak; of note, no aneurysm growth was identified at 5-years. No Type III or Type IV endoleaks were reported in the study.

Table 10.20. Endoleak results from core laboratory analysis

Type	% Patient (number/total number)							
	1-month	6-month	12-month	2-year	3-year	4-year	5-year	Total
Any (new only)	22.5% (9/40)	2.7% (1/37)	5.6% (2/36)	0% (0/27)	0% (0/29)	3.4% (1/29)	0% (0/25)	N/A
Any (new and persistent)	37.5% (15/40)	32.4% (12/37)	30.6% (11/36)	33.3% (9/27)	34.5% (10/29)	34.5% (10/29)	36.0% (9/25)	19
Multiple	0% (0/40)	0% (0/37)	0% (0/36)	0% (0/27)	3.4% (1/29)	6.9% (2/29)	8.0% (2/25)	2
Proximal Type I	0% (0/40)	0% (0/37)	0% (0/36)	0% (0/27)	0% (0/29)	0% (0/29)	0% (0/25)	0
Distal Type I	0% (0/40)	0% (0/37)	2.8% (1/36)	3.7% (1/27)	3.4% (1/29)	3.4% (1/29)	4.0% (1/25)	1
Type II	35.0% (14/40)	32.4% (12/37)	27.8% (10/36)	29.6% (8/27)	31.0% (9/29)	31.0% (9/29)	36.0% (9/25)	17
Type III	0% (0/40)	0% (0/37)	0% (0/36)	0% (0/27)	0% (0/29)	0% (0/29)	0% (0/25)	0
Type IV	0% (0/40)	0% (0/37)	0% (0/36)	0% (0/27)	0% (0/29)	0% (0/29)	0% (0/25)	0
Unknown	2.5% (1/40)	0% (0/37)	0% (0/36)	0% (0/27)	3.4% (1/29)	6.9% (2/29)	4.0% (1/25)	3

Radiographic migration was defined as movement of a component ≥ 10 mm. Clinically significant migration was defined as movement of the stent-graft that requires surgical or endovascular intervention. There were no reported instances of radiographic migration or clinically-significant migration of the ZBIS or iCAST stent during this study.

Table 10.21 reports occlusions identified on imaging on the same side and opposite side of the ZBIS. In total, occlusions were reported in four patients (10%; 4/40). Two patients were reported to have occlusion within the external iliac artery segment of the ZBIS; in both cases patency was restored through a secondary intervention. Additionally, two patients were reported to have occlusion within the IIA

in the iCAST stent; neither patient was treated with a secondary intervention and patency was not restored. Of the two patients with IIA occlusion, one did not have any reported clinical sequalae associated with the occlusion. The other patient had a reported event of buttock claudication; however, this was reported before the occlusion of IIA and is therefore unlikely to be related. There were no reported device integrity issues for the ZBIS or iCAST stent during the study (e.g., fracture, separation).

Table 10.21. Occlusion based on results from core laboratory analysis

Side of Event	1-month	6-month	12-month	2-year	3-year	4-year	5-year
Same side as ZBIS							
Common iliac (CIA) segment	0	0	0	0	0	0	0
External iliac (EIA) segment	2[1,2]	0	0	0	0	0	0
Internal iliac (IIA) segment	0	0	1[3]	1[3]	0	2[3,4]	2[3,4]
Opposite side as ZBIS	0	0	0	0	0	0	0

[1]EIA occlusion within the ZBIS; thrombectomy and stent placement performed.
[2]EIA occlusion within the ZBIS; thrombolysis and stent placement performed.
[3]IIA occlusion within the iCAST stent. No secondary intervention was performed, as the patient was reported to be asymptomatic. Of note, because the 3-year CT scan was not performed, the occlusion could not be evaluated. However, the IIA occlusion persisted at 4 and 5 years.
[4]IIA occlusion within the iCAST stent and sidebranch of the ZBIS. No secondary intervention has been performed. IIA occlusion persisted at 5 years.

10.8 Secondary interventions

A total of nine patients underwent 15 secondary interventions. Secondary interventions have been separated into those on the same side as the ZBIS, those on the side opposite the ZBIS, and those that occurred within the aorta. The indications and types of secondary intervention are reported in **Tables 10.22** and **10.23**, respectively. Six secondary interventions occurred on the same side as the ZBIS, eight secondary interventions occurred on the side opposite the ZBIS, and one secondary intervention occurred within the aorta. Four of the secondary interventions (all reported for one patient) were attributed to adverse events associated with the embolization of the IIA on the side opposite the investigational devices (ZBIS and iCAST). The six secondary interventions which occurred on the same side of the ZBIS occurred in four total patients. These interventions most commonly involved placement of an additional stent for the treatment of an occlusion, thrombosis, or endoleak.

Table 10.22. Indications for secondary intervention (as reported by site)

Reason	0-30 Days	31-180 Days	181-365 Days	366-730 Days	731-1095 Days	1096-1460 Days	1461-1825 Days	Total # SIs
Clinical								
Symptoms	2[1,2]	3[1]	0	0	0	0	0	5
Imaging results								
Aneurysm rupture	0	0	0	0	0	0	0	0
Device stenosis	0	0	0	1[4]	0	0	0	1
Device migration	0	0	0	0	0	0	0	0
Device separation	0	0	0	0	0	0	0	0
Occlusion	1[2]	1[3]	0	0	0	0	0	2
Device kink	0	0	1[4]	1[5]	0	0	0	2
Infection	0	1[1]	0	0	0	0	0	1
Endoleak								
Type I proximal	0	0	0	0	0	0	0	0
Type I distal	0	0	0	0	0	0	0	0
Type II	0	0	0	0	0	1[7]	0	1
Type III	0	0	0	0	0	0	0	0
Type IV	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0
Other imaging results	0	0	0	2[2,5]	0	3[3,6,8]	1[9]	6
Other	0	1[1]	0	0	0	0	0	1
							Total # SIs	15[10]

