COOK® MEDICAL

Zenith Alpha™ Thoracic Endovascular Graft

Instructions for Use

Patient I.D. Card Included

I-ALPHA-THORACIC-442-03

442-03

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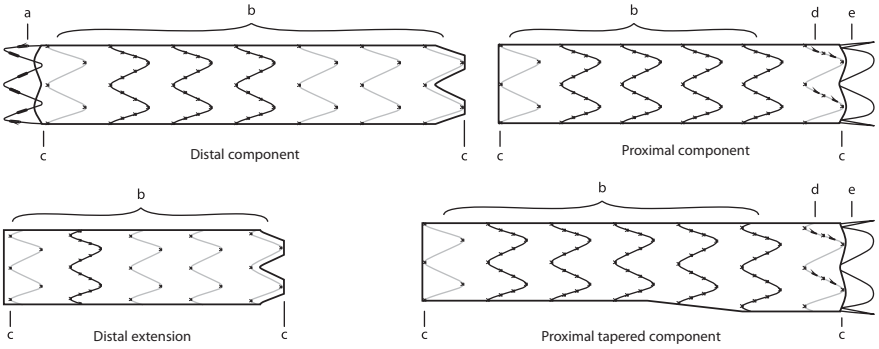
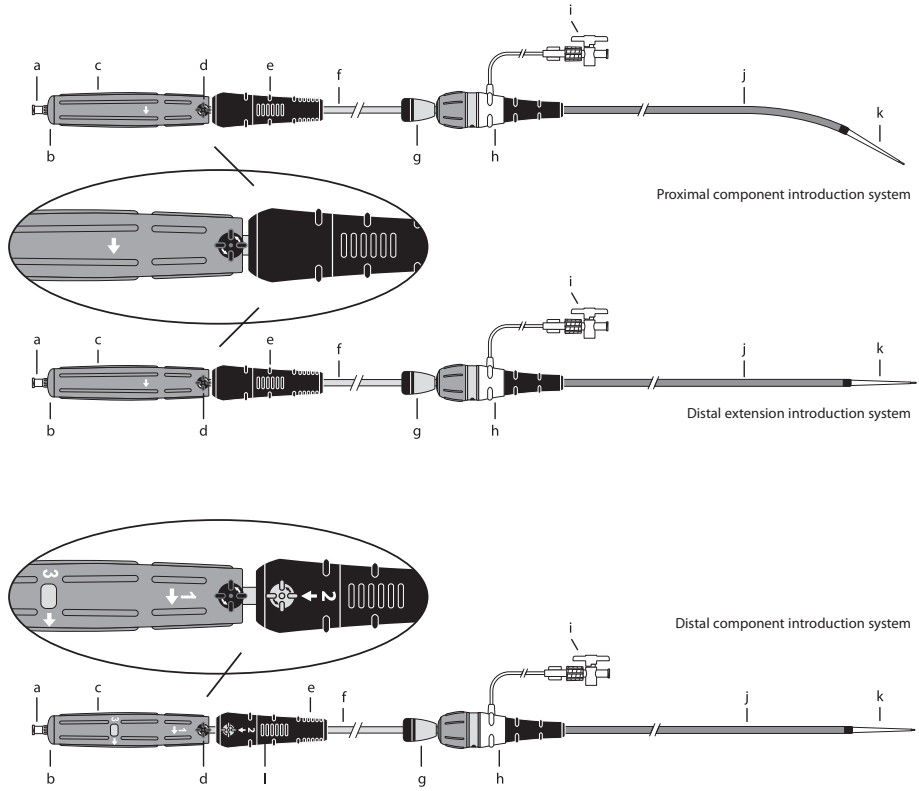


1

Stent Graft Components

a. Distal bare stent with barbs
b. Body stent (internal or external)
c. Gold radiopaque markers (located near stent apices on proximal and distal edges of graft)
d. Proximal sealing stent with barbs
e. Bare alignment stent



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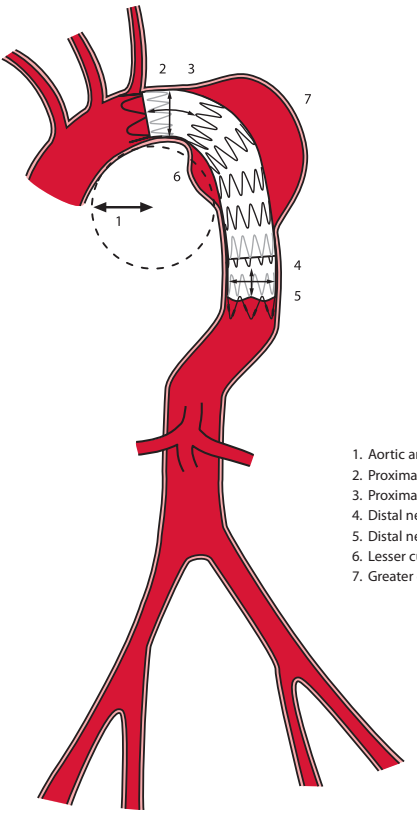
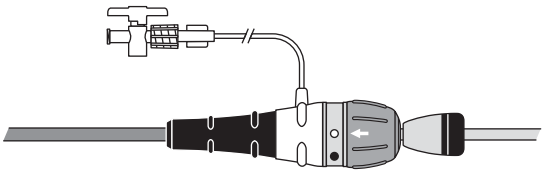
Introduction System Components

a. Cannula hub
b. Back-end cap
c. Blue rotation handle
d. Black safety-lock knob
e. Black gripper (telescoping on distal component)
f. Gray positioner
g. Captor® Sleeve
h. Captor® Hemostatic Valve
i. Connecting tube with stopcock
j. Flexor® Introducer Sheath
k. Dilator tip
l. Gray safety-lock knob



1. Aortic arch radius of curvature ≥ 20 mm
2. Proximal neck diameter 20-42 mm
3. Proximal neck length ≥ 20 mm
4. Distal neck length ≥ 20 mm
5. Distal neck diameter 20-42 mm
6. Lesser curve
7. Greater curve

3



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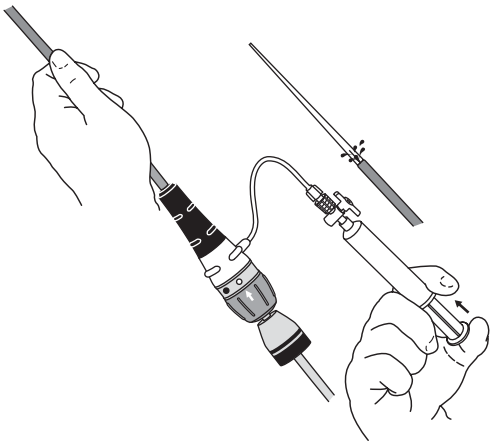

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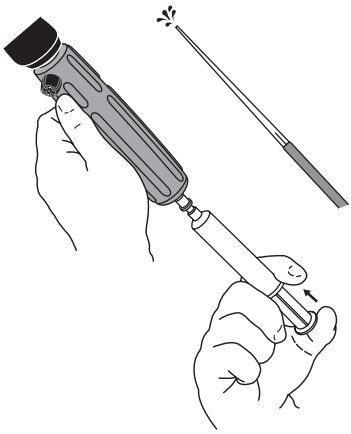

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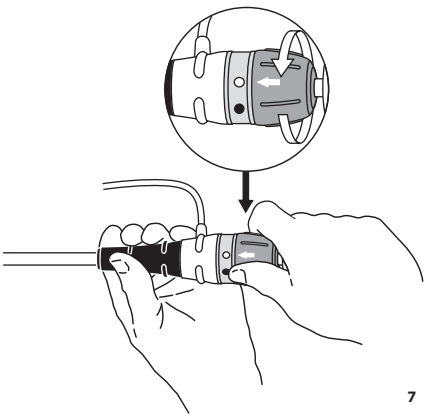

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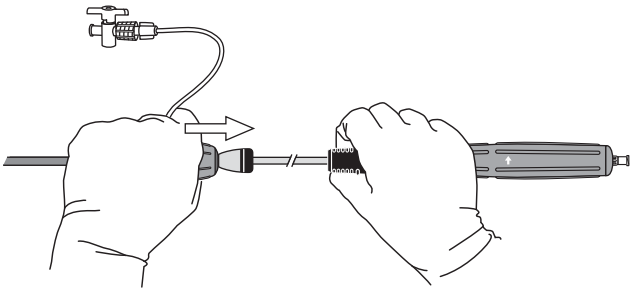

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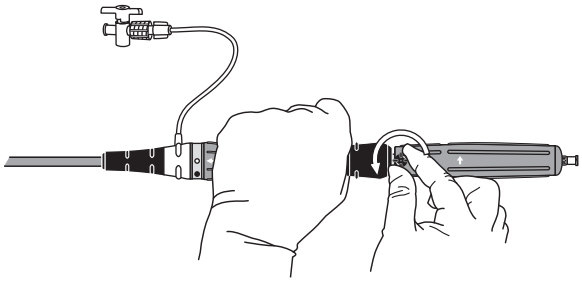

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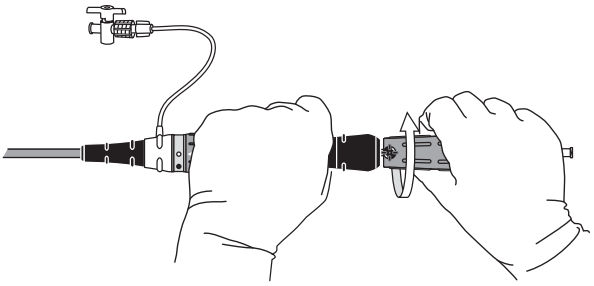

