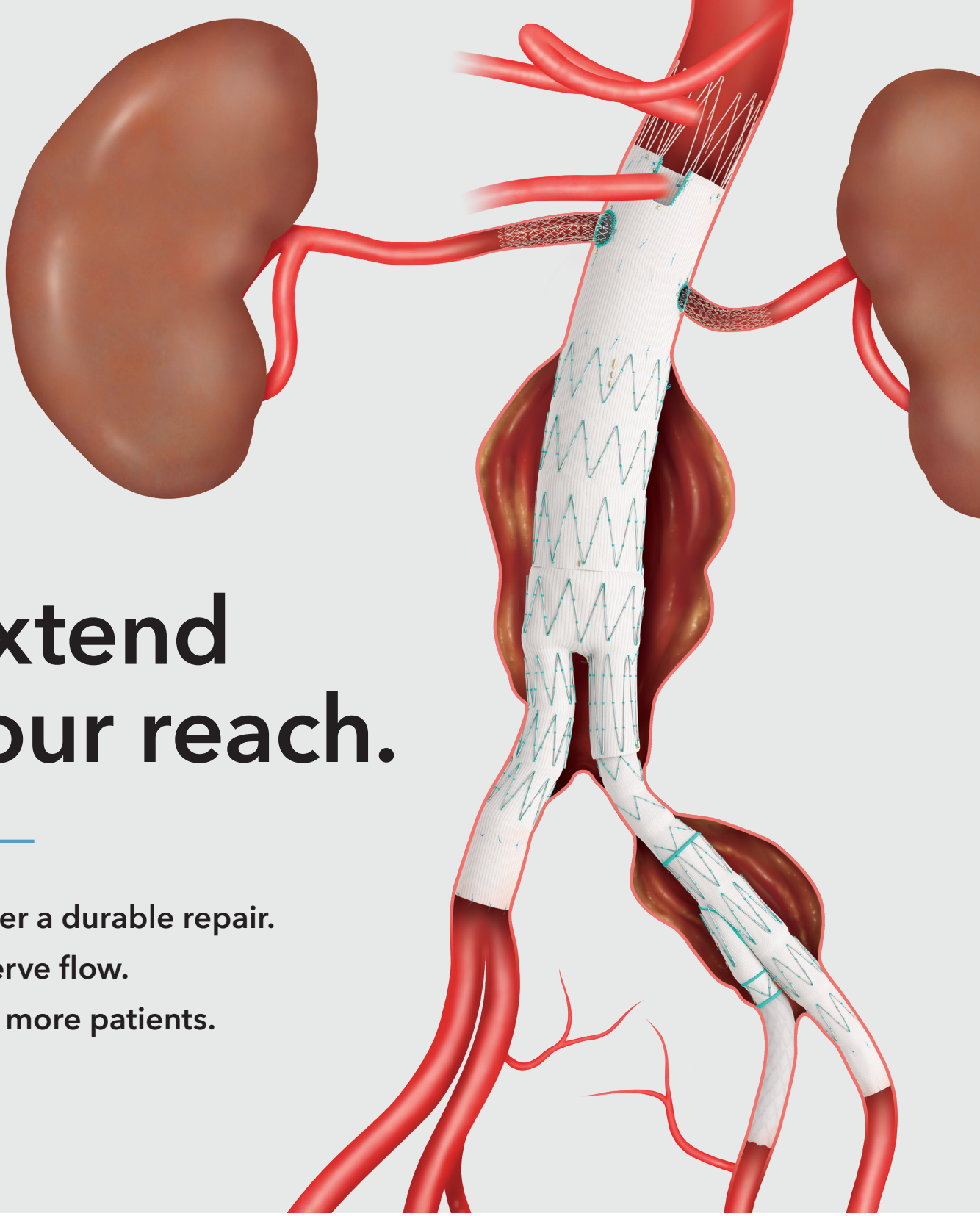


Extend your reach.

Deliver a durable repair.