Note: CIA = common iliac artery; EIA = external iliac artery; IIA = internal iliac artery.
[1]Clinical signs and symptoms (opposite side of ZBIS; POD 1, 93, 94, 112); infection (opposite side of ZBIS; POD 93); and other: extensive soft tissue air dissecting throughout the left gluteus minimus, medius, and maximus muscles with incomplete visualization of open wound of left buttock distribution (opposite side of ZBIS; POD 93).
[2]Clinical signs and symptoms and occlusion of external iliac (same side as ZBIS; POD 12); and other imaging results: stenosis of the native iliac artery at the distal edge of the ZBIS limb (same side as ZBIS; POD 390).
[3]Occlusion of external iliac artery (same side as ZBIS; POD 60); and other imaging results: increased size of common iliac artery aneurysm (opposite side of ZBIS; POD 1222).
[4]Device kink (same side as ZBIS; POD 251); and device stenosis (same side as ZBIS; POD 402).
[5]Device kink (opposite side of ZBIS) and other imaging results: loss of IIA seal (same side as ZBIS) (POD 380).
[6]Other imaging results: enlargement of CIA aneurysm (opposite side as ZBIS; POD 1173).
[7]Persistent endoleak – Type II endoleak (aorta; POD 1263).
[8]Other imaging results: iliac artery aneurysm (opposite side ZBIS). It was also noted presence of bilateral renal artery stenoses (POD 1246).
[9]Other imaging results: IIA aneurysm (opposite side of ZBIS; POD 1519).
[10] Out of the 9 patients with secondary interventions, multiple indications could have been reported. As a result, of the 15 secondary interventions, 19 indications were reported.

Table 10.23. Type of secondary intervention

Type	0-30 Days	31-180 Days	181-365 Days	366-730 Days	731-1095 Days	1096-1460 Days	1461-1825 Days	Total # SIs
Percutaneous								
Thrombolysis	0	1[3]	0	0	0	0	0	1
Thrombectomy	0	0	0	0	0	0	0	0

Balloon angioplasty	0	0	0	1[2]	0	0	1[9]	2
Coil embolization	0	0	0	0	0	1[6]	0	1
Stent placed	0	1[3]	1[4]	3[2,4,5]	0	1[8]	1[9]	7
Ancillary component placed:								
Iliac leg extension	0	0	0	1[5]	0	0	0	1
AAA main body extension	0	0	0	0	0	0	0	0
iCAST stent	0	0	0	1[5]	0	0	0	1
Other	0	0	0	1[5]	0	1[6]	0	2
Other percutaneous	0	0	0	1[4]	0	2[6,7]	0	3
Surgical								
Conversion to open repair	0	0	0	0	0	0	0	0
Surgical bypass procedure	0	0	0	0	0	1[3]	0	1
Other surgical	2[1,2]	3[1]	0	0	0	0	0	5
Other	0	0	1[4]	0	0	1[3]	0	2
							Total # SIs	15[10]

Note: CIA = common iliac artery; EIA = external iliac artery; IIA = internal iliac artery.

[1]Other surgical: gluteal exploration (opposite side of ZBIS; POD 1); other surgical: incision and drainage of buttock and sacrum with extensive gluteus muscle excision or debridement (opposite side of ZBIS; POD 93); other surgical: debridement of buttock and placement of buttock wound vacuum dressing (opposite side of ZBIS; POD 94); other surgical: debridement including skin and subcutaneous tissue of gluteal wound and complex closure of gluteal wound (opposite side of ZBIS; POD 112).

[2]Other surgical: femoral exposure/thrombectomy, placement of iCAST stent in EIA (same side as ZBIS; POD 12); percutaneous: balloon angioplasty and stent placement in EIA (same side as ZBIS; POD 390).

[3]Percutaneous: thrombolysis and stent placement in EIA (same side as ZBIS; POD 60); surgical: EIA to IIA bypass and other: stent placement into right CIA to EIA (opposite side of ZBIS; POD 1222).

[4]Percutaneous; stent placement and other percutaneous: deployment of stent into iliac artery (same side as ZBIS; POD 251); percutaneous: stent placement and other percutaneous in IIA (same side as ZBIS; POD 402).

[5]Percutaneous: stent placement in IIA (same side as ZBIS), ancillary components placed (iliac leg extension, iCAST stent, other stent) in CIA (opposite side as ZBIS) (POD 380).

[6]Percutaneous: ancillary components placed (other) in CIA and EIA, percutaneous other in IIA (opposite side of ZBIS; POD 1173).

[7]Other percutaneous: N-butyl-2-cyanoacrylate (NBCA) embolization (aorta; POD 1263).

[8]Percutaneous: stent placed in EIA and right renal artery (opposite side of ZBIS; POD 1246).

[9]Percutaneous: balloon angioplasty and stent placement in IIA (opposite side of ZBIS; POD 1519).

[10]Out of the 9 patients with secondary interventions, multiple types could have been reported. As a result, of the 15 secondary interventions, 26 types were reported.

10.9 Summary

The ZBIS and iCast stent was associated with high 6-month freedom from patency-related intervention and 30-day freedom from morbidity. Only four patient deaths, CEC adjudicated as not related or unknown, occurred and no conversion to open repair were identified through 5 years. Only one Distal Type I endoleak was observed by the core laboratory analysis at 12-months which persisted through 5 years but did not result in a secondary intervention. No Type III or IV endoleaks were identified during the study. Similarly, no device migrations, separations, or fractures were identified.

