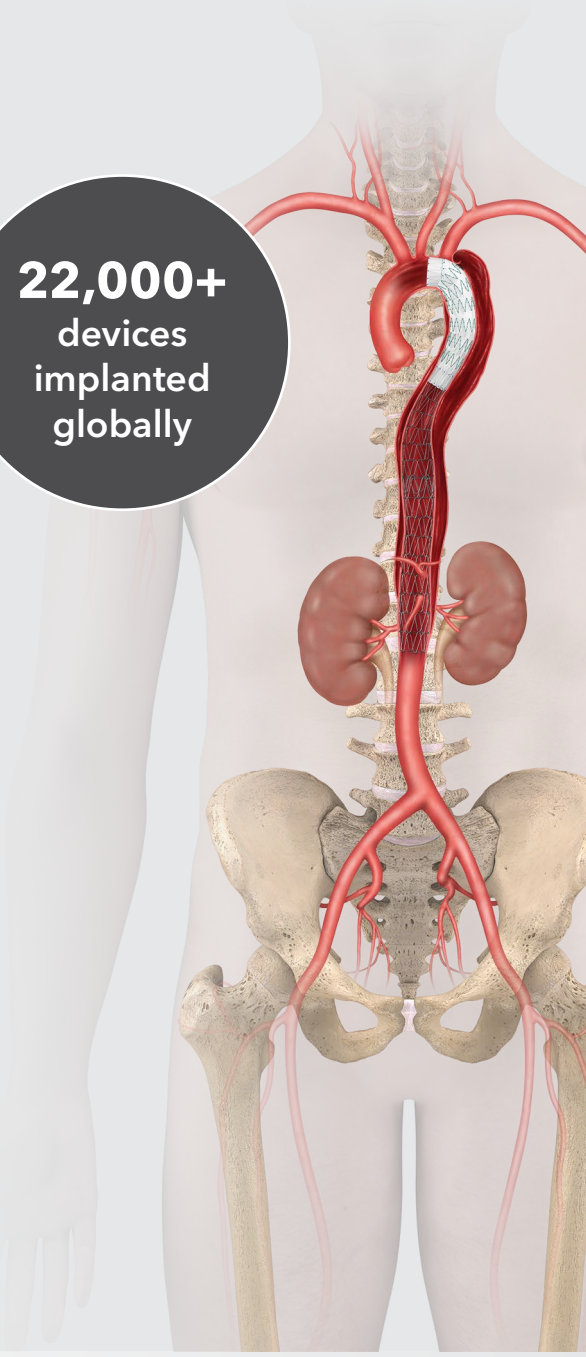
EXPECT DURABILITY

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.

22,000+ devices implanted globally



5 years: Clinical update on Zenith® Dissection

- 2.7% paraplegia*
- 100% complete/partial thrombosis of the false lumen in dissection stent region**
- 100% complete/partial thrombosis of the false lumen in stent-graft region**
- 4.5% stroke rate***

Source: Summary of Clinical Data for IFU 441-02EN (Zenith Dissection Endovascular System). 73 patients were included in the Global Clinical Study.

*through 5 years, **at 5 years, ***after 30 days; all instances of stroke after 30 days were unrelated to the procedure

1 year: Clinical update on Zenith® Dissection†

- 0% paraplegia
- 97.4% complete/partial thrombosis of the false lumen in dissection stent region
- 100% complete/partial thrombosis of the false lumen in stent-graft region
- 1.7% stroke rate

Source: Summary of Clinical Data for IFU 441-01EN (Zenith Dissection Endovascular System). 73 patients were included in the Global Clinical Study.

†at 1 year

Zenith® Dissection

ENDOVASCULAR SYSTEM

EXPECT MORE.

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

COOK® MEDICAL

Zenith® Dissection Endovascular System (Zenith® TX2® Dissection Endovascular Graft with Pro-Form® and Zenith® Dissection Endovascular Stent)

