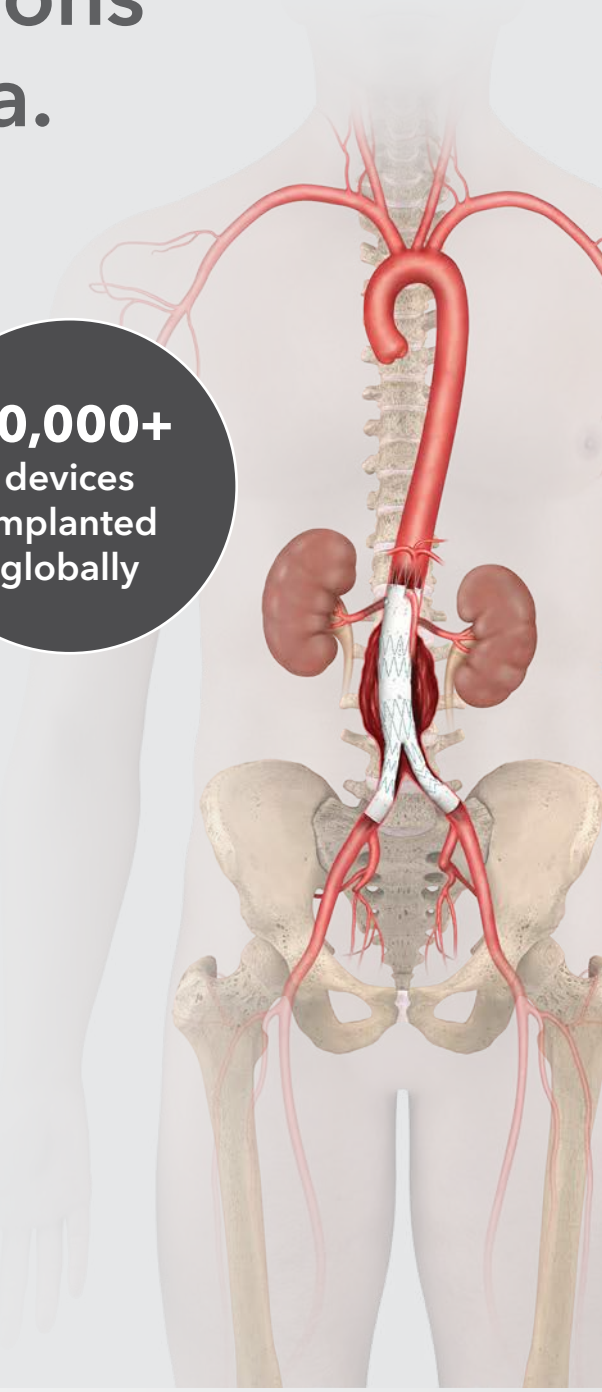
EXPECT DURABILITY

Disease-specific solutions backed by clinical data.

The Zenith portfolio of endovascular products and services are designed to treat more patients with a durable repair.

10,000+ devices implanted globally



At 5 year:

Clinical Update on Zenith® Fenestrated

- **97.3%** survival from aneurysm related mortality
- **0** ruptures or conversions to open repair
- **95.5%** freedom from major morbidity
- **95.5%** decrease (> 5 mm) or no change (< 5 mm) in aneurysm size

Source: Zenith Fenestrated 2016 clinical update. 88 patients were included in the U.S. clinical study.

Zenith® Fenestrated

AAA ENDOVASCULAR GRAFT

EXPECT MORE.

Read the full clinical update by visiting **cookmedical.com/5yrFen**

COOK® MEDICAL

ZENITH® FENESTRATED AAA ENDOVASCULAR GRAFT WITH THE H&L-B ONE-SHOT™ INTRODUCTION SYSTEM

CAUTION: U.S Federal law restricts this device to sale by or on the order of a physician.

INTENDED USE: The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is indicated for the endovascular treatment of patients with abdominal aortic or aorto-iliac aneurysms having morphology suitable for endovascular repair, including: • Adequate iliac/femoral access compatible with the required introduction systems • Non-aneurysmal infrarenal aortic segment (neck) proximal to the aneurysm: -with a length that is at least 4 mm and unsuitable for a non-fenestrated graft, -with a diameter measured outer wall to outer wall of no greater than 31 mm and no less than 19 mm, -with an angle less than 45 degrees relative to the long axis of the aneurysm, and -with an angle less than 45 degrees relative to the axis of the suprarenal aorta. • Ipsilateral iliac artery distal fixation site greater than 30 mm in length and 9-21 mm in diameter (measured outer wall to outer wall). • Contralateral Iliac artery distal fixation site greater than 30 mm in length and 7-21 mm in diameter (measured outer wall to outer wall).

CONTRAINDICATIONS: The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is contraindicated in the following: • Patients with known sensitivities or allergies to stainless steel, polyester, nitinol, solder (tin, silver), polypropylene or gold • Patients with systemic or local infection that may increase the risk of endovascular graft infection.

WARNINGS AND PRECAUTIONS:

General Use Information Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient. • Fenestrated grafts are made to a customized design to a specification requested by the responsible Physician, and are tailored to a specific patient's anatomy. • The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device, which requires precise planning/sizing as well as accurate longitudinal positioning and rotational orientation during placement. • 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. • Preprocedure imaging reconstruction thickness > 3 mm may result in sub-optimal device sizing, or in failure to appreciate focal stenosis from CT. • Implantation of the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System requires high quality imaging. Some types of mobile image intensifiers may not provide adequate imaging quality. • **The long-term performance of fenestrated endovascular grafts, including the stents placed in fenestrations/scallops, 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, changes in the structure or position of the endovascular graft, or stenosis/occlusion of vessels accommodated by fenestrations) should receive enhanced follow-up. Specific follow-up guidelines are described in **Section 12 in the complete INSTRUCTIONS FOR USE**. • After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth, patency of vessels accommodated by a fenestration/scallop, or changes in the structure or position of the endovascular graft. At a minimum, annual imaging is recommended, 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, perigraft flow, 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 Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System 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 12, 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/fenestration 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.