Overall, device patency remained high through 5 years with only four occlusions, including two occlusions of the ZBIS identified within 1-month and two occlusions in the iCAST stent identified at 12 and 24 months. Overall, of the 40 patients treated, six secondary interventions occurred on the same side of the ZBIS in four total patients. These interventions commonly involved placement of an additional stent for the treatment of an occlusion, thrombosis, or endoleak. Finally, the available 5-year follow-up data provide additional information supporting the safety and effectiveness of the ZBIS and iCAST covered stent system.

10.10 Summary of supplemental clinical information – continued access

Upon completing enrollment in the pivotal study, the Agency approved a Continued Access Study. This allowed PRESERVE II investigators to treat more patients with ZBIS and iCast, adhering to the same criteria, follow-up schedule, definitions, and data collection as the pivotal study. A total of 30 patients were treated with ZBIS and iCast between 19 October 2015 and 31 January 2019 at 14 clinical sites, with follow-up through five years complete.

10.11 Demographics and patient characteristics

Patients in the continued access study had an average age of 69.9 ± 8.0 years and were predominately male (96.7%, 29/30). Patients commonly presented with comorbidities including hypertension (76.7%, 23/30) and allergies (36.7%, 11/30), which aligned with the pivotal study patients. **Table 10.24** reports patient follow-up availability through five years.

Table 10.24 Follow-up data availability - Continued Access Cohort (Through 5 Years)

Visit	Eligible for Follow-up	Percent of Data Available		Adequate Imaging for Core Laboratory to Assess Parameter					Events Occurring Before Next Interval			
		Clinical Exam	CT	Size Increase	Endoleak	Patency	Migration	Device Integrity	Death	Conversion	Lost to Follow-up (LTF)	Withdrawal
Procedure	30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0
Pre-discharge	30	100% (30/30)	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0
1-month	30	96.7% (29/30)	100% (30/30)	N/A	100% (30/30)	100% (30/30)	N/A	100% (30/30)	0	0	0	0
6-month	30	93.3% (28/30)	90.0% (27/30)	93.3% (28/30)	93.3% (28/30)	93.3% (28/30)	90.0% (27/30)	90.0% (27/30)	0	0	1	0
12-month	29	93.1% (27/29)	93.1% (27/29)	93.1% (27/29)	89.7% (26/29)	93.1% (27/29)	93.1% (27/29)	93.1% (27/29)	1	0	0	1
2-year	27	92.6% (25/27)	96.3% (26/27)	96.3% (26/27)	92.6% (25/27)	92.6% (25/27)	96.3% (26/27)	96.3% (26/27)	0	0	0	2
3-year	25	92.0% (23/25)	96.0% (24/25)	96.0% (24/25)	88.0% (22/25)	96.0% (24/25)	96.0% (24/25)	96.0% (24/25)	0	0	0	0
4-year	25	92.0% (23/25)	88.0% (22/25)	88.0% (22/25)	88.0% (22/25)	84.0% (21/25)	88.0% (22/25)	88.0% (22/25)	0	0	0	0
5-year	25	84.0% (21/25)	72.0% (18/25)	80.0% (20/25)	84.0% (21/25)	88.0% (22/25)	72.0% (18/25)	72.0% (18/25)	2	0	0	0

Note: In patients experiencing renal failure and unable to undergo contrast-enhanced CT scan, a duplex ultrasound may be used in conjunction with noncontrast CT scan. In these cases, the core laboratory may be able to adequately assess aneurysm size change, endoleak, and patency when an ultrasound is performed in combination with a noncontrast CT scan.
N/A = Not applicable.

10.12 Summary of Continued Access Results

10.12.1 Procedural Outcomes and Study Outcome Measures

The average estimated procedural blood loss was 237.5 ± 236.4 cc (maximum blood loss was 1000 cc), which was similar to the pivotal cohort (i.e., the average estimated blood loss was 275.6 ± 215.5 cc [maximum blood loss was 800 cc]). The average procedure and total fluoroscopy times (incision to incision closure complete) were 139.6 ± 53.5 minutes and 36.7 ± 28.8 minutes, respectively.

The 6-month freedom from patency-related intervention (defined as freedom from a secondary intervention to treat a >60% stenosis of the internal iliac artery [as identified through computed tomography (CT) scan, angiography, or duplex ultrasound and confirmed by core laboratory] associated with clinical symptoms) was 100% (30/30). One procedure was a technical failure due to the intentional occlusion of the internal iliac artery on the same side as ZBIS. However, there were no clinical symptoms resulting from the occlusion of the internal iliac artery, and no further interventions were required. Thus, it was classified as freedom from patency-related intervention. The 30-day freedom from morbidity was 80% (26/30); four patients experienced morbidity index events within 30 days of the procedure. These events included arrhythmias needing new medication, limb thrombosis on the ZBIS side, infections requiring antibiotics, and hospital readmission within 30 days for a pulmonary embolism needing supplemental oxygen at discharge.

10.12.2 Death, and MAEs through 5 years

Early mortality (≤ 30 days) was 0% (0/30). During the 5-year follow-up, death has been reported in three patients (10%, 3/30) with reported causes of MRSA infection of mitral valve in one patient, acute myeloblastic leukemia in one patient, and emphysema, COPD, and lung cancer. No deaths were adjudicated as related to aneurysm repair.

Access site/incision adverse events were reported in two patients (6.7%, 2/30): one patient had an infection requiring antibiotics, and another patient had a seroma that required treatment. Over 5 years, one patient (3.3%, 1/30) had a MI, and another (3.3%, 1/30) had a stroke. There were no reports of renal failure requiring dialysis, bowel ischemia, buttock claudication, or impotence.

10.13 Secondary Interventions, Conversion, Rupture, Aneurysm Growth, Endoleak, and Device Integrity Outcomes through 5 years

The occurrence of aneurysm growth, endoleak, device migration, device integrity, and graft patency over a five-year period were evaluated and reported based on core laboratory findings.