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 Dissection Endovascular System (Zenith TX2 Dissection Endovascular Graft with Pro-Form and Zenith Dissection Endovascular Stent) is indicated for the endovascular treatment of patients with Type B aortic dissection. The Zenith TX2 Dissection Endovascular Graft with Pro-Form is intended to seal the entry tears and to exclude aneurysms associated with chronic dissections. The Zenith Dissection Endovascular Stent is intended to be used as a distal component to provide support to delaminated segments of non-aneurysmal aorta with dissection distal to a Zenith TX2 Dissection Endovascular Graft with Pro-Form. The system is indicated for use in patients having vascular anatomy suitable for endovascular repair, (**Fig. 6** in the complete Instructions for Use) including: • Adequate iliac/femoral access compatible with the required introduction systems • For the Zenith TX2 Dissection Endovascular Graft with Pro-Form: – Non-dissected/aneurysmal aortic segments (fixation sites) distal to the left common carotid artery and proximal to the entry tear with a length of at least 20 mm, – Non-dissected/aneurysmal aortic segments (fixation sites) distal to the left common carotid artery and proximal to the entry tear with a diameter (measured outer-wall-to-outer-wall) of no greater than 38 mm and no less than 20 mm, and • For the Zenith Dissection Endovascular Stent: – Diameter at non-aneurysmal intended implant site (measured outer-wall-to-outer-wall) of no greater than 38 mm (true lumen) and no less than 20 mm (total aortic diameter).

