Zenith Alpha™ Thoracic Endovascular Graft

Instructions for Use
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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

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
**INDICATIONS FOR USE**

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 or in combination with a distal (or ulterior) component. The graft components are constructed of woven polyester fabric sewn to a non-cutting polyester seam (endo-texture). A sliding wire guide consists of a polypropylene suture (Fig.1). Both components are fully stented to provide stability and the expandable 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 facilitate deployment, a flange is positioned on each end of the proximal and distal components. Markers are placed on stent-apex 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 complete deployment 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 graft component is inserted into the iliac arteries and thoracic aorta. In addition, the nitinol stents are attached to the distal and proximal components to provide the necessary attachment and seal of the graft to the vessel wall. On devices with diameters of 40-46 mm, the proximal sealing stent remains constrained to ensure alignment with the inner curvature of the aorta.

**2.4 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 thoracic 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 extending the graft to the aortic arch (with or without arch (transposition) or arch wrapping). The grafts should be selected to cover the aneurysm 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 is required for deployment of the Zenith Alpha Thoracic Graft. The distal length measurements are critical to the performance of the endovascular repair. In practice, a large increase in seal length may be necessary to cover the aneurysm ulcer on the inner curvature, there is a risk that the graft may be deployed in an angulated configuration.

- Adequate iliac or femoral access is required to introduce the device into the vasculature. Careful evaluation of vessel size, anatomy, and disease state of the iliac arteries and femoral vessels is required for safe device deployment. A significant degree of arterial wall inflammation, arterial wall, or increase in arterial diameter may compromise the fixation length (vessel and component overlap) and/or endoleak. An appropriate vascular conduit technique may be necessary to achieve access in some patients.

- Key contraindications for the Zenith Alpha Thoracic Endovascular Exclusion of the thoracic aneurysm or ulcer may include severe angulation (radius of curvature < 20 mm and local angulation > 45 degrees); acute wall thickening (greater than 20 mm); an inverted funnel shape at the proximal fixation site or a funnel shape at the distal fixation site (greater than a 10 degrees in diameter change over 20 mm of fixation site length); and circumferential calcification or calcification at the arterial fixation sites. Irregular calcification and/or plaque may make the proximal fixation site difficult to access. The presence of anatomical limitations, a longer neck length may be required to obtain adequate sealing and fixation. Neck exhibiting these key anatomical 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 grafts around the arch.

- The safety and effectiveness of the Zenith Alpha Thoracic Endovascular Graft has not yet been established in the following patient populations:
  - Infective, mycotic, or inflammatory aneurysms
  - Aneurysms or inflamed aneurysms
  - Diagnosed or suspected genetic connective tissue disease (e.g., Marfan’s or Ehlers-Danlos Syndrome)
  - Dissections
  - Femoral arteries that are atrophic, fibrotic, or calcified
  - Patients who are pregnant, breastfeeding, or planning to become pregnant
  - Patients who are at risk of bleeding
  - Patients who have a condition that threatens to infect the endovascular graft
  - Patients with known sensitivities or allergies to polyester, polypropylene, or nitinol.

- The Zenith Alpha Thoracic Endovascular Graft is not recommended for patients who are at risk for intimal rejection or are unsuitable for intensive care and/or intensive rehospitalization.

- The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular exclusion techniques (and the components of the procedure) need further refinement and improvement prior to the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or development of aortitis or inflammatory aneurysms) may receive enhanced follow-up. Specific follow-up guidelines are described in Section 12, IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP. All patients should be monitored for any adverse clinical change in the course of their and the integrity of the endoprostheses.

- The Zenith Alpha Thoracic Endovascular Graft is not recommended for patients who are unsuitable for or cannot tolerate open surgical repair, including those who are at risk for or increase the risk of embolization. A vascular conduit technique may be necessary to achieve access in some patients.

**Guidelines and Postoperative Follow-up**

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 (surgical and non-surgical) and experienced in the use of endovascular grafts. Specific training and supporting expertise are described in Section 10, Physician Training.

- The Zenith Alpha Thoracic Endovascular Graft should be used in conjunction with open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms or ulcers, unacceptable decrease in lumen size (length) of the aorta or iliac or subclavian/ends. An increase in aneurysm or ulcer size and/or persistent endoleak or migration may lead to rupture or dissection.

- Patients experiencing leaks or reduced blood flow through the graft may be required to undergo secondary endovascular interventions or surgical procedures.

- There is a potential for a catastrophic clinical event, such as rupture or dissection, that may lead to significant morbidity or mortality.