Secondary Interventions: Six patients (20%, 6/30) underwent 11 secondary interventions: four on the same side as the ZBIS, three on the side opposite the ZBIS, and four in the aorta. Three patients (10%, 3/30) received secondary interventions: balloon angioplasty, stent placement for a Type III endoleak, and balloon angioplasty/thrombectomy/stent placement/iliac leg extension on the same side as ZBIS. Two patients underwent stent placement, left iliac limb relining, and coil embolization with ancillary component placement on the side opposite the ZBIS. Two patients underwent balloon angioplasty and fenestrated graft placement followed by coil and glue embolization in the aorta.

Conversion to Open Surgery: There were no conversions to open repair reported through five years.

Aneurysm Growth: Only one common iliac artery aneurysm enlargement (>5 mm) was experienced by one patient (3.3%, 1/30) at the 5-year follow-up.

Endoleak: Throughout the 5-year follow-up schedule, 3 patients (10.0%, 3/30) experienced Type I endoleaks and 1 patient (3.3%, 1/30) experienced a Type III endoleak. Details on the endoleak events are as follows. One patient presented with a distal Type I endoleak involving the iCAST stent at 30 days which persisted at the 6-month follow-up. This event was resolved with a secondary intervention involving stent placement in the internal iliac artery. This same patient had another distal Type I endoleak involving the iliac leg graft on the side opposite the ZBIS at 30 days which persisted at 6-month follow-up. No secondary intervention was performed for this endoleak. Another patient presented with a proximal Type I endoleak involving the AAA main body device (i.e., unrelated to the ZBIS) at the 2-year follow-up. This endoleak (and subsequent AAA growth) was treated with a secondary intervention involving placement of a fenestrated EVAR device. A third patient presented with a Type III endoleak involving the iliac devices on the side opposite the ZBIS at the 2-year follow-up. This endoleak was treated with a secondary intervention involving iliac limb placement. This same patient presented with a distal Type I and a Type III endoleak again involving the iliac devices on the side opposite the ZBIS at the 4-year follow-up. These endoleaks were treated with a secondary intervention involving coil embolization and ancillary component placement.

Device Migration: At the 12-month follow-up, one patient (3.3%, 1/30) experienced migration between the iliac leg graft and distal cuff (non-investigational devices) on side opposite ZBIS, which remained through 5 years. No migration instances involving the ZBIS were observed.

Device Integrity: No fractures or stent covering tears were reported. Importantly, no occurrences of device integrity issues involving the study devices were reported throughout the duration of the study.

Aortic Rupture: No ruptures have been reported through 5 years.

Graft Patency: Four occlusions were reported in three patients (10.0%, 3/30) involving various segments of the ZBIS. Specifically, two occlusions occurred within the external iliac artery segment of the ZBIS, and two occlusions were within the internal iliac artery segment of the ZBIS, with both persisting through the 5-year follow-up. One patient had an external iliac artery occlusion in the ZBIS, requiring thrombectomy and angioplasty. Another experienced a technical failure at procedure requiring internal iliac artery occlusion due to cannulation failure and iCAST stent deployment issues, leading to an Amplatzer plug placement and a persistent occlusion after 5 years. A third patient showed occlusions in the iliac leg graft, ZBIS, and iCAST stent at 2 years, necessitating secondary intervention. The subsequent stent placement intentionally covered the side branch of the ZBIS and iCAST stent, leading to a permanent occlusion of the internal iliac artery at the 5-year mark.

Overall, the clinical outcomes from the continued access study provide additional support for the safety and effectiveness of the ZBIS and iCast for its intended use.

11. HOW SUPPLIED

STERILE—DO NOT RESTERILIZE—SINGLE USE ONLY.

This device is accompanied by an implant card, that should be given to the patient after it has been completed by the Healthcare Professional.

The Zenith Iliac Branch is supplied sterile (100% ethylene oxide) and pre-loaded in peel-open packages. This product is single use and shall not be reused.

12. STORAGE

Keep the device dry and away from sunlight.

13. INSPECTION OF THE DEVICE

Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use the device if damage has occurred, or if both sterile barriers have been damaged or broken. Contact William Cook Australia or your local Cook representative.

If the outer sterile barrier is damaged, inspect the inner barrier prior to use. If the inner barrier is intact, sterile personnel may handle product inside the inner barrier. The inner pouch shall not be handled by sterile personnel or placed on sterile surfaces.

If the inner barrier is damaged but outer barrier is intact, the inner pouch and contents are still considered safe to be handled by sterile personnel and can be placed on sterile surface.

Prior to use, verify correct devices (quantity and size) have been supplied for the patient by matching the device to the order prescribed by the physician for that particular patient. Do not use after the expiration date printed on the label.

14. DEVICE PREPARATION

Refer to **Section 15.5 Zenith Iliac Branch preparation/flush**.

15. INSTRUCTIONS FOR USE

Prior to use of the Zenith Iliac Branch, review this suggested instructions for use booklet. The following instructions embody a basic guideline for device placement. Variations in the following procedures may be necessary. These instructions are intended to help guide the physician and do not take the place of physician judgment.

15.1 General use information

Standard techniques for placement of arterial access sheaths, guiding catheters, angiographic catheters and wire guides should be employed during use of the Zenith Iliac Branch. The Zenith Iliac Branch is compatible with 0.035 inch (0.89 mm) diameter wire guides.

15.2 General deployment information

The Zenith Iliac Branch is designed to be placed via the common femoral artery on the side of the common iliac artery aneurysm to be treated. A Zenith proximal device will be introduced on the side opposite the Zenith Iliac Branch.