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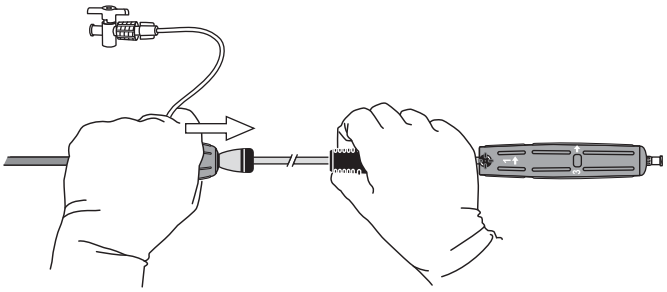

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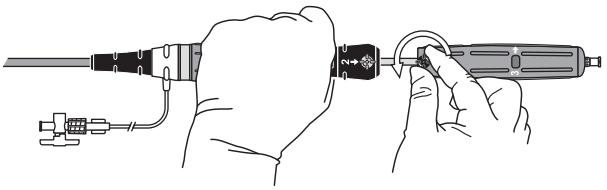

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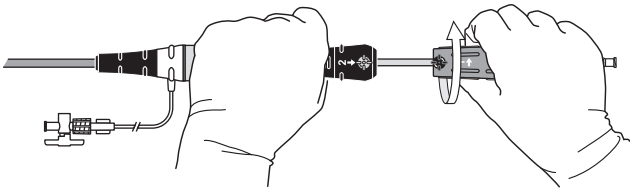

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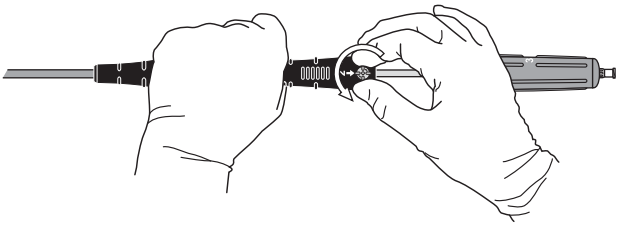

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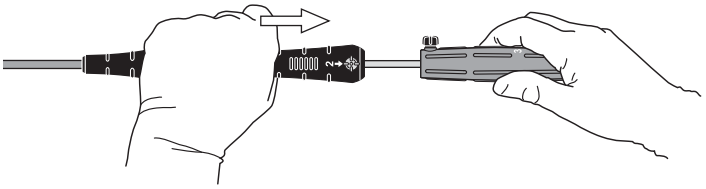

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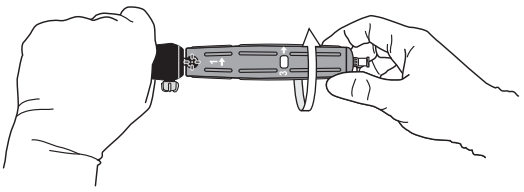

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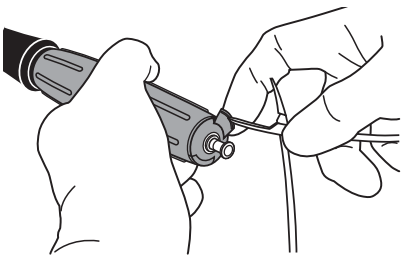

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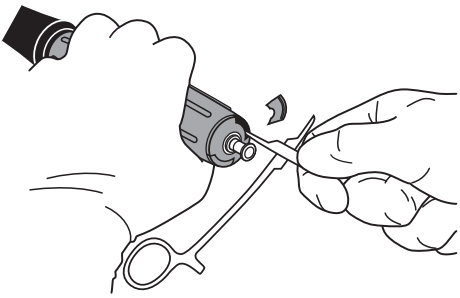

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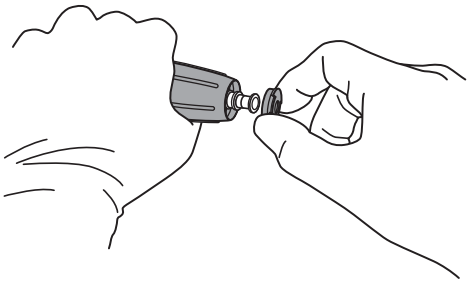

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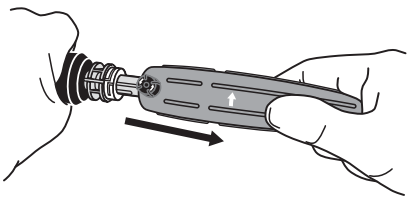

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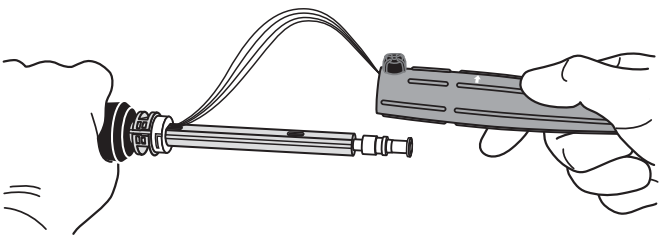

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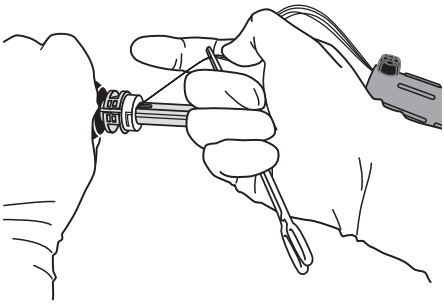

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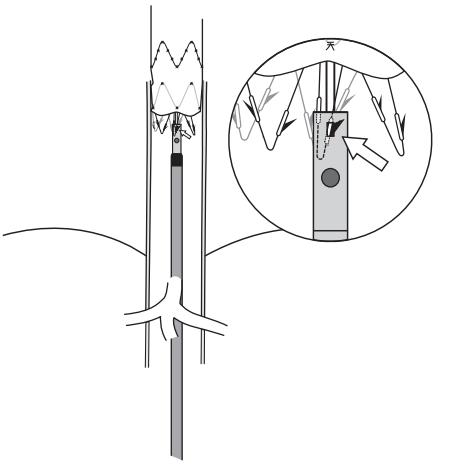

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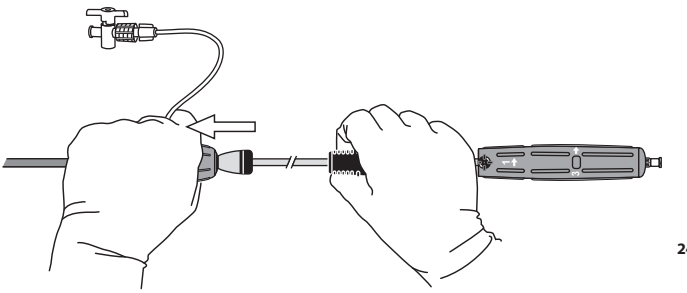

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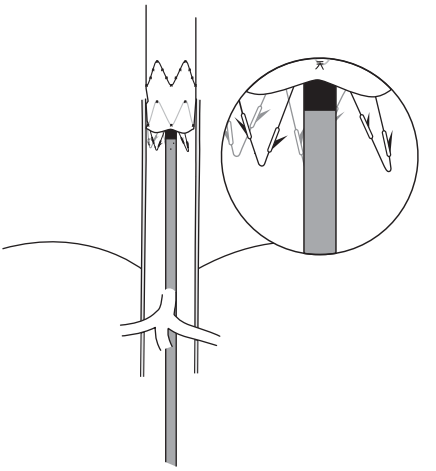

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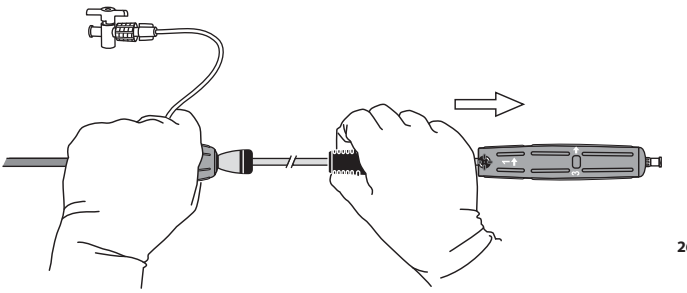

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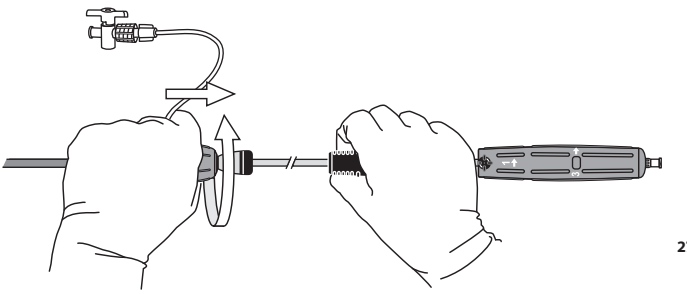

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ZENITH ALPHA™ THORACIC ENDOVASCULAR GRAFT

Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

CAUTION: All contents of the inner pouch (including the introduction system and endovascular graft) are supplied sterile, for single use only.

1 DEVICE DESCRIPTION

1.1 Zenith Alpha Thoracic Endovascular Graft

The Zenith Alpha Thoracic Endovascular Graft is a two-piece cylindrical endovascular graft consisting of proximal and distal components. The proximal component can be either tapered or nontapered and may be used independently (for ulcers/saccular aneurysms) or in combination with a distal component. The stent grafts are constructed of woven polyester fabric sewn to self-expanding nitinol stents with braided polyester and monofilament polypropylene suture. (**Fig. 1**) Both components are fully stented to provide stability and the expansile force necessary to open the lumen of the graft during deployment. Additionally, the nitinol stents provide the necessary attachment and seal of the graft to the vessel wall.

To assist with alignment, the proximal component has an uncovered stent. For added fixation and sealing, the proximal component has an internal sealing stent with fixation barbs that protrude through the graft material. In addition, the bare stent at the distal end of the distal component also contains barbs. On devices with diameters of 40-46 mm, the proximal sealing stent remains constrained to ensure alignment with the inner curvature of the aorta.