CONTRAINDICATIONS: The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent are contraindicated in: • Patients with known sensitivities or allergies to stainless steel, polyester, polypropylene, nitinol or gold. • Patients with a systemic infection who may be at increased risk of endovascular graft/stent 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. • DO NOT place the device in a dissected proximal landing zone. Placement of the device has resulted in proximal post-treatment dissection events (retrograde progression of pre-existing or new Type A dissection) when the dissection extends proximal to the LSA or the proximal landing zone is dissected. • 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 TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent should only be used by physicians and teams trained in vascular interventional techniques (catheter-based and surgical) and in the use of this device. Specific training expectations are described in **Section 10.1, Physician Training,** in the complete Instructions for Use. • Additional/adjunctive endovascular and/or surgical interventions may be required to treat Type B dissections, including conversion to standard open surgical repair following initial endovascular repair should patients experience continued flow in the false lumen of the dissection which may lead to rupture. Further intervention should be considered for patients exhibiting compromise of organ vessel flow, or inadequate seal/fixation length proximal to the dissection. **Patient Selection, Treatment and Follow-Up:** • Access vessel diameter (measured inner-wall to inner-wall) and morphology (tortuosity, occlusive disease, and/or calcification) should be compatible with vascular access techniques and introduction systems of the profile of a 20 French (7.7 mm OD) or 22 French (8.5 mm OD) vascular introducer sheath as is used for the Zenith Dissection Endovascular Graft, compared to 16 French (6.0 mm OD) for the Zenith Dissection Endovascular Stent. Vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude femoral introduction of the endovascular graft and/or may increase the risk of embolization. • **The Zenith TX2 Dissection Endovascular Graft with Pro-Form:** Key anatomic elements that may affect successful exclusion of the dissection entry tear include severe angulation (radius of curvature <35 mm and localized angulation >45 degrees); short proximal fixation site (<20 mm of non-dissected aorta); necks >38 mm or <20 mm; an inverted funnel shape at the proximal fixation site (greater than 10% increase in diameter over 20 mm of fixation site length); and circumferential thrombus and/or calcification at the arterial fixation sites. Irregular calcification and/or plaque may compromise the attachment and sealing at the fixation site. Necks exhibiting these key anatomic elements may be more conducive to graft migration and or loss of seal. • **The Zenith Dissection Endovascular Stent:** Key anatomic elements that may affect successful treatment of dissection include severe angulation (radius of curvature <35 mm and localized angulation >45 degrees) and aortic true lumen diameters >38 mm or total aortic (true lumen plus false lumen) diameter <20 mm. • The safety and effectiveness of the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent have not been evaluated in the following patient populations: – chronic Type B dissections – acute, uncomplicated Type B dissection – allergy to stainless steel, nitinol, polyester, polypropylene, or gold – bowel necrosis – ASA class V – diagnosed or suspected genetic connective tissue disease (e.g., Marfans or Ehlers-Danlos Syndrome) – females who are pregnant, breastfeeding, or planning to become pregnant within 60 months – patients less than 18 years of age – systemic infection (e.g., sepsis) – previous placement of thoracic endovascular graft – prior open repair involving descending thoracic aorta (including suprarenal aorta and/or arch) – surgical or endovascular AAA repair within 30 days before or after dissection repair – bleeding diathesis, uncorrectable coagulopathy, or refuses blood transfusion – hemorrhagic stroke within 30 days (or 14 days for embolic stroke) – untreatable reaction to contrast, which cannot be adequately premedicated – inability to preserve the native left common carotid artery and celiac artery origins – if occlusion of the left subclavian artery ostium is required to obtain adequate neck length for fixation and sealing, transposition or bypass of the left subclavian artery may be warranted. • The long-term performance of the endovascular graft and stent 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 and/or stent. Patients with specific clinical findings (e.g., persisting flow in the false lumen, enlarging aneurysms, or changes in the structure or position of the endovascular graft and or stent) 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 graft and stent are not recommended in patients unable to undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation studies described in **Section 12, IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP,** in the complete Instructions for Use. • The graft and stent are not recommended for patients whose weight or size would compromise or prevent the necessary imaging requirements. • Graft implantation may increase the risk of paraplegia where graft exclusion covers the origins of dominant spinal cord or intercostal arteries. • Highly patent intercostal aortic branches or large collateral vessels are likely to result in retrograde flow after thoracic graft implantation. Patients with uncorrectable coagulopathy may also have an increased risk of Type II endoleak or bleeding complications. **Implant Procedure: The following apply to both the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent:** • Strict adherence to the sizing guidelines provided in Sections 10.4 and 10.5 in the complete Instructions for Use is strongly recommended in order to mitigate the risk for events that could result from selecting inappropriate device sizes. Undersizing has resulted in migration, endoleak/entry-flow and false lumen growth. • **Table 1** in the complete Instructions for Use incorporates appropriate graft oversizing. Sizing outside of the recommendations provided in **Table 1** in the complete Instructions for Use, including that which could result from a difference in location of graft deployment relative to the location used for graft sizing, has resulted in false lumen expansion, endoleak/entry-flow, and migration. Fracture, device infolding, thrombosis, or compression may also result. • 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 used. • 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 sheath, the surface must be wiped with sterile gauze pads soaked in saline solution. Always keep the sheath hydrated for optimal performance. • Maintain wire guide position during introduction system insertion. • Do not bend or kink the introduction system. Doing so may cause damage to the introduction system and the graft/stent. • Always use fluoroscopy for guidance, delivery, and observation of the graft/stent within the vasculature. • The use of the graft/stent 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. • To avoid twisting the endovascular graft and/or stent, never rotate the introduction system during the procedure. Allow the device to conform naturally to the curves and tortuosity of the aorta. • As the sheath is withdrawn, anatomy and graft/stent position may change. Constantly monitor graft position and perform angiography to check position as necessary. • Incorrect deployment or migration of the graft and/or stent may require surgical intervention. • Do not continue advancing the wire guide or any portion of the introduction system if resistance is felt. Stop and assess the cause of resistance; vessel, catheter, or graft damage may occur. Exercise particular care in areas of stenosis, intravascular thrombosis, or calcified or tortuous vessels. • Use caution during manipulation of catheters, wires and sheaths within a dissection. Significant disturbances may dislodge fragments of thrombus, which can cause distal or cerebral embolization. • Avoid damaging the graft and/or stent or disturbing graft/stent positioning after placement in the event reinstrumentation (secondary intervention) of the graft/stent is necessary. • Do not attempt to re-sheath the graft or stent after partial or complete deployment. • To avoid entangling any catheters left in situ, rotate the introduction system during withdrawal. • Any sources for false lumen perfusion left untreated during the implantation procedure should be carefully followed after implantation. **The following apply to the Zenith TX2 Dissection Endovascular Graft with Pro-Form:** • Landing the proximal end of the device in dissected tissue could increase the risk of damage to the septum and could lead to new septal tears, aortic rupture, retrograde dissection, or other complications. • Inaccurate placement, incomplete sealing, inadequate oversizing, or lack of complete circumferential wall contact along the entire length of the Zenith TX2 Dissection Endovascular Graft with Pro-Form within the vessel may result in increased risk of endoleak, migration, or inadvertent occlusion of the left subclavian, left common carotid, and/or celiac arteries. • Consider the potential effects of hypovolemia on aortic diameters when selecting the device size. • If placing multiple grafts, ensure a minimum of 2 stent overlap. • Unless medically indicated, do not deploy the Zenith TX2 Dissection Endovascular Graft with Pro-Form in a location that will occlude arteries necessary to supply blood flow to organs or extremities. Do not cover significant arch or mesenteric arteries (exception may be the left subclavian artery) with the endoprosthesis. Vessel occlusion may occur. If a left subclavian artery is to be covered with the device, the clinician should be aware of the possibility of compromise to cerebral and upper limb circulation. • 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. • Molding balloon use is optional, and if used, it should not be inflated in the aorta outside of the graft. Additionally, complete deflation of the balloon should be confirmed 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. **The following apply to the Zenith Dissection Endovascular Stent:** • Use of the Zenith Dissection Endovascular Stent in an aneurysmal segment of a chronic dissection is not recommended. • As the sheath is withdrawn, do not advance the introduction system. Doing so can cause the stent to become inverted. • As the sheath is withdrawn, stabilize the gray positioner (introduction system shaft). Doing so may prevent elongation of the stent. • Overlapping of bare stent(s) or overlap with the Zenith TX2 Dissection Endovascular Graft with Pro-Form Straight Component or Tapered Component is left to the discretion of the implanting physician. Factors affecting whether or not to overlap, such as locations of reentries or expanded false lumen, should be judged by individual patient anatomy. When overlapping the bare stent within the stent graft component, no more than one-half of a partially overlapped bare stent body should be non-overlapped, so as to prevent flaring of the bare stent. • If the distal end of the stent will be deployed in a funnel-shaped or angulated section of the aorta, or if the distal end of the stent appears conical in shape upon deployment, it is recommended to extend the treated segment distally with an additional stent, or choose a longer stent so it ends in a straight part of the aorta. Similarly, if the distal end of the stent will be deployed at the level of the diaphragm, or in a segment adjacent to the origin of the Celiac Trunk, Superior Mesenteric Artery and/or Renal Arteries, it is also recommended to extend the treated segment distally with an additional stent or choose a longer stent. • Use of a molding balloon inside a section of aorta treated with the Zenith Dissection Endovascular Stent is not recommended. • Avoid twisting or rotating the gray positioner against the introducer sheath assembly. Doing so may cause the loaded stent to become entangled and to deploy in a twisted state, or not to release from the introduction system. • Exercise caution when manipulating a wire guide through an in-situ Zenith Dissection Endovascular Stent; the wire guide may become entangled with the stent. **MRI INFORMATION:** Nonclinical testing has demonstrated that the Zenith TX2 Dissection Endovascular Graft with Pro-Form overlapped with the nitinol Zenith Dissection Endovascular Stent is MR Conditional according to ASTM F2503. A patient with these devices can be scanned safely in a 1.5 T or 3.0 T MR system using the specific testing parameters described in **Section 12.4, MRI Information,** in the complete Instructions for Use.