The suggested order of placement of the multiple components will be:

1. Deployment of the Zenith Iliac Branch, including placement of the bridging stent (through the iliac artery) into the internal iliac artery.
2. Deployment of the Zenith proximal device (i.e.TFFB or ZFEN) (introduced through the opposite iliac artery).
3. Deployment of a Zenith Iliac Leg graft (i.e.ZSLE) via the Zenith Iliac Branch access site into the contralateral limb (i.e.short) of the Zenith proximal device, connecting the lumen of the Zenith proximal device to the Zenith Iliac Branch.
4. Deployment of a Zenith Iliac Leg graft (i.e.ZSLE) into the ipsilateral limb (i.e.long) of the Zenith proximal device (if necessary).

15.3 Pre-implant determinants

Verify from pre-implant planning that the correct device has been selected.

Determinants include:

1. Femoral artery selection for introduction of the delivery system, (i.e., define relevant iliac artery).
2. Angulation of iliac arteries.
3. Diameters of relevant distal iliac vessel(s).
4. Distance from the aortic bifurcation to the hypogastric (internal iliac) artery and attachment site(s).
5. Consider the degree of vascular calcification.

15.4 Patient preparation

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

15.5 Zenith Iliac Branch preparation/flush

1. Remove black-hubbed shipping stylet (from the inner cannula), cannula protector tube (from the inner cannula) and dilator tip protector (from the dilator tip). Remove Peel-Away sheath from back of the hemostatic valve. **(Figure 3)** Push the introduction sheath forward on the dilator tip until the curved catheter is no longer exposed. Elevate distal tip of system and flush through the stopcock on the hemostatic valve until fluid emerges from the sideport near the tip of the introduction sheath. **(Figure 4)** Continue to inject a full 20 cc of flushing solution through the device. Discontinue injection and close stopcock on extension tube.

NOTE: Graft flushing solution of heparinized saline is always used.

NOTE: Ensure the Captor Hemostatic Valve on the Flexor introducer sheath is turned to the open position. **(Figure 5)**

2. Attach syringe with heparinized saline to the hub on the inner cannula. Flush until fluid exits the distal dilator tip. **(Figure 6)**

NOTE: When flushing system, elevate distal end of system to facilitate removal of air.

3. Remove the pre-loaded wire guide from the delivery system.
4. Attach syringe with heparinized saline to the pre-loaded catheter Luer fitting. Flush until fluid exits the distal catheter tip.
5. Insert a suitable hydrophilic nitinol core wire guide, 0.035 inch (0.89 mm) compatible and 260 cm in length, into the pre-loaded catheter.
6. Soak gauze pads in saline solution and use to wipe Flexor introducer sheath to activate the hydrophilic coating. Hydrate both sheath and dilator tip liberally.

15.6 Vascular access and angiography

1. Puncture the selected common femoral artery(s) using standard technique with an 18 or 19UT gauge arterial needle. Upon vessel entry, insert:
   - Wire guides – standard 0.035 inch (0.89 mm) diameter
   - Appropriate size sheaths (e.g., 5 Fr (1.7 mm I.D.) and 8 Fr (2.7 mm I.D.))
   - Flush catheter (often radiopaque sizing catheters – e.g., centimeter sizing catheter or straight flush catheter)

NOTE: Use an 8 Fr (2.7 mm I.D.) sheath advanced into the lower abdominal aorta on the contralateral side.

2. Perform angiography to determine the position of the aortic bifurcation and internal iliac artery on the side of Zenith Iliac Branch implantation.

15.7 Zenith Iliac Branch placement

1. Ensure the delivery system has been flushed with heparinized saline and that all air is removed from the system.
2. Give systemic heparin and check flushing solutions. Flush after each catheter and/or wire guide exchange.

NOTE: Monitor the patient's coagulation status throughout the procedure.

3. On side of Zenith Iliac Branch implantation, wire with a stiff wire guide (AUS2 or LES) 0.035 inch (0.89 mm), 260 cm long and advance through catheter and up into the upper thoracic aorta. Remove the flush catheter and sheath. Maintain wire guide position.

NOTE: The location and orientation of the internal iliac artery origin as well as the aortic bifurcation should be identified from pre-operative or intraoperative imaging prior to device insertion.

4. Before insertion, check orientation of the internal iliac segment using fluoroscopy to ensure its position is appropriately aligned to the anatomy.

NOTE: The device will be completely covered by the outer sheath at this stage, but this image with the sheath withdrawn demonstrates the four gold radiopaque markers which are aligned with the outer aspect of the internal iliac segment, and the groove that accommodates the in dwelling catheter. **(Figure 7)**

NOTE: The second marker from the distal end (2D) is the "Aiming" marker for the most proximal location of the proximal end of the bridging stent that extends the internal iliac segment into the internal iliac artery. The second marker from the proximal end (2P) is the "Aiming" marker for the most distal location of the distal end of the iliac leg graft that will connect the internal iliac segment to the bifurcated stent graft that will be deployed above the aortic bifurcation.

NOTE: Orientation can be confirmed by visual inspection since the groove in the tapered dilator tip (where the pre-loaded wire guide emerges from the system) is aligned with the internal iliac segment.

5. Insert Zenith Iliac Branch delivery system over the wire guide, into the iliac artery until the tip of the in dwelling catheter, sitting in the groove in the dilator tip beneath the outer sheath, is just above the aortic bifurcation and in rotational alignment with the opposite common iliac artery origin. **(Figure 8)**

CAUTION: Maintain wire guide position during delivery system insertion.

CAUTION: To avoid any twist in the endovascular graft, during any rotation of the delivery system, be careful to rotate all of the components of the system together (from outer sheath to inner cannula).

NOTE: Slight advancement of the hydrophilic wire guide through the tip of the catheter may aid in visualization of the catheter tip position.