To facilitate fluoroscopic visualization of the stent graft, gold radiopaque markers are positioned on each end of the proximal and distal components. Gold markers are placed on stent apices at the proximal and distal aspects of the graft margins, denoting the edge of the graft material, to assist with deployment accuracy.

1.2 Introduction System

The Zenith Alpha Thoracic Endovascular Graft is shipped preloaded onto an introduction system. It has a sequential deployment method with built-in features to provide continuous control of the endovascular graft throughout the deployment procedure. The introduction system enables precise positioning before deployment of the proximal and distal components.

The main body graft components are deployed from a 16 French (6 mm OD), 18 French (7.1 mm OD), or 20 French (7.7 mm OD) introduction system. The proximal component's introduction system is slightly precurved to assist in proximal inferior wall apposition of the graft during deployment. (**Fig. 2**) These systems use either a single locking mechanism (for the proximal component and distal extension) or dual locking mechanisms (for the distal component) to secure the endovascular graft onto the introduction system until the physician releases it. All introduction systems are compatible with a .035 inch wire guide.

The introduction system features a Flexor® Introducer Sheath with a Captor® Hemostatic Valve. For added hemostasis, the Captor Hemostatic Valve can be loosened or tightened for the introduction and/or removal of ancillary devices into and out of the sheath. The Flexor Introducer Sheath resists kinking and is hydrophilic coated. Both features are intended to enhance trackability in the iliac arteries and thoracic aorta.

1.3 Zenith Alpha Thoracic Endovascular Graft Ancillary Component

An endovascular ancillary component is available. The Zenith Alpha Thoracic Endovascular Graft ancillary components are cylindrical components constructed from the same woven polyester fabric, self-expanding nitinol stents, and polyester and polypropylene suture used to construct the main body graft components. At the distal and proximal graft margins, the z-stents are attached to the inner surface for enhanced sealing. (**Fig. 1**) Distal extensions can be used to provide additional length to the endovascular graft distally or to increase the length of overlap between components. Additional proximal components may be used to extend graft coverage proximally.

The Zenith Alpha Thoracic Endovascular Graft Distal Extension is deployed from a 16 French (6 mm OD), 18 French (7.1 mm OD), or 20 French (7.7 mm OD) introduction system. (**Fig. 2**) A single locking mechanism secures the endovascular graft to the introduction system until it is released by the physician. The locking mechanism is released by turning the blue rotation handle. All systems are compatible with a .035 inch wire guide.

To facilitate fluoroscopic visualization of the distal extension, gold radiopaque markers are positioned on the ends of the graft. Gold markers are placed on stent apices at the proximal and distal aspects of the graft margins, denoting the edge of the graft material, to assist with deployment accuracy.

2 INDICATIONS FOR USE

The Zenith Alpha Thoracic Endovascular Graft is indicated for the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta having vascular morphology suitable for endovascular repair (**Fig. 3**), including:

- Iliac/femoral anatomy that is suitable for access with the required introduction systems
- Nonaneurysmal aortic segments (fixation sites) proximal and distal to the thoracic aneurysm or ulcer:
  - with a length of at least 20 mm, and
  - with a diameter measured outer-wall-to-outer-wall of no greater than 42 mm and no less than 20 mm

3 CONTRAINDICATIONS

The Zenith Alpha Thoracic Endovascular Graft is contraindicated in:

- Patients with known sensitivities or allergies to polyester, polypropylene, nitinol, or gold
- Patients who have a condition that threatens to infect the endovascular graft

4 WARNINGS AND PRECAUTIONS

4.1 General

- Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.
- The Zenith Alpha Thoracic Endovascular Graft should be used only 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**.
- Additional endovascular interventions or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms or ulcers, unacceptable decrease in fixation length (vessel and component overlap) and/or endoleak. An increase in aneurysm or ulcer size and/or persistent endoleak or migration may lead to rupture of the aneurysm or ulcer.
- Patients experiencing leaks or reduced blood flow through the graft may be required to undergo secondary endovascular interventions or surgical procedures.
- Always have a qualified surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

4.2 Patient Selection, Treatment and Follow-Up

- The Zenith Alpha Thoracic Endovascular Graft is designed to treat aortic neck diameters no smaller than 20 mm and no larger than 42 mm. The Zenith Alpha Thoracic Endovascular Graft is designed to treat proximal aortic necks (distal to either the left subclavian or left common carotid artery) of at least 20 mm in length. Additional proximal aortic neck length may be gained by covering the left subclavian artery (with or without discretionary transposition) when necessary to optimize device fixation and maximize aortic neck length. Graft length should be selected to cover the aneurysm or ulcer as measured along the greater curve of the aneurysm, plus a minimum of 20 mm of seal zone on the proximal and distal ends. A distal aortic neck length of at least 20 mm proximal to the celiac axis is required. These sizing measurements are critical to the performance of the endovascular repair. In patients with a large proximal aortic vessel diameter and aneurysms on the inner curvature, there is a risk that the graft may deploy in an angulated position if the sealing zone is less than 20 mm.
- Adequate iliac or femoral access is required to introduce the device into the vasculature. Careful evaluation of vessel size, anatomy, and disease state is required to ensure successful sheath introduction and subsequent withdrawal, as vessels that are significantly calcified, occlusive, tortuous, or thrombus lined may preclude introduction of the endovascular graft and/or increase the risk of embolization. A vascular conduit technique may be necessary to achieve access in some patients.
- Key anatomic elements that may affect successful exclusion of the thoracic aneurysm or ulcer include severe angulation (radius of curvature < 20 mm and localized angulation > 45 degrees); short proximal or distal fixation sites (< 20 mm); an inverted funnel shape at the proximal fixation site or a funnel shape at the distal fixation site (greater than a 10% change 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 sites. In the presence of anatomical limitations, a longer neck length may be required to obtain adequate sealing and fixation. Necks exhibiting these key anatomic elements may be more conducive to graft migration. In patients with large aneurysms on the outer curvature close to the left subclavian, it may be difficult to track the device around the arch, and extra support may be needed using a brachio-femoral wire.
- The safety and effectiveness of the Zenith Alpha Thoracic Endovascular Graft and ancillary components have not been evaluated in the following patient populations:
  - aortobronchial and aortoesophageal fistulas
  - aortitis or inflammatory aneurysms
  - diagnosed or suspected genetic connective tissue disease (e.g., Marfans or Ehlers-Danlos Syndrome)
  - dissections
  - females who are pregnant, breastfeeding, or planning to become pregnant within 60 months
  - leaking, pending rupture or ruptured aneurysm
  - patients less than 18 years of age
  - mycotic aneurysms
  - pseudoaneurysms resulting from previous graft placement
  - systemic infection (e.g., sepsis)
  - access vessels that preclude safe insertion
  - inability to preserve the left common carotid artery and celiac artery
  - previous repair in descending thoracic aorta
  - surgical or endovascular AAA repair within 30 days before or after TAA repair
  - bleeding diathesis, uncorrectable coagulopathy, or refuses blood transfusion
  - stroke within 3 months
  - untreatable reaction to contrast, which cannot be adequately premedicated
- Successful patient selection requires specific imaging and accurate measurements; please see **Section 4.3, Pre-Procedure Measurement Techniques and Imaging**.
- 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.
- In-graft thrombus has been observed when the Zenith Alpha Endovascular Graft has been used to treat blunt thoracic aortic injuries. This risk may potentially be associated with excessive oversizing in the distal seal zone of the device.
- The Zenith Alpha Thoracic Endovascular Graft is not recommended for patients who cannot tolerate contrast agents necessary for intraoperative and postoperative follow-up imaging, or who are unable to undergo, or 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**. All patients should be monitored closely and checked periodically for change in the condition of their disease and the integrity of the endoprosthesis.
- The Zenith Alpha Thoracic Endovascular Graft is not recommended for patients whose weight and/or size would compromise or prevent the necessary imaging requirements.
- Graft implantation may increase the risk of paraplegia or paraparesis where graft exclusion covers the origins of dominant spinal cord or intercostal arteries.
  - **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 aneurysms or ulcers, 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**.
  - The long-term performance of endovascular grafts has not yet been established in young patients and patients performing extreme sports.
  - After endovascular graft placement, patients should be regularly monitored for endoleak flow, thoracic aneurysm or ulcer growth, or changes in the structure or position of the endovascular graft.

4.3 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.
- Lack of non-contrast CT imaging may result in failure to appreciate iliac or aortic calcification that may preclude access or reliable device fixation and seal.
- Pre-procedure imaging reconstruction thicknesses > 3 mm may result in suboptimal device sizing, or in failure to appreciate focal stenoses from CT.
- Clinical experience indicates that contrast-enhanced spiral computed tomographic angiography (CTA) with 3D reconstruction is the strongly recommended imaging modality to accurately assess patient anatomy prior to treatment with the Zenith Alpha Thoracic Endovascular Graft. If contrast-

enhanced spiral CTA with 3D 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 so that it is perpendicular to the aortic vessel neck proximal to the thoracic aneurysm or ulcer, typically 45-75 degrees left anterior oblique (LAO) for the arch.
- **Diameter**: A contrast-enhanced spiral CTA is strongly recommended for measuring aortic diameter. Diameter measurements should be determined from the outer-wall-to-outer-wall vessel diameter and not the lumen diameter. The spiral CTA scan must include the great vessels through the femoral heads at an axial slice thickness of 3 mm or less. **CTA measurements should be based on a CTA of a fully resuscitated patient.**
- Clinical experience has shown that temporary changes in aortic diameter during blood loss can lead to incorrect aortic measurement on preoperative CTA, inadequate sizing, and increased risks of graft complications, migration and endoleak. If preoperative CTA is done during hemodynamic instability, repeat CTA when the patient is stable or use IVUS at the time of the procedure to confirm diameter measurements. If there is significant periaortic hematoma in the region of the subclavian artery the hematoma should not be counted in the diameter measurement, as there is a risk of oversizing the graft.
- **Length**: Clinical experience indicates that 3D CTA reconstruction is the strongly recommended imaging modality to accurately assess proximal and distal neck lengths for the Zenith Alpha Thoracic Endovascular Graft. These reconstructions should be performed in sagittal, coronal, and varying oblique views depending upon individual patient anatomy. If 3D reconstruction is not available, the patient should be referred to a facility with these capabilities. **Length measurements should be taken along the greater curvature of the aorta, including the aneurysm, if present.**

  NOTE: The greater curvature is the longest measurement following the curve of the aneurysm and may be on the outer or inner curvature of the aorta depending on the location of the aneurysm.