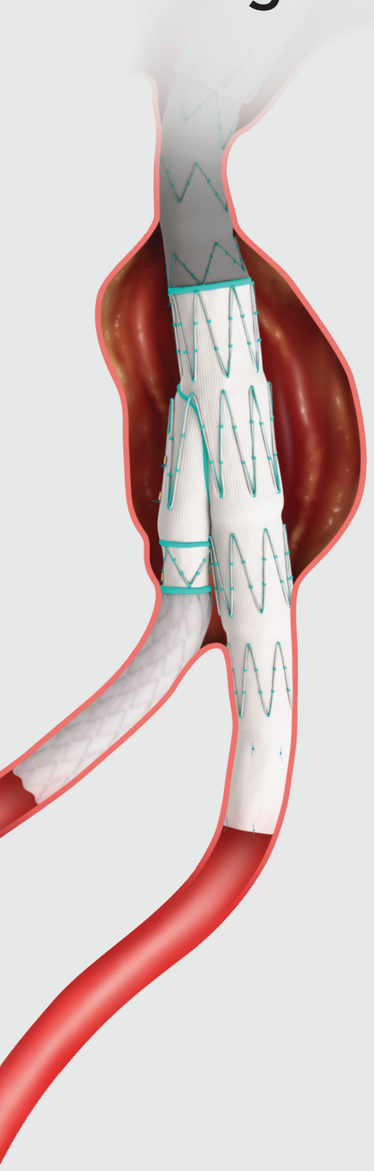
Preserve flow.

Treat more patients.

Zenith® Iliac Branch

COOK® MEDICAL

Designed to deliver a durable repair



PIVOTAL CLINICAL TRIAL DATA:
Primary safety and effectiveness endpoint

100%
6-month freedom from patency-related reintervention[1]

5-YEAR RESULTS:

100%
technical success[1]

4
number of patients requiring a secondary reintervention on ZBIS side[1]

0%
iliac artery aneurysm enlargement on ZBIS side[1]

97.3%
freedom from buttock claudication[1]

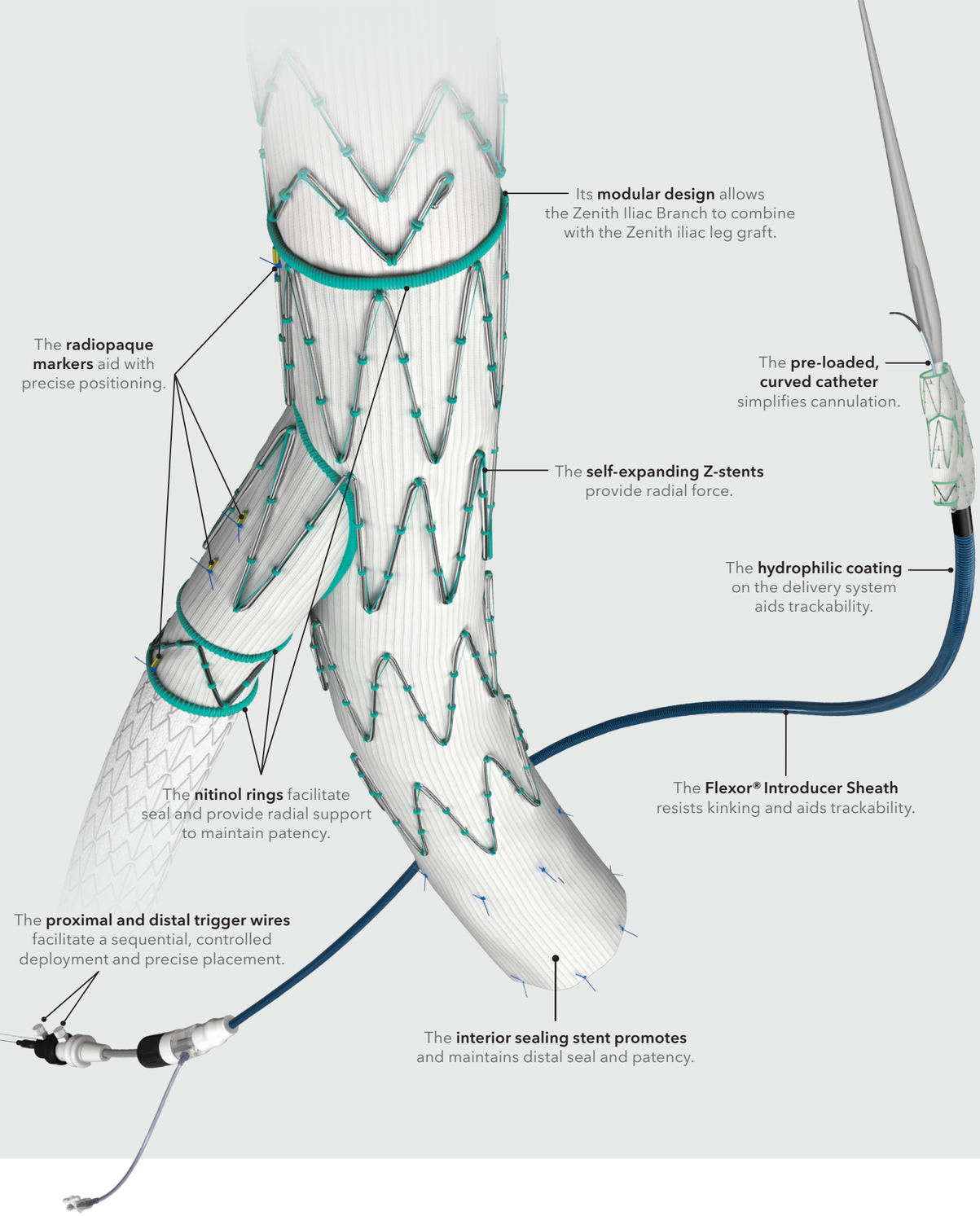
4
occlusions on ZBIS side[1]