15.8 Through-and-through wire guide placement

1. Advance the hydrophilic wire guide and catheter into the aorta. Position the wire guide for snaring by advancing it through the tip of the curved catheter as required.
2. Advance a suitable snare through the access sheath in the opposite iliac artery, snare the tip of the hydrophilic wire guide, and pull it through to form a through-and-through wire guide. **(Figure 9)**

CAUTION: During this manoeuver, the hydrophilic through-and-through wire guide should be advanced so that some slack is maintained at the aortic bifurcation.

15.9 Proximal Zenith Iliac Branch deployment

1. Advance the 8 Fr (2.7 mm I.D.) sheath in the opposite limb until it is above the level of the aortic bifurcation, and perform angiography through it to determine the location of the internal iliac artery on the side of the device implantation. **(Figure 10)**
2. Ensure the graft system is oriented such that the distal end of the internal iliac segment (as indicated by the most distal radiopaque marker) is positioned 10 mm proximal to the proximal edge of the internal iliac artery orifice with rotational orientation such as to allow easy access into the internal iliac artery with minimal angulation of the bridging stent. If the radiopaque markers are not in the appropriate position, rotate the entire system until the markers are in line with the internal iliac artery orifice and/or advance or withdraw the system as necessary. **(Figure 11)**

CAUTION: To avoid any twist in the endovascular graft, during any rotation of the delivery system, be careful to rotate all of the components of the system together (from outer sheath to inner cannula).

3. When the position of the device is satisfactory, stabilize the gray positioner (the shaft of the delivery system) while withdrawing the outer introduction sheath. Deploy the Zenith Iliac Branch until the distal end of the internal iliac segment is exposed. **(Figure 12)**
4. Stop withdrawing sheath.

WARNING: Do not withdraw the sheath any further, or the external iliac component will expand and prevent further positional changes.

15.10 Up-and-over sheath placement

1. Withdraw the opposite iliac access sheath leaving the hydrophilic nitinol core through-and-through wire guide in place.
2. Advance a suitably sized up-and-over sheath over the hydrophilic nitinol core through-and-through wire guide until the tip of the sheath's dilator tip comes in contact with the tip of the pre-loaded catheter. **(Figure 13)**

NOTE: It may be necessary to apply gentle traction on both ends of the wire guide to aid in advancement.

CAUTION: If the pre-loaded catheter is not advanced over the aortic bifurcation use extra care during wire manipulation to avoid damage to the vasculature.

3. Clamp the hydrophilic through-and-through wire guide at both ends (where it emerges from the pre-loaded catheter and the up-and-over sheath).
4. Continue to advance the sheath over the secured wire guide while applying gentle, intermittent tension on the pre-loaded catheter so that the sheath and catheter will advance over the bifurcation, into the proximal opening of the device, and out through the internal iliac segment. **(Figure 14)**

NOTE: Dependent upon the length of the dilator tip of this sheath, it may be necessary to advance the sheath over its dilator tip, to ensure sheath placement within the internal iliac segment.

5. Remove the dilator of the up-and-over sheath.

15.11 Cannulation of internal iliac artery

1. Puncture the hemostatic valve of the up-and-over sheath as far to one side as possible and insert a suitable wire guide and catheter combination. **(Figure 15)**
2. Advance the wire guide and catheter through the up-and-over sheath into the internal iliac artery. **(Figure 16)**
3. Replace the wire guide in the internal iliac artery with a support wire guide (e.g., Rosen wire guide). Ensure that the wire guide placement is stabilized in the internal iliac artery.

15.12 Bridging stent placement

1. Remove the catheter from within the up-and-over sheath, leaving the sheath and wire guides in place, and advance the pre-mounted bridging stent of suitable size over the support wire guide until it enters the internal iliac artery. **(Figure 17)**

NOTE: Pre-loading the pre-mounted bridging stent into an additional sheath may be desirable to provide protection as the stent is advanced through the up-and-over sheath and into the internal iliac artery. Suitable sheath/wire guides/stent combinations must be selected such that the inner sheath can pass through the up-and-over sheath in a co-axial manner while allowing the through-and-through wire to remain in place.

2. Check angiography as required to determine that the position of the bridging stent is satisfactory with respect to the internal iliac segment overlap and the intended internal iliac artery fixation site.

NOTE: When deployed, the bridging stent should overlap the Zenith Iliac Branch internal iliac segment by 10–14 mm.

NOTE: Angiography should be possible through the up-and-over sheath during this stage of the procedure or through the catheter in the common iliac artery.

3. Withdraw the hydrophilic nitinol core through-and-through wire guide and the pre-loaded catheter.
4. Adjust the position of the Zenith Iliac Branch, if necessary, so that the distal opening of the internal iliac segment is in a suitable location in relationship to the origin of the internal iliac artery.

15.13 Distal Zenith Iliac Branch deployment

1. Withdraw the introducer sheath of the Zenith Iliac Branch until the external iliac component is fully deployed. **(Figure 18)**
2. Remove the safety lock from the black trigger-wire release mechanism. Under fluoroscopy withdraw and remove the trigger-wire by sliding the black trigger-wire release mechanism off the handle and then remove via its slot over the inner cannula. **(Figure 19)**

NOTE: The distal stent is still secured by the trigger-wire.

15.14 Bridging stent deployment

1. Withdraw the up-and-over sheath to a suitable position to allow deployment of the bridging stent.

NOTE: Refer to the bridging stent instructions for use for deployment instructions.

2. Deploy the bridging stent and perform additional ballooning as required. **(Figure 20)**

NOTE: The bridging stent should be expanded to at least 8 mm in the internal iliac segment of the Zenith Iliac Branch, and expanded to the appropriate size to achieve seal in the internal iliac artery.

NOTE: The bridging stent should overlap the Zenith Iliac Branch internal iliac segment by a minimum of 10 mm, and a maximum of no further than the second marker on the distal end of the side branch, with a distal fixation site within the internal iliac artery of at least 10 mm (preferably 20–30 mm).

