

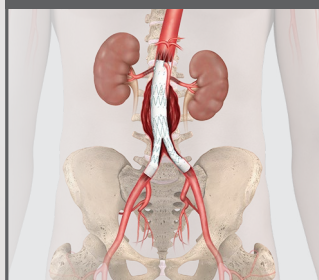
EXPECT DURABILITY

# Complete infrarenal solution. Designed to treat more patients with a durable repair.

Absence of sac regression after endovascular aneurysm repair may predict a lower long-term survival.

**Source:** O'Donnell TFX, Deery SE, Boitano LT, et al. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. *J Vasc Surg.* 2019;69(2):414-422.

## Zenith® Fenestrated



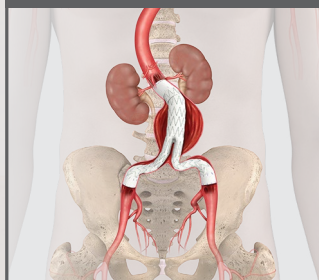
5  
years:

### Clinical update on Zenith Fenestrated

**94.7%** decrease ( $> 5$  mm) or no change ( $\leq 5$  mm) in aneurysm size  
**76.3%** sac shrinkage  
**18.4%** exhibited no change

**Source:** Zenith Fenestrated 2019 clinical update. 88 patients were included in the US clinical study.

## Zenith Flex®



At 5  
years:

### Clinical update on Zenith Flex

**91%** exhibited no aneurysm growth  
**72%** sac shrinkage ( $> 5$  mm)  
**19%** aneurysm size stabilized

**Source:** Zenith Flex 2012 clinical update. 351 patients were included in the US clinical study, including high risk, standard risk and roll-in patients combined. Zenith AAA Endovascular Graft Annual Clinical Update (2012).

At 14  
years:

**74.1%** freedom from aneurysm sac growth  
(Estimated)

**Source:** Verzini F, Romano L, Parlani G, et al. Fourteen-year outcomes of abdominal aortic endovascular repair with the Zenith stent graft. *J Vasc Surg.* 2017;65(2):318-329.

## Zenith® abdominal portfolio

EXPECT MORE.

Read the full clinical update by visiting  
[cookmedical.com](http://cookmedical.com).



**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.**

## ZENITH FLEX™ AAA ENDOVASCULAR GRAFT WITH THE Z-TRAK™ INTRODUCTION SYSTEM

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

**INDICATIONS FOR USE:** The Zenith Flex AAA Endovascular Graft with the Z-Trak Introduction System is indicated for the endovascular treatment of patients with abdominal aortic or aortoiliac 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 of at least 15 mm, -with a diameter measured outer wall to outer wall of no greater than 32 mm and no less than 18 mm, -with an angle less than 60 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. • Iliac artery distal fixation site greater than 10 mm in length and 7.5-20 mm in diameter (measured outer wall to outer wall).

**CONTRAINDICATIONS:** The Zenith Flex AAA Endovascular Graft with the Z-Trak Introduction System is contraindicated in: • Patients with known sensitivities or allergies to stainless steel, polyester, solder (tin, silver), polypropylene, or gold. • Patients with a systemic infection who may be at increased risk of endovascular graft infection.

### WARNINGS AND PRECAUTIONS:

**General** Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient. • Always have a qualified surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary. • The Zenith Flex AAA Endovascular Graft with the Z-Trak Introduction Systems should only be used by physicians and teams trained in vascular interventional techniques (catheter-based and surgical) and in the use of these devices. Specific training expectations are described in **Section 10.1, Physician Training in the complete INSTRUCTIONS FOR USE**. • Additional endovascular interventions or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing an enlarging aneurysm, unacceptable decrease in fixation length (vessel and component overlap) and/or endoleak. An increase in aneurysm size and/or persistent endoleak or migration 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.