0%
migration[1]

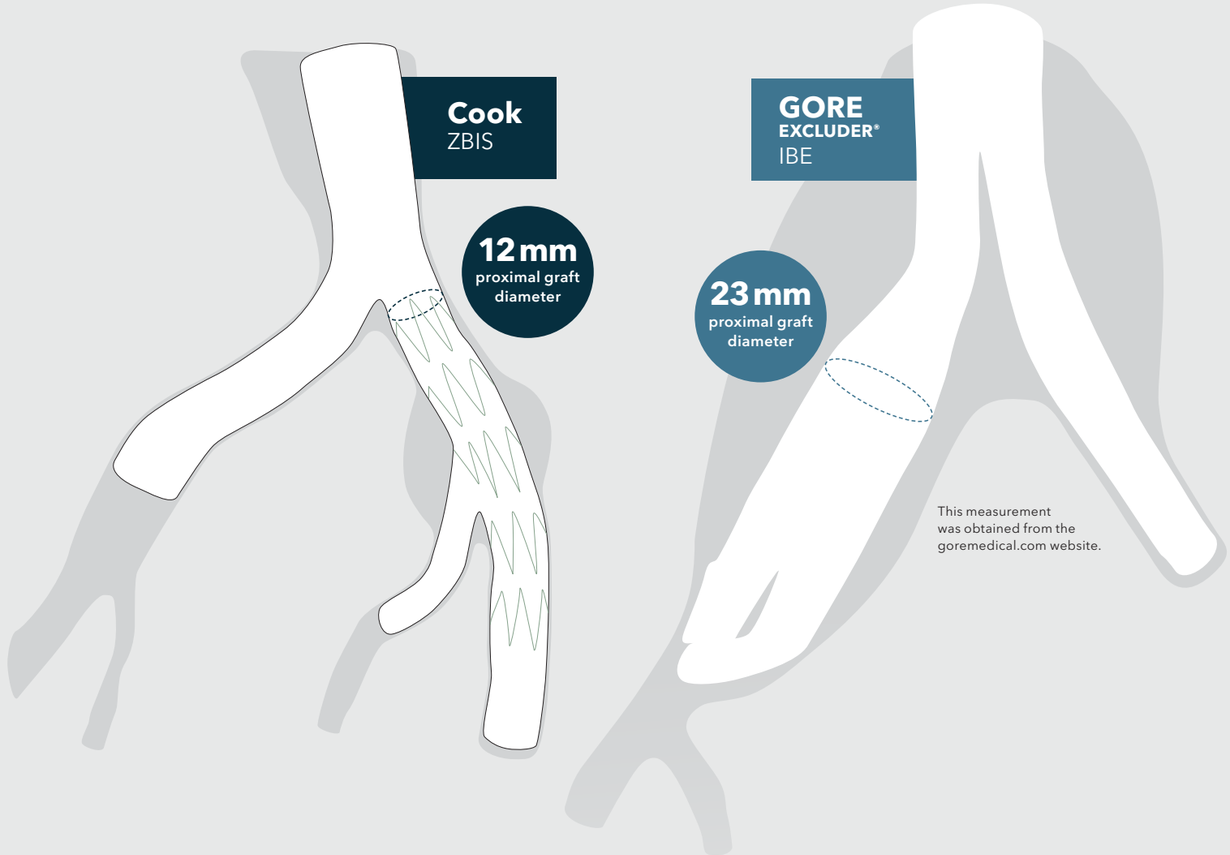
1. US Pivotal Clinical Trial Data PMA (P020018/S064)