Patient Selection, Treatment and Follow-Up Inappropriate patient selection may result in poor performance of the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System. • 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 14 French to 22 French vascular introducer sheath. Iliac conduits may be used to ensure the safe insertion of the introduction system. 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/trauma. • Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (> 45 degrees for infrarenal neck to axis of AAA or > 45 degrees for suprarenal neck relative to the immediate infrarenal neck); short proximal aortic neck (<4 mm); greater than 10% increase in diameter over 15 mm of proximal aortic neck length; and circumferential thrombus and/or calcification at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. Irregular calcification and/or plaque may compromise the fixation and sealing of the implantation sites. Necks exhibiting these key anatomic elements may be more conducive to graft migration. • The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging. • The use of this device requires administration of radiographic agents. Patients with pre-existing renal insufficiency may have an increased risk of post-operative renal failure. • The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is not recommended in patients of excessive weight and/or size that would limit, compromise, or prevent the necessary imaging requirements. • Inability to maintain patency of at least one internal iliac artery or occlusion of an indispensable inferior mesenteric artery may increase the risk of pelvic/bowel ischemia. • Multiple large, patent lumbar arteries, mural thrombus and a patent inferior mesenteric artery may all predispose a patient to Type II endoleaks. Patients with uncorrectable coagulopathy may also have an increased risk of Type II endoleak or bleeding complications. • Patients with recurrent aortic aneurysmal disease or with disease above the renal arteries may be prone to further aortic dilation in the renal/visceral segment, which could compromise device integrity/fixation. • The Zenith Fenestrated AAA Endovascular Graft has not been evaluated in the following patient populations: -Less than 18 years of age -Females who are pregnant or breast-feeding -Leaking/ruptured or symptomatic aneurysms -Patients with connective tissue disorders -Patients with previous stent placement in vessels to be accommodated by fenestrations

Implant Procedure Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant 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 4X4 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 Fenestrated AAA Endovascular Graft. • 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 Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System 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 Fenestrated AAA Endovascular Graft within the vessel may result in increased risk of endoleak, migration or inadvertent occlusion of the renal or internal iliac arteries. Renal artery patency must be maintained to prevent/reduce the risk of renal failure and subsequent complications. It is recommended that all vessels accommodated by a small fenestration be stented in order to secure positive alignment of the graft fenestration with the vessel origin. • Inadequate fixation of the Zenith Fenestrated AAA Endovascular Graft may result in increased risk of migration of the stent graft. Incorrect deployment or migration of the endoprosthesis may require surgical intervention. • The Zenith Fenestrated AAA Endovascular Graft incorporates a suprarenal stent with fixation barbs. Exercise extreme caution when manipulating interventional devices in the region of the suprarenal stent. • 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. • Unless medically indicated, do not deploy the Zenith Fenestrated AAA Endovascular Graft in a location that will occlude arteries necessary to supply blood flow to organs or extremities. Do not cover significant renal or mesenteric arteries (exception is the inferior mesenteric artery) with the endoprosthesis. • Take care during manipulation of catheters, wires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus, which can cause distal embolization. • Care should be taken not to damage the graft or disturb graft positioning after graft placement in the event reinstrumentation of the graft is necessary.

Molding Balloon Use Prior to molding in the vicinity of any fenestration stent(s) confirm that the aortic section of the stent has been flared. • Confirm complete deflation of balloon prior to repositioning. • Do not inflate balloon in the vessel outside of graft, as doing so could result in damage to the vessel (e.g., rupture).

MRI Safety and Compatibility Non-clinical testing has demonstrated that the Zenith Fenestrated AAA Endovascular Graft is MR Conditional. A patient with this endovascular graft in place for at least 6 months can be scanned safely under the following conditions: • Static magnetic field of 3.0 Tesla or 1.5 Tesla • Maximum spatial magnetic gradient of 720 Gauss/cm or less • Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning or less (i.e., per scanning sequence) • Normal operating mode.

Static Magnetic Field The static magnetic field for comparison to the above limits is the static magnetic field pertinent to the patient (i.e., outside of scanner covering, accessible to a patient or individual).

ADVERSE EVENTS

Potential adverse events that may occur and/or require intervention include, but are not limited to: • 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 • 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; perigraft flow; barb separation and corrosion • Fever and localized inflammation • Fistula (e.g., aortoenteric, arteriovenous) • Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection) • Hepatic failure • Impotence • Infection of the aneurysm, device or access site, including abscess formation, transient fever and pain • Lymphatic complications and subsequent attendant problems (e.g., lymph fistula) • Neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis) • Occlusion of device or native vessel • Organ impairment/loss due to side-branch vessel occlusion (in particular, renal and/or gastrointestinal impairment/loss) • Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation) • Renal complications and subsequent attendant problems (e.g., artery stenosis or occlusion, contrast toxicity, infarct, insufficiency, failure) • Surgical conversion to open repair • Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection • Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death) • Vessel damage • Wound complications and subsequent attendant problems (e.g., dehiscence, infection, hematoma, seroma, cellulitis).

See instructions for use for full product information.

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