Predictable outcomes

zero stent fractures

minimal endoleaks

sac regression

minimal reinterventions

zero ruptures

At **5** years:

Clinical update on Zenith Flex

91% exhibited no aneurysm growth.

72% experienced sac shrinkage (> 5 mm).

In **19%**, the aneurysm's 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% (estimated) had freedom from aneurysm sac growth.

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.

Minor device design changes were implemented in 2004. Data shown reflects both device iterations. For more information on those changes, consult FDA PMA# P020018.

Zenith Flex®

AAA ENDOVASCULAR GRAFT

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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 reinstrumentation (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.

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