  NOTE: Large aneurysms and difficult anatomy may require extra care in planning.

4.4 Device Selection

- **Strict adherence to the Zenith Alpha Thoracic Endovascular Graft IFU sizing guide both in terms of component diameter (Tables 1 and 2 in Section 10.5, Device Diameter Sizing Guidelines) as well as component type/length (as stated below and in Section 10.6, Device Length Sizing Guidelines) is strongly recommended in order to mitigate the risk for events (e.g., migration, endoleak, aneurysm growth) that could result from selecting inappropriate device sizes.**
- **Tables 1** and **2** incorporate appropriate device oversizing. Sizing outside of the recommendations provided in **Tables 1** and **2**, including that which could result from a difference in location of graft deployment relative to the location used for graft sizing, can result in aneurysm growth, endoleak, and migration, as observed in the clinical studies (refer to the **Device Performance** sections in the summary of clinical data). Fracture, device infolding, or compression may also result.
- Graft length should be selected to cover the aneurysm or ulcer as measured along the greater curve of the aneurysm, plus a minimum of 20 mm of seal zone on the proximal and distal ends.
- To treat more focal aortic lesions, such as ulcers/saccular aneurysms, a proximal component can be used alone.
- In aneurysms the graft may settle into the greater curve of the aneurysm over time. Accordingly, extra graft length needs to be planned:
  - A two-component repair (proximal and distal component) is recommended, as it provides the ability to adapt to the length change over time. A two-component repair (proximal and distal component) also provides active fixation at both the proximal and distal seal sites.
  - The minimum required amount of overlap between devices is three stents. Less than a three-stent overlap may result in endoleak (with or without component separation). However, no part of the distal component should overlap the proximal sealing stent of the proximal component, and no part of the proximal component should overlap the distal sealing stent of the distal component, as doing so may cause malapposition to the vessel wall. Device lengths should be selected accordingly.
  - If an acceptable two-component (proximal and distal component) treatment plan cannot be achieved (e.g., excessive aortic coverage, even with maximal overlap of shortest components), the proximal component must be selected with enough length to achieve and maintain the minimum 20 mm sealing zones at both ends even when positioned in the greater curve of the aneurysm. Failure to do so could result in migration, endoleak, and aneurysm growth, as observed in the clinical study (refer to the **Device Performance** sections in the summary of clinical data from the aneurysm/ulcer study).

4.5 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 used.
- Appropriate procedural imaging is required to successfully position the Zenith Alpha Thoracic Endovascular Graft and ensure accurate apposition to the aortic wall.
- Fluoroscopy should be used during introduction and deployment to confirm proper operation of the introduction system components, proper placement of the graft, and desired procedural outcome.
- The use of the Zenith Alpha Thoracic Endovascular Graft 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).
- Use caution during manipulation of catheters, wires, and sheaths within the thoracic aneurysm or ulcer. Significant disturbances may dislodge fragments of thrombus or plaque, which can cause distal or cerebral embolization, or cause rupture of the thoracic aneurysm, ulcer or aorta.
- 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 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 Zenith Alpha Thoracic Endovascular Graft.
- To avoid twisting the endovascular graft, never rotate the introduction system during the procedure. Allow the device to conform naturally to the curves and tortuosity of the vessels.
- To avoid damage to the sheath, be careful to advance all components of the system together (from outer sheath to inner cannula).
- 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.
- As the sheath and/or wire guide is withdrawn, anatomy and graft position may change. Constantly monitor graft position and perform angiography to check the position as necessary.
- During sheath withdrawal, the uncovered proximal stent and covered proximal stent with barbs are in contact with the vessel wall. At this stage it may be possible to advance the device, but retraction may cause aortic wall damage.
- Inaccurate placement and/or incomplete sealing of the Zenith Alpha Thoracic Endovascular Graft 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.
- Inadequate fixation of the Zenith Alpha Thoracic Endovascular Graft may result in increased risk of migration of the stent graft. Incorrect deployment or migration of the stent graft may require surgical intervention.
- Inadvertent partial deployment or migration of the endoprosthesis may require surgical removal.
- Land the proximal and the distal ends of the device in parallel aortic neck segments without acute angulation (> 45 degrees) or circumferential thrombus/calcification to ensure fixation and seal.
- Be sure to land the proximal and distal ends of the device in an aortic neck segment with a diameter that matches the initial sizing of the device. Landing in a segment that is different from the location used to size the device may potentially result in inadequate (< 10%) or excessive (> 25%) graft diameter oversizing and therefore migration, endoleak, thoracic aneurysm or ulcer growth, or increased risk of thrombosis.
- The Zenith Alpha Thoracic Endovascular Graft incorporates an uncovered proximal stent, a covered proximal stent (on the proximal component) with fixation barbs, and an uncovered distal stent (on the distal component) with fixation barbs. Exercise extreme caution when manipulating interventional and angiographic devices in the region of the uncovered proximal stent and uncovered distal stent.
- When using a distal component, take care to avoid landing the distal bare stent in tortuous anatomy (i.e., localized angulation > 45 degrees).
- Unless medically indicated, do not deploy the Zenith Alpha Thoracic Endovascular Graft in a location that will occlude arteries necessary to supply blood flow to organs or extremities. Do not cover significant arch or mesenteric arteries (an exception may be the left subclavian artery) with the device. 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 and collateral circulation to the spinal cord.
- Take care not to advance the sheath while the stent graft is still within it. Advancing the sheath at this stage may cause the barbs to perforate the introducer sheath.
- Do not attempt to resheath 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.
- To avoid entangling any catheters left in situ, rotate the introduction system during withdrawal.
- In the final angiogram confirm that there are no endoleaks or kinks, that the proximal and distal gold radiopaque markers demonstrate that there is adequate overlap between components, and that there is sufficient graft length to maintain over time a minimum of 20 mm in proximal and distal seal.

  NOTE: If endoleaks or other problems are observed (e.g., inadequate seal length or overlap length), refer to **Section 11.2, Ancillary Devices: Distal Extension**.
- In the event that reinstrumentation (secondary intervention) of the graft is necessary, avoid damaging the graft or disturbing the graft's position.

4.6 Molding Balloon Use – Optional

- Do not inflate the balloon in the aorta outside of the graft, as doing so may cause damage to the aorta. Use the molding balloon in accordance with its labeling.
- Use care when inflating the balloon within the graft in the presence of calcification, as excessive inflation may cause damage to the aorta.
- 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.

4.7 MRI Safety Information

Nonclinical testing has demonstrated that the Zenith Alpha Thoracic Endovascular Graft is MR Conditional according to ASTM F2503. A patient with this endovascular graft 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 Safety Information**

5 POTENTIAL ADVERSE EVENTS

Adverse events associated with either the Zenith Alpha Thoracic Endovascular Graft or the implantation procedure 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
- Aortic valve damage
- Aorto-bronchial fistula
- Aorto-esophageal fistula
- 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, tamponade, 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

- Endovascular graft: improper component placement, incomplete component deployment, component migration and/or separation, suture break, occlusion, infection, stent fracture, stent corrosion, graft material wear, dilatation, erosion, puncture, perigraft flow, barb separation
- Femoral neuropathy
- Fever and localized inflammation
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, urinary 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, lymphocele)
- Local or systemic neurologic complications and subsequent attendant problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, spinal cord shock, paralysis)
- Occlusion of coronary arteries
- Pulmonary embolism
- 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
- Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death)
- Vessel damage
- Wound complications and subsequent problems (e.g., dehiscence, infection)

Device Related Adverse Event Reporting

Any adverse event (clinical incident) involving the Zenith Alpha Thoracic Endovascular Graft should be reported to Cook immediately. To report an incident, call the Customer Relations Department at 800.457.4500 (24 hour) or 812.339.2235.

6 SUMMARY OF CLINICAL DATA

A summary of the clinical data can be found on www.cookmedical.com.

7 PATIENT SELECTION AND TREATMENT

(See **Section 4, WARNINGS AND PRECAUTIONS**)

7.1 Individualization of Treatment

Cook recommends that the Zenith Alpha Thoracic Endovascular Graft component diameters be selected as described in **Tables 1** and **2**. 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 and lengths) are not certain. This approach allows for greater intraoperative flexibility.

The risks and benefits should be carefully considered for each patient before use of the Zenith Alpha Thoracic Endovascular Graft. Additional considerations for patient selection include, but are not limited to:

- Patient's age and life expectancy
- Comorbidities (e.g., cardiac, pulmonary, or renal insufficiency prior to surgery, morbid obesity)
- Patient's suitability for open surgical repair
- The risk of thoracic aneurysm or ulcer rupture compared to the risk of treatment with the Zenith Alpha Thoracic Endovascular Graft
- Ability to tolerate general, regional, or local anesthesia
- Ability and willingness to undergo and comply with the required follow-up
- Iliofemoral access vessel size and anatomy (thrombus, calcification and/or tortuosity) should be compatible with vascular access techniques and accessories of the delivery profile of a 16 French (6 mm OD) to 20 French (7.7 mm OD) vascular introducer sheath
- Vascular anatomy suitable for endovascular repair, including:
  - radius of curvature greater than or equal to 20 mm along the entire length of aorta intended to be treated.
- Nonaneurysmal aortic segments (fixation sites) proximal and distal to the thoracic aneurysm or ulcer:
  - with a length of at least 20 mm,
  - with a diameter measured outer-wall-to-outer-wall of no greater than 42 mm and no less than 20 mm, and with localized angulations less than 45 degrees

The final treatment decision is at the discretion of the physician and patient.