NOTE: Do not yet remove the balloon from the internal iliac segment of the Zenith Iliac Branch.

3. Remove the safety lock from the white trigger-wire release mechanism. Under fluoroscopy withdraw and remove the trigger-wire by sliding the white trigger-wire release mechanism off the handle and then remove via its slot over the inner cannula. **(Figure 21)**
4. Re-inflate the balloon in the internal iliac segment to stabilize the device and withdraw the introducer system through the graft into the introducer sheath.

CAUTION: Care should be taken to avoid displacing or damaging the Zenith Iliac Branch when removing the introducer system or when advancing other components through it.

NOTE: Ensure that the wire guide remains in a satisfactory position to cannulate the Zenith proximal device.

5. Deflate and remove the balloon.
6. Withdraw the up-and-over wire guide and sheath into the opposite common iliac artery.

15.15 Zenith proximal device deployment

1. Introduce a catheter, and stiff wire guide (AUS2 or LES) standard 0.035 inch (0.89 mm), 260 cm long through the iliac artery access in the side opposite the Zenith Iliac Branch.
2. Remove the existing sheaths and catheters, and introduce and deploy the main body of the Zenith proximal device according to standard Zenith protocol (see relevant Zenith Graft instructions for use).
3. Cannulate the short (contralateral) limb of the Zenith proximal device through the Zenith Iliac Branch.
4. Deploy an iliac leg graft (i.e.ZSLE-16-XX-ZT) of suitable length through the Zenith Iliac Branch such that the recommended overlap is achieved as shown below.

Recommended overlap of Zenith Iliac Leg Graft connecting the contralateral limb of Zenith proximal device to the Zenith Iliac Branch

Overlap into the contralateral limb of the Zenith proximal device	Minimum 1 1/4 stents
	Maximum 1 3/4 stents
Overlap into the body of the Zenith Iliac Branch	Minimum 1 1/2 stents
	Maximum of no further than the second marker on the proximal end of the device

5. Continue deployment of the Zenith proximal device as outlined in the relevant instructions for use.

15.16 Molding balloon insertion

NOTE: Prior to molding balloon use, carefully remove any accessory devices.

1. For the Zenith proximal device use molding balloon as outlined in the relevant instructions for use.
2. For the Zenith Iliac Branch prepare the molding balloon as follows:
   - Flush wire lumen with heparinized saline
   - Remove all air from balloon

3. In preparation for the insertion of the molding balloon, open the Captor Hemostatic Valve by turning counter-clockwise.
4. Advance the molding balloon over the stiff wire guide and through the Captor Hemostatic Valve of the Zenith Iliac Branch introduction system to the overlap between the common iliac segment of the Zenith Iliac Branch and the Zenith Iliac Leg graft (i.e.ZSLE) and expand.

CAUTION: Confirm complete deflation of balloon prior to repositioning.

CAUTION: Captor Hemostatic Valve must be open prior to repositioning of molding balloon.

NOTE: When ballooning in the vicinity of the bifurcation of the Zenith Iliac Branch, ensure that the balloon does not cross the bifurcation.

NOTE: Do not balloon in the vicinity of the internal iliac segment to avoid disruption of the bridging stent.

5. Withdraw the molding balloon to the Zenith Iliac Branch distal fixation site and expand.

CAUTION: Do not inflate balloon in vessel outside of graft.

6. Remove molding balloon and replace it with an angiographic catheter to perform completion angiograms.
7. Remove or replace all stiff wire guides to allow iliac arteries to resume their natural position.

15.17 Final angiogram

1. Position angiographic catheter just above the level of the aortic bifurcation. Perform angiographs to verify that the common iliac artery and corresponding internal iliac artery are patent and that there are no endoleaks.
2. Confirm there are no endoleaks or kinks. Remove the sheaths, wires and catheters.

NOTE: If endoleaks or other problems are observed and require intervention, consider use of additional Zenith AAA Ancillary Components.

3. Repair vessels and close in standard surgical fashion.

16. IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

16.1 General

The long-term safety and effectiveness of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive additional follow-up. Patients should be counselled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of Aortoiliac and Iliac Aneurysms.

Physicians should evaluate patients on an individual basis and prescribe their follow-up relative to the needs and circumstances of each individual patient. The recommended imaging schedule is presented in **Table 16.1**This schedule continues to be the minimum requirement for patient follow-up and should be maintained even in the absence of clinical symptoms (e.g., pain, numbness, weakness). Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the stent graft) should receive follow-up at more frequent intervals.

Table 16.1 Recommended imaging schedule for endograft patients

	Angiogram	**CT (Contrast and non-contrast)**	**Abdominal Radiographs**
Pre-procedure	X_1	X_1	
Procedural	X		
Pre-discharge (within 7 days)		$X_{2,3,4}$	X
1 month		$X_{2,3,4}$	X
6 month		$X_{2,4}$	X
12 month (annually thereafter)		$X_{2,4}$	X

[1] Imaging should be performed within 6 months before the procedure.

[2] Duplex ultrasound may be used for those patients experiencing renal failure or who are otherwise unable to undergo contrast enhanced CT scan. With ultrasound, non-contrast CT is still recommended.

[3] Either pre-discharge or 1 month CT recommended.

[4] If Type I or III endoleak, prompt intervention and additional follow-up post-intervention recommended. See **Section 16.5 Additional surveillance and treatment**.