- The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular exclusion techniques (and the components of the procedure) need further refinement and improvement prior to the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or development of aortitis or inflammatory aneurysms) may receive enhanced follow-up. Specific follow-up guidelines are described in Section 12, IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP. All patients should be monitored for any adverse clinical change in the course of their and the integrity of the endoprostheses.

- The Zenith Alpha Thoracic Endovascular Graft is not recommended for patients who are unsuitable for or cannot tolerate open surgical repair, including those who are at risk for or increase the risk of embolization. A vascular conduit technique may be necessary to achieve access in some patients.
enhanced spiral CTA with 3D reconstruction is not available, the patient should be referred to a facility with these capabilities.

- Clinicians recommend positioning the r-a-C arm during procedural angiography to facilitate passage of the introduction system 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 curvature. Diameter measurements should be determined from the arc’s outside wall and proximal to the aneurysm or ulcer. The spiral CTA scan must include the entire aneurysm and the thoracic aortic arch. The spiral CTA scan may include the great vessels through the femoral head at an axial slice thickness of 3 mm or less. CTA measurements should be based on these cutaneous measurements.
- Clinical experience has shown that temporary changes in aortic diameter may occur during blood pressure measurement on preoperative, inadequate sizing, and increased risks of graft complications, migration and endoleak. If preoperative CTA is done during hemodynamic instability, report graft size 10% below the reference CTA for the purpose of the procedure to confirm diameter measurements. If there is significant peripheral artery disease, a dedicated aortography or aortogram of the aneurysm should not be counted in the diameter measurement, as there is a risk of compression in the arch.
- Length: Clinical experience indicates that 3D CTA reconstructions is the strongly recommended imaging modality to accurately assess proximal and distal lengths and the appropriate sizes of the Zenith Alpha Thoracic Endovascular Graft. These reconstructions should be performed in sagittal, coronal, and varying oblique planes 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 aneurysm, if present.

**NOTE:** The greatest 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 area of the arch.

**NOTE:** Large aneurysms and difficult anatomy may require extra care in catheter, or graft damage may occur. Exercise particular care in areas of stenosis, intravascular thrombosis, or calcified or tortuous vessels.

### 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 Details) and component type/length (as stated below and in Section 10.6, Device Length Sizing Guide) is strongly recommended for events (e.g., migration, endoleak, aneurysm growth) that could result from selecting inappropriate device sizes.

<table>
<thead>
<tr>
<th>Table 1 and 2</th>
<th>Inappropriate device oversizing.</th>
<th>Outside of the recommendations provided in Tables 1 and 2, which include the use of a single component for aortic arch repair, it is not recommended to select 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 section in the Summary of Clinical Data for device infolding, or compression may also occur.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Length</strong></td>
<td><strong>Graft length</strong> should not be less than 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.</td>
<td></td>
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<tr>
<td><strong>Two-component repair (proximal and distal component)</strong></td>
<td>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). 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. Both components should be in contact with the vessel wall. Device lengths should be selected accordingly.</td>
<td></td>
</tr>
<tr>
<td><strong>If an acceptable sizing guide is not available</strong></td>
<td>The Zenith Alpha Endovascular Graft incorporates an uncovered 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.</td>
<td></td>
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</table>

**NOTE:** When using a distal component, take care to avoid landing the distal bare stent in tortuous anatomy (i.e., localized angulation > 45°).

- **Unless medically indicated, do not deploy the Zenith Alpha Thoracic Endovascular Graft in a location that may result in the inability to supply blood flow to organs or extremities. Do not cover significant or mesenteric arteries (an exception may be the left subclavian artery) with the aortic component. Be sure to check that the graft is not at risk of being covered to the device, the clinician should be aware of the possibility of compromised cerebral and upper limb circulation and collateral circulation to the spinal cord.**

- **To take care not to advance the sheath while the stent graft is still within it.**

- **Do not attempt to reload 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 injury to 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 seal sites are apposed, that there is adequate overlap between components, and that there is sufficient graft length to maintain over a time maximum of 20 mm in proximal and distal seal.**

**NOTE:** If endoleaks or other problems are observed (i.e., inadequate seal length), refer to Section 11.2, Ancillary Devices: Distal Extension.