8 PATIENT COUNSELING INFORMATION

The physician and patient (and/or family members) should review the risks and benefits when discussing this endovascular device and procedure, including:

- Risks and differences between endovascular repair and open surgical repair
- Potential advantages of traditional open surgical repair
- Potential advantages of endovascular repair
- The possibility that subsequent interventional or open surgical repair of the thoracic aneurysm or ulcer may be required after initial endovascular repair

In addition to the risks and benefits of an endovascular repair, the physician should assess the patient's commitment to and compliance with postoperative follow-up as necessary to ensure continuing safe and effective results. Listed below are additional topics to discuss with the patient as to expectations after an endovascular repair:

- **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 aneurysms or ulcers, 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**.
- Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of thoracic aortic aneurysms or ulcers. At a minimum, annual imaging and adherence to routine postoperative follow-up requirements is required and should be considered a life-long commitment to the patient's health and well-being.
- The patient should be told that successful thoracic aneurysm or ulcer repair does not arrest the disease process. It is still possible to have associated degeneration of vessels.
- Physicians must advise every patient that it is important to seek prompt medical attention if he/she experiences signs of graft occlusion, thoracic aneurysm or ulcer enlargement or rupture. Signs of graft occlusion include, but may not be limited to, pulse-less legs, ischemia of intestines, and cold extremities. Thoracic aneurysm or ulcer rupture may be asymptomatic, but usually presents as back or chest pain, persistent cough, dizziness, fainting, rapid heartbeat, or sudden weakness.
- Due to the imaging required for successful placement and follow-up of endovascular devices, the risk of radiation exposure to developing tissue should be discussed with women who are or suspect they are pregnant.
- Men who undergo endovascular or open surgical repair may experience impotence.

The physician should complete the Patient ID Card and give it to the patient so that he/she can carry it with him/her at all times. The patient should refer to the card any time he/she visits additional health practitioners, particularly for any additional diagnostic procedures (e.g., MRI).

9 HOW SUPPLIED

- The Zenith Alpha Thoracic Endovascular Graft is sterilized by ethylene oxide gas, is preloaded onto an introduction system, and is supplied in peel-open packages.
- The device is intended for single use only. Do not resterilize the device.
- The product is sterile if the package is unopened and undamaged. Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product; instead, return the product to Cook.
- Prior to use, verify that the correct devices (quantity and size) have been supplied for the patient by matching the device to the order prescribed by the physician for that particular patient.
- The device is loaded into a 16 French, 18 French or 20 French Flexor Introducer Sheath. Its surface is treated with a hydrophilic coating that, when hydrated, enhances trackability. To activate the hydrophilic coating, the surface must be wiped with a sterile gauze pad soaked in saline solution under sterile conditions.
- Do not use after the expiration date printed on the label.
- Store in a dark, cool, dry place.

10 CLINICAL USE INFORMATION

10.1 Physician Training

CAUTION: Always have a qualified surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

CAUTION: The Zenith Alpha Thoracic Endovascular Graft should only be used by physicians and teams trained in vascular interventional techniques (endovascular and surgical) and in the use of this device. The recommended skill and knowledge requirements for physicians using the Zenith Alpha Thoracic Endovascular Graft are outlined below:

Patient Selection

- Knowledge of the natural history of thoracic aortic aneurysms/ulcers and comorbidities associated with thoracic aortic aneurysm or ulcer repair.
- Knowledge of radiographic image interpretation, patient selection, device selection, planning, and sizing.

A multidisciplinary team that has combined procedural experience with:

- Femoral and brachial cutdown, arteriotomy, and repair or conduit technique
- Percutaneous access and closure techniques
- Nonselective and selective wire guide and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Appropriate use of radiographic contrast material
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

10.2 Inspection Prior to Use

Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product; instead, return the product to Cook. Prior to use, verify correct devices (quantity and size) have been supplied for the patient by matching the device to the order prescribed by the physician for that particular patient.

10.3 Materials Required

(Not included in the endovascular graft system)

- A selection of Zenith Alpha Thoracic Endovascular Graft distal ancillary components in diameters compatible with the proximal and distal components.
- Fluoroscope with digital angiography capabilities (C-arm or fixed unit)
- Contrast media
- Power injector
- Syringe
- Heparinized saline solution
- Sterile gauze pads

10.4 Materials Recommended

The following products are recommended for implantation of any component in the Zenith product line. For information on the use of these products, refer to the individual product's Suggested Instructions for Use:

- .035 inch (0.89 mm) extra stiff wire guide, 260/300 cm:
  - Cook Lunderquist® Extra Stiff Wire Guides (LESDC)
  - Cook Amplatz Ultra Stiff Wire Guides (AUS)
- .035 inch (0.89 mm) standard wire guide:
  - Cook .035 inch wire guides
  - Cook .035 inch Bentson Wire Guide
  - Cook Nimble® Wire Guides
- Molding balloons:
  - Cook Coda® Balloon Catheters
- Introducer sets:
  - Cook Check-Flo® Introducer Sets
- Sizing catheter:
  - Cook Aurous® Centimeter Sizing Catheters
- Angiographic radiopaque marker catheters:
  - Cook Beacon® Tip Angiographic Catheters
  - Cook Beacon® Tip Royal Flush Catheters, 125 cm
- Entry needles:
  - Cook single-wall entry needles
- Endovascular dilators:
  - Cook endovascular dilator sets

10.5 Device Diameter Sizing Guidelines

The choice of diameter should be determined from the outer-wall-to-outer- wall vessel diameter and not the lumen diameter. Undersizing (as observed during the clinical studies; refer to the **Device Performance** sections in the summary of clinical data) or oversizing may result in incomplete sealing or compromised flow. In order to ensure accurate diameter measurements for the purpose of graft sizing, particularly when in curved segments of the aorta, measure the

aortic diameter using 3D reconstructed views perpendicular to the aortic centerline of flow. The proximal diameter of the distal component can be up to 8 mm larger than the distal diameter of the proximal component. It is strongly recommended that you ensure a minimum three-stent overlap between components.

For patients with a significant periaortic hematoma in the region of the subclavian artery the hematoma should not be counted in the diameter measurement, as there is a risk of oversizing the graft.

CTA measurements should be based on a CTA of a fully resuscitated patient.

Table 1 – Proximal, Distal and Proximal Tapered Component (P, D, PT) Graft Diameter Sizing Guide*

Intended Aortic Vessel Diameter[1,2] mm	Graft Diameter[3] mm	Overall Length of Proximal Component mm	Overall Length of Distal Component mm	Overall Length of Tapered Proximal Component mm	Introducer Sheath Fr	Introducer Sheath Outer Diameter (OD) mm
20	24	105/127**	n/a	n/a	16	6.0
21	24	105/127**	n/a	n/a	16	6.0
22	26	105/149**	n/a	n/a	16	6.0
23	26	105/149**	n/a	n/a	16	6.0
24	28	109/132**/155/201	160/229**	n/a	16	6.0
25	28	109/132**/155/201	160/229**	n/a	16	6.0
26	30	109/132**/155/201	160/229**	108	16	6.0
27	30	109/132**/155/201	160/229**	108	16	6.0
28	32	109/132**/155/201	160/229**	178/201	18	7.1
29	32	109/132**/155/201	160/229**	178/201	18	7.1
30	34	113/137**/161/209	142/190	161/209	18	7.1
31	36	113/137**/161/209	142/190	161/209	18	7.1
32	36	113/137**/161/209	142/190	161/209	18	7.1
33	38	117/142**/167/217	147/197	167/217	18	7.1
34	38	117/142**/167/217	147/197	167/217	18	7.1
35	40	117/142**/167/217	147/197	167/217	20	7.7
36	40	117/142**/167/217	147/197	167/217	20	7.7
37	42	121/147**/173/225	152**/204	173/225	20	7.7
38	42	121/147**/173/225	152**/204	173/225	20	7.7
39	44	125/152**/179/233	157**/211	179/233	20	7.7
40	46	125/152**/179/233	157**/211	179/233	20	7.7
41	46	125/152**/179/233	157**/211	179/233	20	7.7
42	46	125/152**/179/233	157**/211	179/233	20	7.7

*All dimensions are nominal.
**Non stock items.
[1]Maximum diameter along the fixation site, measured outer-wall-to-outer-wall.
[2]Round the measured aortic diameter to the nearest mm.
[3]Additional considerations may affect the choice of diameter.

Table 2 – Distal Extension (DE) Graft Diameter Sizing Guide*

Intended Aortic Vessel Diameter[1,2] mm	Graft Diameter[3] mm	Overall Length of Component mm	Introducer Sheath Fr	Introducer Sheath Outer Diameter (OD) mm
20	24	104**/148**	16	6.0
21	24	104**/148**	16	6.0
22	26	104/148**	16	6.0
23	26	104/148**	16	6.0
24	28	108**/154**	16	6.0
25	28	108**/154**	16	6.0
26	30	108/154**	16	6.0
27	30	108/154**	16	6.0
28	32	108**/154**	18	7.1
29	32	108**/154**	18	7.1
30	34	112/160**	18	7.1
31	36	112**/160**	18	7.1
32	36	112**/160**	18	7.1
33	38	91/141**	18	7.1
34	38	91/141**	18	7.1
35	40	91**/141**	20	7.7
36	40	91**/141**	20	7.7
37	42	94/146**	20	7.7
38	42	94/146**	20	7.7
39	44	97**/151**	20	7.7
40	46	97/151**	20	7.7
41	46	97/151**	20	7.7
42	46	97/151**	20	7.7

*All dimensions are nominal.
**Non stock items.
[1]Maximum diameter along the fixation site, measured outer-wall-to-outer-wall.
[2]Round the measured aortic diameter to the nearest mm.
[3]Additional considerations may affect the choice of diameter.