Table 16.2 Acceptable imaging protocols

	Non-Contrast	**Contrast**
IV contrast	No	Yes
Acceptable machines	Spiral CT or high performance MDCT capable of > 40 seconds	Spiral CT or high performance MDCT capable of > 40 seconds
Injection volume	n/a	150 cc
Injection rate	n/a	>2.5 cc/sec
Injection mode	n/a	Power
Bolus timing	n/a	Test bolus: SmartPrep, C.A.R.E.or equivalent

Coverage - start	Humeral Head	Humeral Head
Coverage - finish	Proximal femur	Proximal femur
Collimation	<3 mm	<3 mm
Reconstruction	2.5 mm throughout – soft algorithm	2.5 mm throughout – soft algorithm
Axial DFOV	32 cm	32 cm
Post-injection runs	None	None

Annual imaging follow-up should include abdominal radiographs and both contrast and non-contrast CT examinations. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs, non-contrast CT and duplex ultrasound may be used.

O The combination of contrast and non-contrast CT imaging provides information on aneurysm diameter change, endoleak, patency, tortuosity, progressive disease, fixation length and other morphological changes.

O The abdominal radiographs provide information on device integrity (separation between components and stent fracture).

O Duplex ultrasound imaging may provide information on aneurysm diameter change, endoleak, patency, tortuosity and progressive disease. In this circumstance, a non-contrast CT should be performed to use in conjunction with the ultrasound. Ultrasound may be a less reliable and sensitive diagnostic method compared to CT.

Table 16.1 lists the minimum imaging follow-up for patients with the Zenith Iliac Branch. Patients requiring enhanced follow-up should have interim evaluations.

16.2 CT recommendations

Image sets should include all sequential images at lowest possible slice thickness (≤3 mm). Do NOT perform large slice thickness (>3 mm) and/or omit consecutive CT images sets, as it prevents precise anatomical and device comparisons over time. When using a multiphase scan, the table positions must match.

Non-contrast and contrast enhanced baseline and follow-up imaging are important for optimal patient surveillance. It is important to follow acceptable imaging protocols during the CT exam. **Table 16.2** lists examples of acceptable imaging protocols.

16.3 Abdominal radiographs

The following views are required:

O Kidneys, Ureters, and Bladder (KUB) View

O Record the table-to-detector distance and use the same distance at each subsequent examination.

Ensure entire device is captured on each single image format lengthwise. If there is any concern about the device integrity (e.g., kinking, stent breaks, relative component migration), it is recommended to use magnified views. The attending physician should evaluate images for device integrity (entire device length including components) using 2-4X magnification visual aid.

16.4 Ultrasound

Ultrasound imaging may be performed in place of contrast CT when patient factors preclude the use of image contrast media (NOTE: Imaging is limited to the aortoiliac segment). Ultrasound may be paired with non- contrast CT. A complete aortoiliac duplex is to be recorded for maximum aneurysm diameter, endoleaks, stent patency and stenosis. Included on the recording should be the following information as outlined below:

O Transverse and longitudinal imaging should be obtained of the common internal and external iliac arteries to determine if endoleaks are present utilizing color flow and color power Doppler (if accessible).

O Spectral analysis confirmation should be performed for any suspected endoleaks.

O Transverse and longitudinal imaging of the maximum aneurysm dimension should be obtained.

16.5 Additional surveillance and treatment

Additional surveillance and possible treatment is recommended for:

O Aneurysms with Type I endoleak

O Aneurysms with Type III endoleak

O Aneurysm enlargement, ≥5 mm of maximum diameter (regardless of endoleak status)

O Migration

O Inadequate seal length

Consideration for reintervention or conversion to open repair should include the attending physician's assessment of an individual patient's co-morbidities, life expectancy and the patient's personal choices.

Patients should be counselled that subsequent re-interventions including catheter-based and open surgical conversion are possible following endograft placement.

17. DISPOSAL OF DEVICE

After the procedure, the delivery system of this device may be contaminated with potentially infectious substances of human origin and should be disposed of in accordance with institutional guidelines.

18. PATIENT COUNSELING INFORMATION

Please inform the patient as necessary of the relevant warnings, precautions, contraindications, measures to be taken and limitations of use that the patient should be aware of.

The physician must advise the patient to contact their healthcare provider if he/she experiences changes in their medical condition or in case of concern.

The physician must ensure that the patient has received the implant card and that the patient understands the purpose of the implant card.

Physicians must advise all patients that it is important to seek prompt medical attention if he/she experiences signs of limb occlusion, aneurysm enlargement or rupture.

The physician and patient (and/or family members) should review the risks and benefits when discussing this endovascular device and procedure including:

O Risks and differences between endovascular repair and surgical repair.

O Potential advantages of traditional open surgical repair.

O Potential advantages of endovascular repair.

O Potential advantages of alternative endovascular procedures.

O The possibility that subsequent interventional or open surgical repair of the aneurysm may be required after initial endovascular repair.

In addition to the risks and benefits of an endovascular repair, the physician should assess the patient's commitment and compliance to post-operative follow-up as necessary. Listed below are additional topics to discuss with the patient as to expectations after an endovascular repair:

O Patients should be counselled on the importance of adhering to the follow-up schedule both during the first year and at yearly intervals thereafter. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of abdominal aortic aneurysms (AAA). At a minimum, annual imaging and adherence to routine post-operative follow-up requirements is required and should be considered a life-long commitment to the patient's health and well-being.

O The long-term safety and effectiveness of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in **Section 16 Imaging guidelines and post-operative follow-up**.

19. SERIOUS INCIDENT REPORTING

Any adverse event (clinical incident) involving Zenith Iliac Branch should be reported to Cook immediately. To report an incident call the Customer Relations Department at 800-457-4500 (24 hours) or 812-339-2235.

Manufacturer

Date of manufacture

Use-by date

Batch code / Lot number

Catalogue number

Sterilized using ethylene oxide

Do not resterilize

Do not re-use / Single use only

Packaging unit

Do not use if package is damaged and consult instructions for use

Double sterile barrier system with protective packaging outside

Double sterile barrier system

Keep away from sunlight

Keep dry

Consult instructions for use or consult electronic instructions for use

Medical device

Rx only Prescription only

MR Conditional

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