**Patient Selection, Treatment and Follow-Up** The Zenith Flex AAA Endovascular Graft is designed to treat aortic neck diameters no smaller than 18 mm and no larger than 32 mm. The Zenith Flex AAA Endovascular Graft is designed to treat proximal aortic necks (distal to the lowest renal artery) of at least 15 mm in length. Iliac artery distal fixation site greater than 10 mm in length and 7.5 - 20 mm in diameter (measured outer wall to outer wall) is required. These sizing measurements are critical to the performance of the endovascular repair. • Key anatomical elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (>60 degrees for infrarenal neck to axis of AAA or >45 degrees for suprarenal neck relative to the immediate infrarenal neck); short proximal aortic neck (<15 mm); an inverted funnel shape (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. In the presence of anatomical limitations, a longer neck may be required to obtain adequate sealing and fixation. Irregular calcification and/or plaque may compromise the attachment and sealing at the fixation sites. Necks exhibiting these key anatomical elements may be more conducive to graft migration or endoleak. • Adequate iliac or femoral access is required to introduce the device into the vasculature. 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 a 16 French to 22 French 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. A vascular conduit technique may be necessary to achieve success in some patients. • The Zenith Flex AAA Endovascular Graft with the Z-Trak Introduction System is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and postoperative follow-up imaging. All patients should be monitored closely and checked periodically for a change in the condition of their disease and the integrity of the endoprosthesis. • The Zenith Flex AAA Endovascular Graft with the Z-Trak Introduction System is not recommended in patients exceeding weight and/or size limits which 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. • The safety and effectiveness of the Zenith Flex AAA Endovascular Graft with the Z-Trak Introduction System has not been evaluated in the following patient populations: traumatic aortic injury -leaking, pending rupture or ruptured aneurysms -mycotic aneurysms -pseudoaneurysms resulting from previous graft placement -revision of previously placed endovascular grafts -uncorrectable coagulopathy -indispensable mesenteric artery -genetic connective tissue disease (e.g., Marfans or Ehlers-Danlos Syndromes) -concomitant thoracic aortic or thoracoabdominal aneurysms -active systemic infections -pregnant or nursing females -morbidly obese patients -less than 18 years of age -patients with less than 15 mm in length or greater than 60 degrees angulation of the proximal aortic neck relative to the long axis of the aneurysm. • Successful patient selection requires specific imaging and accurate measurements; please see **Pre-Procedure Measurement Techniques and Imaging**. • All lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when preoperative case planning measurements (treatment diameters/lengths) are not certain. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes.

**Pre-Procedure Measurement Techniques and Imaging** 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 thicknesses >3 mm may result in sub-optimal device sizing, or in failure to appreciate focal stenoses from CT. • Clinical experience indicates that contrast-enhanced spiral computed tomographic angiography (CTA) with 3-D reconstruction is the strongly recommended imaging modality to accurately assess patient anatomy prior to treatment with the Zenith Flex AAA Endovascular Graft. If contrast-enhanced spiral CTA with 3-D reconstruction is not available, the patient should be referred to a facility with these capabilities. • Clinicians recommend positioning the x-ray C-arm during procedural angiography such that the origins of the renal arteries, and particularly the lowest patent renal artery, are well demonstrated prior to deployment of the proximal edge of the graft material (sealing stent) of the main body. Additionally, angiography should demonstrate the iliac artery bifurcations such that the distal common iliacs are well defined relative to the origin of the internal iliac arteries bilaterally, prior to deployment of the iliac leg components.

**Diameters** Utilizing CT, diameter measurements should be determined from the outer wall to outer wall vessel diameter (not lumen measurement) to help with proper device sizing and device selection. The contrast-enhanced spiral CT scan must start 1 cm superior to the celiac axis and continue through the femoral heads at an axial thickness slice of 3 mm or less.

**Lengths** Utilizing CT, length measurements should be determined to accurately assess infrarenal proximal neck length as well as planning main body sizes and leg components for the Zenith Flex AAA Endovascular Graft. These reconstructions should be performed in sagittal, coronal, and 3-D. • **The long-term performance 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 aneurysm or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in **Section 12, IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP in the complete INSTRUCTIONS FOR USE**. • The Zenith Flex AAA Endovascular Graft with the Z-Trak Introduction System is not recommended in patients unable to undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation studies as described in **Section 12, IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP in the complete INSTRUCTIONS FOR USE**. • After endovascular graft placement, patients should be regularly monitored for perigraft flow, 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, 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.