10.6 Device Length Sizing Guidelines

- Graft length should be selected to cover the aneurysm or ulcer as measured along the greater curve of the aneurysm, plus a minimum of 20 mm of seal zone on the proximal and distal ends.
- To treat more focal aortic lesions, such as ulcers/saccular aneurysms, a proximal component can be used alone.
- In aneurysms the graft may settle into the greater curve of the aneurysm over time. Accordingly, extra graft length needs to be planned:
  - A two-component repair (proximal and distal component) is recommended, as it provides the ability to adapt to the length change over time. A two-component repair (proximal and distal component) also provides active fixation at both the proximal and distal seal sites.
  - The minimum required amount of overlap between devices is three stents. Less than a three-stent overlap may result in endoleak (with or without component separation). However, no part of the distal component should overlap the proximal sealing stent of the proximal component, and no part of the proximal component should overlap the distal sealing stent of the distal component, as doing so may cause malapposition to the vessel wall. Device lengths should be selected accordingly.
  - If an acceptable two-component (proximal and distal component) treatment plan cannot be achieved (e.g., excessive aortic coverage, even with maximal overlap of shortest components), the proximal component must be selected with enough length to achieve and maintain the minimum 20 mm sealing zones at both ends even when positioned in the greater curve of the aneurysm. Failure to do so could result in migration, endoleak, and aneurysm growth, as observed in the clinical study (refer to the **Device Performance** sections in the summary of clinical data from the aneurysm/ulcer study).

11 DIRECTIONS FOR USE

Anatomical Requirements

- Iliofemoral access vessel size and anatomy (minimal thrombus, calcium and/or tortuosity) should be compatible with vascular access techniques and accessories. Arterial conduit technique may be required.
- Proximal and distal aortic neck lengths should be a minimum of 20 mm.
- Aortic neck diameters measured outer-wall-to-outer-wall should be between 20-42 mm.
- A proximal neck diameter that is 4 mm or more larger than the distal neck diameter requires the use of a proximal tapered component.
- No localized angulation should be larger than 45 degrees.
- Measurements to be taken during the pre-treatment assessment are shown in **Fig. 3**.

Proximal and Distal Component Overlap

A minimum overlap of three stents is recommended; however, the proximal sealing stent of the proximal component or distal sealing stent of the distal component should not be overlapped.

Prior to use of the Zenith Alpha Thoracic Endovascular Graft, review the **Suggested Instructions for Use** booklet. The following instructions are intended to help guide the physician and do not take the place of physician judgment.

General Use Information

Standard techniques for placement of arterial access sheaths, guiding catheters, angiographic catheters, and wire guides should be employed during use of the Zenith Alpha Thoracic Endovascular Graft. The Zenith Alpha Thoracic Endovascular Graft is compatible with .035 inch diameter wire guides. Brachio-femoral wire guide technique may be required if the patient has a difficult anatomy.

Endovascular stenting 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 to restrict flow.

Pre-Implant Determinants

Verify from pre-implant planning that the correct device has been selected. Determinants include:

- Femoral artery selection for introduction of the introduction system(s)
- Angulation of aorta, aneurysm, and iliac arteries
- Quality of the proximal and distal fixation sites
- Diameters of proximal and distal fixation sites and distal iliac arteries
- Length of proximal and distal fixation sites

Patient Preparation

1. Refer to institutional protocols relating to anesthesia, anticoagulation, and monitoring of vital signs.
2. Position the patient on the imaging table to allow fluoroscopic visualization from the aortic arch to the femoral bifurcations.
3. Expose the femoral artery using standard surgical technique.
4. Establish adequate proximal and distal vascular control of the femoral artery.

11.1 The Zenith Alpha Thoracic Endovascular Graft

11.1.1 Proximal and Distal Components Preparation/Flush

1. Remove the yellow-hubbed inner stylet from the dilator tip. Verify that the Captor Sleeve is within the Captor Hemostatic Valve; do not remove the Captor Sleeve. (**Fig. 4**)
2. Elevate the distal tip of the system and flush through the hemostatic valve until fluid exits the tip of the introducer sheath. (**Fig. 5**) Continue to inject a full 60 mL of flushing solution through the device. Discontinue injection and close the stopcock on the connecting tube.

   NOTE: Graft flushing solution of heparinized saline is often used.
3. Attach a syringe with heparinized saline to the hub on the blue rotation handle. (**Fig. 6**) Flush until fluid exits the distal sideports and dilator tip.
4. Soak sterile gauze pads in saline solution and use them to wipe the Flexor Introducer Sheath to activate the hydrophilic coating. Hydrate both sheath and dilator tip liberally.

11.1.2 Placement of Proximal Component

1. Puncture the selected artery using standard technique with an 18 gage access needle. Upon vessel entry, insert:
   - Wire guide (standard .035 inch, 260/300 cm, 15 mm J tip or Bentson).
   - Appropriate size sheath (e.g., 5 French).
   - Pigtail flush catheter (often radiopaque-banded sizing catheters; e.g., Cook Centimeter Sizing CSC-20 catheter).
2. Perform angiography at the appropriate level. If using radiopaque markers, adjust position of the catheter as necessary and repeat angiography.
3. Ensure the graft system has been flushed and primed with heparinized saline (appropriate flush solution), and that all air has been removed.
4. Give systemic heparin. Flush all catheters and wet all wire guides with heparinized saline. Reflush catheters and rewet wire guides after each exchange.
5. Replace the standard wire guide with a stiff .035 inch, 260/300 cm, LESDC wire guide and advance through the catheter and up to the aortic arch.

   NOTE: If the anatomy is difficult, consider using a brachio-femoral approach instead.
6. Remove the pigtail flush catheter and sheath.

   NOTE: At this stage, the second femoral artery can be accessed for angiographic catheter placement. Alternatively, consider using a brachial approach.
7. Introduce the freshly hydrated introduction system over the wire guide and advance it until the desired graft position is reached.

   CAUTION: To avoid inadvertent displacement of the graft during withdrawal of the sheath, it may be appropriate to momentarily decrease the patient's mean arterial pressure to approximately 80 mm Hg (at the discretion of the physician).

   CAUTION: To avoid twisting the endovascular graft, never rotate the introduction system when you introduce it. Allow the device to conform naturally to the curves and tortuosity of the vessels.

   NOTE: The dilator tip will soften at body temperature.
8. Verify wire guide position in the aortic arch. Ensure correct graft position.
   CAUTION: Care should be taken not to advance the sheath while the stent graft is still within it. Advancing the sheath at this stage may cause the barbs to perforate the introducer sheath.
9. Ensure that the Captor Hemostatic Valve on the Flexor Introducer Sheath is turned to the open position. (**Fig. 7**)
10. Stabilize the gray positioner (introduction system shaft) and withdraw the sheath until the graft is fully expanded and the valve assembly with the Captor Sleeve docks with the black gripper. (**Fig. 8**)

    CAUTION: As the sheath is withdrawn, anatomy and graft position may change. Prior to complete unsheathing of the graft, check distal gold markers to make sure visceral arteries will not be covered. Constantly monitor graft position and perform angiography to check position as necessary.

    CAUTION: During sheath withdrawal, the proximal barbs are exposed and are in contact with the vessel wall. At this stage it may be possible to advance the device, but retraction may cause aortic wall damage.

    NOTE: If extreme difficulty is encountered when attempting to withdraw the sheath, place the device in a less tortuous position that enables the sheath to be retracted. Very carefully withdraw the sheath until it just begins to retract, and stop. Move back to original position and continue deployment.
11. Verify graft position and, if necessary, adjust it forward. Recheck graft position with angiography.

    NOTE: If an angiographic catheter is placed parallel to the stent graft, use this to perform position angiography.
12. While holding the black gripper, turn the black safety-lock knob in the direction of the arrows until a slight click is felt, indicating that the blue rotation handle is engaged. (**Fig. 9**) Make sure the black safety-lock knob is in the unlocked position.
13. Under fluoroscopy, turn the blue rotation handle in the direction of the arrow until a stop is felt. (**Fig. 10**) This indicates that the uncovered stent and proximal end of the graft have opened and that the distal attachment to the introducer has been released.

    NOTE: If the blue rotation handle stops before completing the rotation (so that the proximal end of the graft is not released from the introduction system), verify the position of the black safety-lock knob and, if necessary, turn it counterclockwise to the unlocked position.

    NOTE: If the black safety-lock knob is removed from the system after it has been turned counterclockwise to the unlocked position, the blue rotation handle will remain engaged. Continue with the procedure.

    NOTE: If it is still difficult to rotate the blue rotation handle, refer to **Section 13, RELEASE TROUBLESHOOTING** for instructions on how to disassemble the blue rotation handle.
14. Remove the introduction system, leaving the wire guide in the graft.

    CAUTION: To avoid entangling any catheters left in situ, rotate the introduction system during withdrawal.

    NOTE: Inaccuracies in device size selection or placement, changes or anomalies in patient anatomy, or procedural complications may require placement of additional endovascular grafts and extensions to achieve the minimum length of proximal and distal seal and length of overlap between components.

11.1.3 Placement of Distal Component

1. If an angiographic catheter is placed in the femoral artery, it should be repositioned to demonstrate the aortic anatomy where the distal component is to be deployed.
2. Introduce the freshly hydrated introduction system over the wire guide until the desired graft position is reached, with at minimum a three-stent overlap (75 mm) with the proximal component. No part of the distal component should overlap the proximal sealing stent of the proximal component, and no part of the proximal component should overlap the distal sealing stent of the distal component, as doing so may cause malapposition to the vessel wall.
3. Check the graft position by angiography and adjust if necessary.
4. Ensure that the Captor Hemostatic Valve on the Flexor Introducer Sheath is turned to the open position. (**Fig. 7**)
5. Stabilize the gray positioner (introduction system shaft) and begin withdrawing the sheath.

   CAUTION: As the sheath is withdrawn, anatomy and graft position may change. Constantly monitor graft position and perform angiography to check position as necessary.