POTENTIAL ADVERSE EVENTS: Adverse events that may occur and/or require intervention include, but are not limited to: • Amputation • Anesthetic complications and subsequent problems (e.g., aspiration) • Aortic enlargement • Aortic rupture and death • Aortic damage, including perforation, dissection, bleeding, and rupture • Arterial or venous thrombosis and/or pseudoaneurysm • Bleeding, hematoma, or coagulopathy • Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis) • Cardiac complications and subsequent problems (e.g., arrhythmia, tamponade, myocardial infarction, congestive heart failure, hypotension, hypertension) • Claudication (e.g., buttock, lower limb) • Death • Dissection extension (i.e., either proximal or distal extension) • Edema • Embolization (micro and macro) with transient or permanent ischemia or infarction • Endoleak • Endoprosthesis: improper component placement; incomplete component deployment; poor conformability of the graft to the vessel wall; component migration and/or separation; suture break; occlusion; infection; stent fracture; graft material wear; dilatation; erosion; puncture and perigraft flow • Fever and localized inflammation • Fistula (e.g., aortobronchial, aortoesophageal, arteriovenous) • Genitourinary complications and subsequent problems (e.g., ischemia, erosion, fistula, urinary incontinence, hematuria, infection) • Hepatic failure • Impotence • Infection of the dissection, device or access site, including abscess formation, transient fever and pain • Local or systemic neurologic complications and subsequent problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, spinal cord shock, paralysis) • Lymphatic complications and subsequent problems (e.g., lymph fistula, lymphocele) • Occlusion of device or native vessel • Persisting flow in the false lumen • Pulmonary/respiratory complications and subsequent problems (e.g., pneumonia, respiratory failure, prolonged intubation) • Renal complications and subsequent problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure) • Surgical conversion to open repair • Unintentional dissection septum rupture • Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula • Vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture, death) • Wound complications and subsequent problems (e.g., dehiscence, infection)

See Instructions for Use for full product information.