A total of 40 patients were treated with ZBIS and the iCast covered stent between 01 April 2014 and 06 May 2015. Study patients were enrolled across 18 investigational sites in the United States.

Designed to preserve flow.



Designed to treat more patients.



This measurement was obtained from the goremedical.com website.

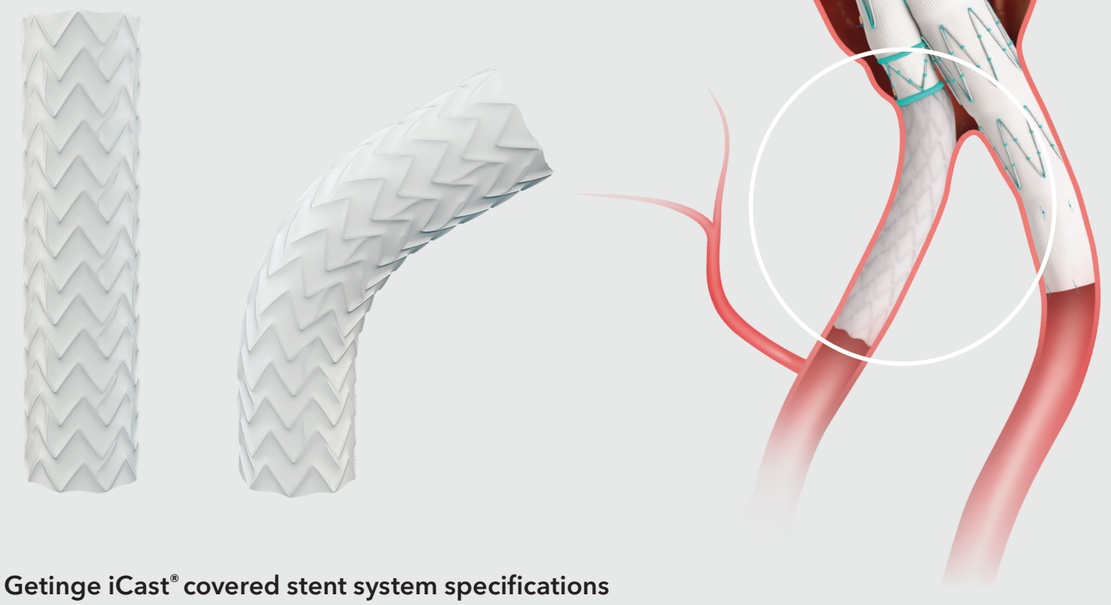
Zenith Iliac Branch Grafts

Order Number	Reference Part Number	Distal Body Diameter mm	Common Iliac Segment Length mm	External Iliac Segment Length mm	Introducer Sheath ID Fr
G60340	**ZBIS-10-45-41-US**	10	45	41	20
G60342	**ZBIS-10-61-41-US**	10	61	41	20
G60344	**ZBIS-12-45-41-US**	12	45	41	20
G60345	**ZBIS-12-61-41-US**	12	61	41	20
G60341	**ZBIS-10-45-58-US***	10	45	58	20
G60343	**ZBIS-10-61-58-US***	10	61	58	20
G60346	**ZBIS-12-45-58-US***	12	45	58	20
G60347	**ZBIS-12-61-58-US***	12	61	58	20