**In the event that reintervention (recanulization) of the graft is necessary, avoid damaging the graft or disturbing the graft’s position.**

### 4.6 Molding Balloons Use – Optional

- **Do not inflate the balloon in the aorta outside of the device, 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 (i.e., refer to Section 11.1, Ancillary Devices: Molding Balloon label).**

- **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

- **Technical information has demonstrated that the Zenith Alpha Thoracic Endovascular Graft is MRI Conditional according to ASTM F2103. A patient with this endovascular graft can be scanned safely in a 1.5 T or 3 T MRI system, using the existing existing sequences (or, if otherwise, refer to Section 12.4, MRI Safety Information).**

### 5 POTENTIAL ADVERSE EVENTS

- **Aneurysm or ulcer growth, or increased risk of thrombosis.**

- **Aortic damage, including perforation, dissection, bleeding, rupture and death.**

- **Aortic valve damage**

- **Aortic regurgitation**

- **Aneurysm enlargement**

- **Aneurysm rupture and death**

- **Arteriovenous fistula**

- **Arterial or venous thrombosis and or pseudoaneurysm**

- **Arterial thrombosis**

- **Bleeding, hematoma, or coagulopathy**

- **Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)**

- **Cardiac complications and subsequent attendant problems (e.g., arrhythmia, hypertension)**

- **Cerebrovascular complications (e.g., stroke, subarachnoid hemorrhage)**

- **Cerebral ischemia**

- **Death**

- **Edema**

- **Embolization (micro and macro) with transient or permanent ischemia or infarction**

- **Endoleak**

- **Endoabdominal aortic aneurysm (EAA) with evidence of growth and/or rupture**

- **Extravasation (micro and macro) with transient or permanent ischemia or infarction**

- **Interventional device embolization, or dislodgment, of the introducer system, or introduction system if the introducer system fails to advance or cause the aneurysm or ulcer to move.**

- **Inferior vena cava (IVC) involvement or rupture**

- **Laparotomy**

- **Ligation**

- **Lung complications (e.g., pneumonia, pulmonary embolism, pleural effusion)**

- **Perioperative morbidity**

- **Pseudoaneurysm**

- **Renal complications (e.g., acute kidney injury)**

- **Sepsis**

- **Spinal cord complications**

- **Systemic complications**

- **Thromboembolic event**

- **Vascular complications (e.g., dissection, pseudoaneurysm, rupture)**
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.

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 Individualized Treatment

Cook recommends that the Zenith Alpha Thoracic Endovascular Graft component diameters be selected as described in Tables 1 and 2. All lengths are the minimum diameters that must be chosen for the component to be available to the physician, especially when preoperative case planning measurements (treatment diameters and lengths) are not certain. This approach provides 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 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 open repair, regional, or local anesthesia
• Ability and willingness to undergo and comply with the required follow-up
• Inferior vena cava size and anatomy (thrombus, calcification and/or tortuosity) should be assessed. Measurements of access cannus and accessories and of the delivery profile of a 16 French (Fr) MD OD to 20 French (Fr) MD OD vascular interventional system
• Vascular anatomy suitable for endovascular repair, including:
  • radius of curvature greater than or equal to 20 mm along the entire length of the aneurysm
  • Nonaneurysmal aortic segments (fixation sites) proximal and distal to the thoracic aneurysm or ulcer
  • 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
• Wound complications and subsequent problems (e.g., dehiscence, infection)

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

8 PATIENT COUNSELING INFORMATION

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

• Endovascular graft: improper component placement, incomplete component deployment, component migration or separation, suture break, occlusion, infection, stent fracture, stress corrosion, graft material wear, flattening, erasure, puncture, penitrate flap, backup stent
• Femoral neuroatherosis
• Fever and localized inflammation
• Hemodynamic compromise and subsequent attendant problems (e.g., ischemia, occlusion, limb-threatening ischemia)
• Nonaneurysmal aortic segments (fixation sites) proximal and distal to the thoracic aneurysm or ulcer
• Vascular access site complications, including infection, hematoma, pseudoneurom, pseudoaneurysm
• Vascular space or vascular trauma (e.g., femoral vessel dissection, bleeding, rupture, death)
• Vein damage

• Due to the imaging required for successful placement and follow-up of endovascular device, the risk of radiation exposure to developing tissue should be discussed with women who are or may be pregnant. Men undergoing endovascular or open surgical repair may experience impotence.

The physician should complete the Patient ID Card and give it to the patient so that the device is properly identified. The patient should refer to the card any time he/she visits additional health practitioners, particularly for any additional data collection procedures (e.g., MRI).