   NOTE: If extreme difficulty is encountered when attempting to withdraw the sheath, place the device in a less tortuous position that enables the sheath to be retracted. Very carefully withdraw the sheath until it just begins to retract, and stop. Move back to original position and continue deployment.
6. Withdraw the sheath until the Captor Valve with the Captor Sleeve docks with the black telescoping gripper and the graft is fully expanded. (**Fig. 11**)
7. To release the distal attachment, hold the black telescoping gripper and turn the black safety-lock knob in the direction of the arrows until a slight click is felt, indicating that the blue rotation handle is engaged. (**Fig. 12**) Make sure the black safety-lock knob is in the unlocked position. Turn the blue rotation handle in the direction of the arrow next to label 1 until a stop is felt. (**Fig. 13**)

   NOTE: If the blue rotation handle stops before completing the rotation, verify the position of the black safety-lock knob and, if necessary, turn it counterclockwise to the unlocked position.

   NOTE: If the black safety-lock knob is removed from the system after it has been turned counterclockwise to the unlocked position, the blue rotation handle will remain engaged. Continue with the procedure.
8. Turn the gray safety-lock knob indicated by label 2, on the black telescoping gripper in the direction of the arrows until a slight click is felt, indicating that the black telescoping gripper is engaged. (**Fig. 14**)

   NOTE: Care should be taken to avoid landing the bare stent in regions of localized angulation > 45 degrees. If the bare stent is landed in localized angulations > 45 degrees, it may be difficult to release the bottom cap,

as observed in the clinical study. Using a brachio-femoral wire guide technique can increase support of the system and ease the release of the bottom cap.

9. To release the distal bare stent, stabilize the introduction system and slide the sheath together with the black telescoping gripper (by holding the Captor Valve) in a distal direction until it locks automatically into position next to the blue rotation handle. (**Fig. 15**) The release window on the blue rotation handle next to label 3 will turn green. (**Fig. 16**) If the window has not turned green, slide the black telescoping gripper until it locks with the blue rotation handle.
10. If the bare stent cannot be fully released from the cap, complete the deployment procedure and refer to **Section 13, RELEASE TROUBLESHOOTING**.
11. Turn the blue rotation handle in the direction of the arrow next to label 3 until a stop is felt and the proximal end of the graft opens.
    If difficulty is encountered rotating the blue rotation handle, refer to **Section 13, RELEASE TROUBLESHOOTING** for instructions on how to disassemble the blue rotation handle.
12. Remove the inner introduction system entirely, leaving the sheath and wire guide in place.
13. Close the Captor Hemostatic Valve on the Flexor Introducer Sheath by turning it to the closed position.
    CAUTION: To avoid entangling any catheters left in situ, rotate the introduction system during withdrawal.

11.1.4 Main Body Molding Balloon Insertion – Optional

1. Prepare the molding balloon as follows and/or per the manufacturer's instructions:
   - Flush the wire lumen with heparinized saline.
   - Remove all air from the balloon.
2. In preparation for insertion of the molding balloon, open the Captor Hemostatic Valve by turning it to the open position. (**Fig. 7**)
3. Advance the molding balloon over the wire guide and through the hemostatic valve of the main body introduction system to the level of the proximal fixation seal site. Maintain proper sheath positioning.
4. Tighten the Captor Hemostatic Valve around the molding balloon with gentle pressure by turning it to the closed position.
   CAUTION: Do not inflate balloon in the aorta outside of the graft.
5. Expand the molding balloon with diluted contrast media (as directed by the manufacturer) in the area of the proximal covered stent, starting proximally and working in the distal direction.
   CAUTION: Confirm complete deflation of balloon prior to repositioning.
6. If applicable, withdraw the molding balloon to the proximal component/distal component overlap and expand.
7. Withdraw the molding balloon to the distal fixation site and expand.
8. Open the Captor Hemostatic Valve, remove the molding balloon and replace it with an angiographic catheter to perform completion angiography.
9. Tighten the Captor Hemostatic Valve around the angiographic catheter with gentle pressure by turning it clockwise.
10. Remove or replace all stiff wire guides to allow the aorta to resume its natural position.

11.1.5 Final Angiogram

1. Position angiographic catheter just above the level of the endovascular graft. Perform angiography to verify correct positioning of the graft. Verify patency of arch vessels and celiac trunk.
2. In the final angiogram confirm that there are no endoleaks or kinks, that the proximal and distal gold radiopaque markers are positioned to provide adequate overlap between components, and that there is sufficient graft length to maintain over time a minimum of 20 mm in proximal and distal seal.
   NOTE: If endoleaks or other problems are observed (e.g., inadequate seal length or overlap length), refer to **Section 11.2, Ancillary Devices: Distal Extension**.
3. Remove the sheaths, wires, and catheters.
4. Repair vessels and close in standard surgical fashion.

11.2 Ancillary Devices: Distal Extension

General Use Information

Inaccuracies in device size selection or placement, changes or anomalies in patient anatomy, or procedural complications can require placement of additional endovascular grafts and extensions. Regardless of the device placed, the basic procedure(s) will be similar to the maneuvers required and described previously in this document. It is vital to maintain wire guide access.

Standard techniques for placement of arterial access sheaths, guiding catheters, angiographic catheters, and wire guides should be employed during use of the Zenith Alpha Thoracic Endovascular Graft ancillary devices.

The Zenith Alpha Thoracic Endovascular Graft ancillary devices are compatible with .035 inch diameter wire guides. Additional proximal main body components may be used to extend graft coverage proximally. Distal extensions are used to extend the distal body of an in situ endovascular graft or to increase the length of overlap between graft components.

11.2.1 Distal Extension Preparation/Flush

1. Remove the yellow-hubbed inner stylet from the dilator tip. Verify that the Captor Sleeve is within the Captor Hemostatic Valve; do not remove the Captor Sleeve. (**Fig. 4**)
2. Elevate distal tip of system and flush through the hemostatic valve until fluid exits the tip of the introducer sheath. (**Fig. 5**) Continue to inject a full 60 mL of flushing solution through the device. Discontinue injection and close the stopcock on the connecting tube.
   NOTE: Graft flushing solution of heparinized saline is often used.
3. Attach a syringe with heparinized saline to the hub on the blue rotation handle. (**Fig. 6**) Flush until fluid exits the distal sideports and dilator tip.
4. Soak sterile gauze pads with saline and use to wipe the Flexor Introducer Sheath to activate the hydrophilic coating. Hydrate both sheath and dilator liberally.

11.2.2 Placement of the Distal Extension

1. Puncture the selected artery using standard technique with an 18 gage access needle. Alternatively, use the in situ wire guide that was used previously for introduction system/graft insertions. Upon vessel entry, insert:
   - Wire guide (standard .035 inch, 260/300 cm, 15 mm J tip or Bentson).
   - Appropriate size sheath (e.g., 5 French).
   - Pigtail flush catheter (often radiopaque-banded sizing catheters; e.g., Cook Centimeter Sizing CSC-20 catheter).
2. Perform angiography at the appropriate level. If using radiopaque markers, adjust position as necessary and repeat angiography.
3. Ensure the graft system has been primed with heparinized saline, and all air has been removed.
4. Give systemic heparin. Flush all catheters and wire guides with heparinized saline. Reflush catheters and rewet wire guides after each exchange.
5. Replace the standard wire guide with a stiff .035 inch, 260/300 cm, LESDC wire guide and advance it through the catheter and up to the aortic arch.
6. Remove the pigtail flush catheter and sheath.
   NOTE: At this stage, the second femoral artery can be accessed for flush catheter placement. Alternatively, consider using a brachial approach.
7. Introduce the freshly hydrated introduction system over the wire guide and advance until the desired graft position is reached. Ensure that the distal extension overlaps the distal component by a minimum of three stents (plus the distal uncovered stent).
   CAUTION: To avoid twisting the endovascular graft, never rotate the introduction system when you introduce it. Allow the device to conform naturally to the curves and tortuosity of the vessels.
   NOTE: The dilator tip softens at body temperature.
   NOTE: To facilitate introduction of the wire guide into the introduction system, it may be necessary to slightly straighten the introduction system dilator tip.
8. Verify wire guide position in the aortic arch. Ensure correct graft position.
9. Ensure that the Captor Hemostatic Valve on the Flexor Introducer Sheath is turned counterclockwise to the open position. (**Fig. 7**)
10. Stabilize the gray positioner (introduction system shaft) and withdraw the sheath until the graft is fully expanded and the valve assembly with the Captor Sleeve docks with the black gripper. (**Fig. 8**)
    CAUTION: As the sheath or wire guide is withdrawn, anatomy and graft position may change. Constantly monitor graft position and perform angiography to check position as necessary.
    NOTE: If extreme difficulty is encountered when attempting to withdraw the sheath, place the device in a less tortuous position that enables the sheath to be retracted. Very carefully withdraw the sheath until it just begins to retract, and stop. Move back to original position and continue deployment.
11. Verify graft position and, if necessary, adjust it forward. Recheck graft position with angiography.
12. While holding the black gripper, turn the black safety-lock knob in the direction of the arrow until a slight click is felt, indicating that the blue rotation handle is engaged. (**Fig. 9**) Make sure the black safety-lock knob is in the unlocked position.
13. Under fluoroscopy, turn the blue rotation handle in the direction of the arrow until a stop is felt. (**Fig. 10**) This indicates that the proximal end of the graft has opened, and that the distal attachment to the introducer has been released.
    NOTE: If the blue rotation handle stops before completing the rotation, verify the position of the black safety-lock knob and, if necessary, turn it counterclockwise to the unlocked position.
    NOTE: If the black safety-lock knob is removed from the system after it has been turned counterclockwise to the unlocked position, the blue rotation handle will remain engaged. Continue with the procedure.
    NOTE: If difficulty is still encountered during rotating the blue rotation handle, refer to **Section 13, RELEASE TROUBLESHOOTING** for instructions on how to disassemble the blue rotation handle.
14. Remove the inner introduction system entirely, leaving the sheath and wire guide in place.
    CAUTION: To avoid entangling any catheters left in situ, rotate the introduction system during withdrawal.
15. Close the Captor Hemostatic Valve on the Flexor Introducer Sheath by turning it in a clockwise direction until it stops.