Nonstock

Procedural essentials

iCast covered stent system



Getinge iCast® covered stent system specifications

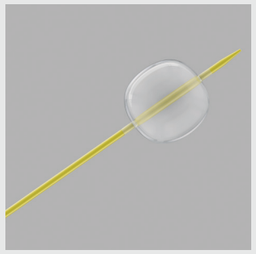
Cook Order Number	Cook RPN/ Getinge Iliac Code	Diameter (mm)	Length (mm)	Post Nominal Pressure 8 ATM mm		Post Burst Rate Pressure 12 ATM mm		Introducer Sheath Fr
				OD	Length	OD	Length	
iCast covered stent–80 cm Catheter Length								
G60492	**48838**	8	38	8.1	34.7	8.5	34.7	7
G60493	**48859**	8	59	8.0	56.0	8.4	56.5	7
G60494	**48938**	9	38	8.9	33.7	9.3	32.7	7
G60495	**48959**	9	59	8.9	54.6	9.3	54.0	7
G60513	**48038**	10	38	10.0	30.8	10.4	30.9	7*
iCast covered stent–120 cm Catheter Length								
G60509	**42838**	8	38	8.1	34.7	8.5	34.7	7
G60510	**42859**	8	59	8.0	56.0	8.4	56.5	7
G60511	**42938**	9	38	8.9	33.7	9.3	32.7	7
G60512	**42959**	9	59	8.9	54.6	9.3	54.0	7
G60513	**42038**	10	38	10.0	30.8	10.4	30.9	7*

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

Indy OTW® Vascular Retriever

The Indy OTW Vascular Retriever has a unique interconnected four-loop snare design with over-the-wire-capability, allowing you to target and contain a foreign body and withdraw to a peripheral vascular location.

Order Number	Reference Part Number	Sheath Outer Diameter Fr	Accepts Wire Guide Diameter inch	Sheath Length mm	Basket Diameter mm
G51835	INDY-8.0-35-55-40	8.0	0.035	55	40
G51836	INDY-8.0-35-100-40	8.0	0.035	100	40

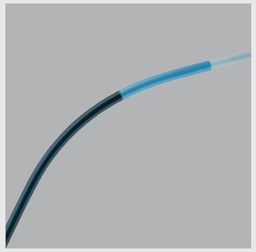


Coda® Balloon Catheter

The Coda and Coda LP Balloon Catheters are intended for temporary occlusion of large vessels or to expand vascular prostheses.

Order Number	Reference Part Number	Catheter Fr	Catheter Length cm	Recommended Introducer Fr	Accepts Wire Guide Diameter inch	Inflated Balloon Diameter mm	Max Inflated Balloon Volume mL
G03832	CODA-2-9.0-35-100-32	9.0	100	12	0.035	32	30
G03831	CODA-2-9.0-35-120-32	9.0	120	12	0.035	32	30
G23773	CODA-2-10.0-35-140-46*	10.0	140	14	0.035	46	60

*The Coda 46 mm balloon catheter should not be used for dilation of vascular prostheses in iliac or other non-aortic vessels. Injury to vessel wall and/or rupture may occur. The Coda 46 mm balloon catheter should not be used in vessels less than 24 mm in diameter.



Flexor® Check-Flo® Ansel Introducers

Flexor introducers and guiding sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neurovasculature.

Order Number	Reference Part Number	Fr	Length cm	Accepts Wire Guide Diameter inch	Tip Configuration
G47700	KCFW-10.0-35-45-RB-HFANL1-HC	10	45	0.035	Multipurpose
G47701	KCFW-12.0-35-45-RB-HFANL1-HC	12	45	0.035	Multipurpose

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).

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.

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.

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.

WARNINGS: 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** in the complete Instructions for Use. • 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** in the complete Instructions for Use. • 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. **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. **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) ≥16 mm – 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. **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. **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.

PRECAUTIONS: 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

POTENTIAL ADVERSE EVENTS: Adverse events that may occur and/or require intervention include: Allergic reaction and/or anaphylactoid response to x-ray contrast dye, antiplatelet 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)

See Instructions for Use for full product information.

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AI-ESC-IR-OHNS-PI-RH-SUR-A4