**Device Selection** Strict adherence to the Zenith Flex AAA Endovascular Graft IFU sizing guide is strongly recommended when selecting the appropriate device size (**Tables 10.5.1 through 10.5.2 in the complete INSTRUCTIONS FOR USE**). Appropriate device oversizing has been incorporated into the IFU sizing guide. Sizing outside of this range can result in endoleak, fracture, migration, device infolding or compression.

**Implant Procedure** (Refer to **Section 11, DIRECTIONS FOR USE in the complete INSTRUCTIONS FOR USE**) Appropriate procedural imaging is required to successfully position the Zenith Flex AAA Endovascular Graft and assure accurate apposition to the aortic wall. • Do not bend or kink the delivery system. Doing so may cause damage to the delivery system and the Zenith Flex AAA Endovascular Graft. • 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). • 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, catheter or graft damage may occur. Exercise particular care in areas of stenosis, intravascular thrombosis or in calcified or tortuous vessels. • Inadvertent partial deployment or migration of the endoprosthesis may require surgical removal. • Unless medically indicated, do not deploy the Zenith Flex 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. Vessel occlusion may occur. During the clinical study, this device was not studied in patients with two occluded internal iliac arteries. • Do not attempt to re-sheath the graft after partial or complete deployment. • Repositioning the stent graft distally after partial deployment of the covered proximal stent may result in damage to the stent graft and/or vessel injury. • Inaccurate placement and/or incomplete sealing of the Zenith Flex 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. • Inadequate fixation of the Zenith Flex 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. • 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. • To activate the hydrophilic coating on the outside of the Flexor introducer sheath, the surface must be wiped with sterile gauze pads soaked in saline solution. Always keep the sheath hydrated for optimal performance. • Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection. • Maintain wire guide position during delivery system insertion. • 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 Flex AAA Endovascular Graft with the Z-Trak Introduction Systems requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure postoperatively. Care should be taken to limit the amount of contrast media used during the procedure and to observe preventative methods of treatment to decrease renal compromise (e.g., adequate hydration). • As the sheath and/or wire guide is withdrawn, anatomy and graft position may change. Constantly monitor graft position and perform angiography to check position as necessary. • The Zenith Flex AAA Endovascular Graft incorporates a suprarenal stent with fixation barbs. Exercise extreme caution when manipulating interventional and angiographic devices in the region of the suprarenal stent. • Use caution during manipulation of catheters, wires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus, which can cause distal embolization or rupture of the aneurysm. • Avoid damaging the graft or disturbing graft positioning after placement in the event reintervention (secondary intervention) of the graft is necessary. • Before deployment of the suprarenal stent, verify that the position of the access wire guide extends just distal to the aortic arch. • Verify that the predetermined contralateral iliac leg is selected for insertion on the contralateral side of the patient before implantation.

**Molding Balloon Use** Do not inflate the balloon in vessel outside of the graft, as doing so may cause damage to the vessel. Use the balloon in accordance with its labeling. • Use care in inflating the balloon within the graft in the presence of calcification, as excessive inflation may cause damage to the vessel. • Confirm complete deflation of the balloon prior to repositioning. • For added hemostasis, the Captor Hemostatic Valve can be loosened or tightened to accommodate the insertion and subsequent withdrawal of a molding balloon.

**MRI Information** Non-clinical testing has demonstrated that the Zenith AAA Endovascular Graft is MR Conditional. A patient with this endovascular graft can be scanned safely immediately after placement under the following conditions:

**Static Magnetic Field** Static magnetic field of 3.0 Tesla or less. • Highest spatial magnetic gradient field of 720 Gauss/cm.

**POTENTIAL ADVERSE EVENTS:** 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 • 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; perigraft flow; 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) • Neurologic local or systemic complications and subsequent attendant problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, paralysis) • 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.**