11.2.3 Distal Extension Molding Balloon Insertion – Optional

1. Prepare the molding balloon as follows and/or per the manufacturer's instructions:
   - Flush the wire lumen with heparinized saline.
   - Remove all air from the balloon.
2. In preparation for insertion of the molding balloon, open the Captor Hemostatic Valve by turning it counterclockwise. (**Fig. 7**)
3. Advance the molding balloon over the wire guide and through the Captor Hemostatic Valve of the introduction system to the level of the distal component/distal extension overlap. Maintain proper sheath positioning.
4. Tighten the Captor Hemostatic Valve around the molding balloon with gentle pressure by turning it clockwise.
   CAUTION: Do not inflate balloon in the aorta outside of the graft.
5. Expand the molding balloon with diluted contrast media (as directed by the manufacturer) in the area of the overlap, starting proximally and working in the distal direction.
   CAUTION: Confirm complete deflation of balloon prior to repositioning.
6. Withdraw the molding balloon to the distal fixation site and expand.
7. Loosen the Captor Hemostatic Valve, remove the molding balloon and replace it with an angiographic catheter to perform completion angiography.
8. Tighten the Captor Hemostatic Valve around the angiographic catheter with gentle pressure by turning it clockwise.
9. Remove or replace all stiff wire guides to allow aorta to resume its natural position.

11.2.4 Final Angiogram

1. Position angiographic catheter just above the level of the endovascular graft. Perform angiography to verify correct positioning. Verify patency of arch vessels and celiac trunk.
2. In the final angiogram confirm that there are no endoleaks or kinks, that the proximal and distal gold radiopaque markers are positioned to provide adequate overlap between components, and that there is sufficient graft length to maintain over time a minimum of 20 mm in proximal and distal seal.
   NOTE: If endoleaks or other problems are observed (e.g., inadequate seal length or overlap length), refer to **Section 11.2, Ancillary Devices: Distal Extension**.
3. Remove the sheaths, wires, and catheters.
4. Repair vessels and close in standard surgical fashion.

12 IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP

12.1 General

- **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 aneurysms or ulcers, or changes in the structure or position of the endovascular graft) should receive additional follow-up. Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of thoracic aneurysms or ulcers.
- Physicians should evaluate patients on an individual basis and prescribe their follow-up relative to the needs and circumstances of each individual patient. The recommended imaging schedule is presented in **Table 3**. This schedule continues to be the minimum requirement for patient follow-

up and should be maintained even in the absence of clinical symptoms (e.g., pain, numbness, weakness). Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or changes in the structure or position of the stent graft) should receive follow-up at more frequent intervals.

- Annual imaging follow-up should include thoracic device radiographs and both contrast and non-contrast CT examinations. If renal complications or other factors preclude the use of image contrast media, thoracic device radiographs and non-contrast CT may be used in combination with transesophageal echocardiography for assessment of endoleak.
- The combination of contrast and non-contrast CT imaging provides information on device migration, aneurysm diameter or ulcer depth change, endoleak, patency, tortuosity, progressive disease, fixation length, and other morphological changes.
- The thoracic device radiographs provide information on device migration and device integrity (separation between components, stent fracture, and barb separation) that may or may not be visible on CT depending on the quality of the scan.

Table 3 lists the minimum requirements for imaging follow-up for patients with the Zenith Alpha Thoracic Endovascular Graft. Patients requiring enhanced follow-up should have interim evaluations.

Table 3 – Recommended Imaging Schedule for Endograft Patients

	Angiogram	CT (contrast and non-contrast)	Thoracic Device Radiographs
Pre-procedure		X[1]	
Procedural	X		
1 month		X[2]	X
6 month		X[2]	X
12 month (annually thereafter)		X[2]	X

[1]Imaging should be performed within 6 months before the procedure.

[2]MR imaging may be used for those patients experiencing renal failure or who are otherwise unable to undergo contrast-enhanced CT, with transesophageal echocardiography being an additional option in the event of suboptimal MR imaging. For Type I or III endoleak, prompt intervention and additional follow-up post-intervention is recommended. See **Section 12.5, Additional Surveillance and Treatment.**

12.2 Contrast and Non-Contrast CT Recommendations

- Image sets should include all sequential images at lowest possible slice thickness (≤ 3 mm). Do NOT perform large slice thickness (> 3 mm) and/or omit consecutive CT image sets, as it prevents precise anatomical and device comparisons over time
- The same scan parameters (i.e., spacing, thickness, and FOV) should be used at each follow-up. Do not change the scan table x- or y- coordinates while scanning.
- Sequences must have matching or corresponding table positions. It is important to follow acceptable imaging protocols during the CT exam.

Table 4 lists examples of acceptable imaging protocols.

Table 4 – Acceptable Imaging Protocols

	Non-contrast	Contrast
IV contrast	No	Yes
Acceptable machines	Spiral CT or high performance MDCT capable of > 40 seconds	Spiral CT or high performance MDCT capable of > 40 seconds
Injection volume	n/a	Per institutional protocol
Injection rate	n/a	> 2.5 mL/sec
Injection mode	n/a	Power
Bolus timing	n/a	Test bolus: Smart Prep, C.A.R.E. or equivalent
Coverage - start	Neck	Subclavian aorta
Coverage - finish	Diaphragm	Profunda femoris origin
Collimation	< 3 mm	< 3 mm
Reconstruction	2.5 mm throughout - soft algorithm	2.5 mm throughout - soft algorithm
Axial DFOV	32 cm	32 cm
Post-injection runs	None	None

12.3 Thoracic Device Radiographs

The following films are required: supine-frontal (AP), cross-table lateral, 30 degree RPO, and 30 degree LPO.

Follow the following protocols during each examination:

- Record the table-to-film distance and use the same distance at each subsequent examination.
- Ensure entire device is captured on each single image format lengthwise.
- The middle photocell, thoracic spine technique, or manual technique should be used for all views to ensure adequate penetration of the mediastinum.

If there is any concern about the device integrity (e.g., kinking, stent breaks, barb separation, relative component migration), it is recommended to use magnified views. The attending physician should evaluate films for device integrity (entire device length, including components) using 2-4X magnification visual aid.

12.4 MRI Safety Information

Nonclinical testing has demonstrated that the Zenith Alpha Thoracic Endovascular Graft is MR Conditional according to ASTM F2503. A patient with this endovascular graft can be scanned safely after placement under the following conditions.

- Static magnetic field of 1.5 or 3.0 tesla
- Maximum spatial magnetic field of 1600 gauss/cm (16.0 T/m) or less
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of ≤ 2 W/kg (normal operating mode) for 15 minutes of continuous scanning

Under the scan conditions defined above, the Zenith Alpha Thoracic Endovascular Graft is expected to produce a maximum temperature rise of less than 2.1 °C after 15 minutes of continuous scanning.

In nonclinical testing, the image artifact caused by the device extends approximately 5 mm from the Zenith Alpha Thoracic Endovascular Graft when imaged with a gradient echo pulse sequence and a 3.0 T MR system. The image artifact obscures a portion of the device lumen.

For U.S. Patients Only

Cook recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation. The MedicAlert Foundation can be contacted in the following manners:

Mail:	MedicAlert Foundation International 2323 Colorado Avenue Turlock, CA 95382
Phone:	888.633.4298 (toll-free) 209.668.3333 from outside the US
Fax:	209.669.2450
Web:	www.medicalert.org

12.5 Additional Surveillance and Treatment

(Refer to **Section 4, WARNINGS AND PRECAUTIONS**)

Additional surveillance and possible treatment is recommended for:

- Type I endoleak
- Type III endoleak
- Aneurysm or ulcer enlargement ≥ 5 mm of maximum aneurysm diameter or ulcer depth (regardless of endoleak status)
- Migration
- Inadequate seal length
- Graft thrombosis or occlusion
- Loss of device integrity
  - barb separation
  - stent fracture
  - relative component migration

Consideration for reintervention or conversion to open repair should include the attending physician's assessment of an individual patient's comorbidities, life expectancy, and the patient's personal choices. Patients should be counseled that subsequent reinterventions, including catheter based and open surgical conversion, are possible following endograft placement.

13 RELEASE TROUBLESHOOTING

NOTE: Technical assistance from a Cook product specialist may be obtained by contacting your local Cook representative.

13.1 Difficulty Removing Release Wires

Turning the blue rotation handle pulls the release wire back, releasing the stent graft attachment to the introducer. If the stent graft is not completely released, it is possible to disassemble the blue rotation handle by following the steps below:

1. Use surgical forceps to pull the back-end clips out (**Fig. 17** and **18**) and remove the back-end cap. (**Fig. 19**)
2. Stabilize the gray positioner and slide the blue rotation handle backward to pull the release wires until the graft is released. Do not pull the release wires completely out of the blue rotation handle. (**Fig. 20** and **21**)
3. If leakage through the valve occurs, remove the inner introduction system entirely, leaving the sheath and wire guide in place.
4. Close the Captor Hemostatic Valve on the Flexor Introducer Sheath by turning it to the closed position.

   NOTE: If extreme force is needed, wind the release wires around the surgical forceps. (**Fig. 22**)

13.2 Distal Component - Bare Stent Deployment

If the bare stent cannot be fully deployed from the cap: (**Fig. 23**)

1. Advance the Flexor sheath to the distal edge of the stent graft. (**Fig. 24** and **25**)
2. Stabilize the Flexor sheath and pull back the blue rotation handle. (**Fig. 26**) The bare stent will now be released from the cap but still be inside the sheath. Withdraw the sheath slowly with a rotating movement (**Fig. 27**) until the bare stent is outside the sheath.

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