9 HOW SUPPLIED

• The Zenith Alpha Thoracic Endovascular Graft is sterilized by ethylene oxide gas, is preloaded into 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 package after opening to verify that no damage has occurred as a result of a shipping. Do not use this device if damage has occurred or if the sterility seal is broken or if the package is damaged. 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 to reach the device to the order prescribed by the physician for that particular patient.
• The device is labeled in English. Use 16 French or 20 French 0.035 inch wire introducer sheath. Its surface is treated with a hydrophilic coating that, when hydrated, enhances tractability. To achieve the hydrophilic coating, the outer surface may be impregnated 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 reinvention 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 open surgical.

A multidisciplinary team that has combined procedural experience with:

• Femoral and brachial cutdown, arteriotomy, and repair or conduit technique Pericardiocentesis for greater intraoperative flexibility.

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 rescue and 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 seal is broken or if the package is damaged. 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 to match 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
• Heparized saline solution
• Sterile gauze pads

10.4 Materials Recommended

The following products are recommended for implantation of any component in the Zenith Alpha Thoracic Endovascular Graft system. The following materials do not come with these products, refer to the individual product’s Suggested Instructions for Use:

• 0.035 inch (0.89 mm) extra stiff wire guide, 200/300 cm (Cook)
• Cook© Extra Stiff Wire Guide (EXGW)©
• Cook Amplatz Ultra Stiff Wire Guides (UAW)©
• 0.035 inch (0.89 mm) standard wire guide: Cook© .035 wire guide wire
• Cook© .035 inch Benton Wire Guide
• Cook© Nimble Wire Guides
• Cook® Introducer Set
• Cook CheckFl® Introducer Sets
• Cook© Oral Catheters
• Sizing catheters
• Cook® Aurora® Centimeter Sizing Catheters
• Anagographic radiopaque contrast media
• Cook Beacon® Tip Angiographic Catheters
• Cook Beacon® Tip Royal Flush Catheters, 125 cm Entry
• Cook® single-wall entry needles
• Endovascular dilators
• Cook© endovascular dilator sets

10.5 Device Diameter Sizing Guidelines

The choice of device diameter should be determined from the outer-wall-to-outer-wall vessel diameter and not the lumen diameter. Under sizing (as observed during the Device Performance sections in the summary of clinical data) or oversizing may result in incomplete seat or compromised flow in the target vessel. The physician should choose the diameter of the device based on the inclusion criteria of the device summary, particularly when in curved segments of the aorta, measure the radius of curvature greater than or equal to 20 mm along the entire length of the aneurysm
• Nonaneurysmal aortic segments (fixation sites) proximal and distal to the thoracic aneurysm or ulcer
• Vascular access site complications, including infection, hematoma, pseudoneurom, pseudoaneurysm
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>
<thead>
<tr>
<th>Intended Aortic Vessel Diameter**</th>
<th>Graft Diameter mm</th>
<th>Overall Length of Proximal Component mm</th>
<th>Overall Length of Distal Component mm</th>
<th>Overall Length of Tapered Proximal Component mm</th>
<th>Introducer Sheath Fr</th>
<th>Introducer Sheath Outer Diameter (OD) mm</th>
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<tbody>
<tr>
<td>20</td>
<td>24</td>
<td>105/127**</td>
<td>n/a</td>
<td>n/a</td>
<td>16</td>
<td>6.0</td>
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<td>105/127**</td>
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*All dimensions are nominal.
**Non stock items.
1Maximum diameter along the fixation site, measured outer-wall to-outer-wall.
2Round the measured aortic diameter to the nearest mm.
3Additional considerations may affect the choice of diameter.

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.
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 withdrawn. Vary the position of 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 clockwise direction (so that the proximal end of the graft is not released from the introduction system when you introduce it). Allow the device to decrease the patient's mean arterial pressure to approximately 60-70 mm Hg (app. 80 mm Hg at the discretion of the physician).

CAUTION: To avoid inadvertent deployment of the graft during withdrawal, make sure the appropriate amount of overlap is maintained. Decrease the patient's mean arterial pressure to approximately 80 mm Hg (at the discretion of the physician).

CAUTION: Avoid entangling any catheters left in situ, rotate the introducer system during withdrawal.

NOTE: Inaccuracies in device size selection or placement, changes or anatomical variants necessitate placement of additional endovascular grafts and extensions to achieve the minimum length of proximal and distal seal and length of overlap between components.

11.3 Placement of Distal Component

If the angiographic catheter is placed in the femoral artery, it should be repositioned to demonstrate the iliac anatomy where the distal component is to be deployed.

1. Introduce the fully hydrated endovascular graft system over the wire guide until the device is at the desired position. If necessary, deploy the distal endovascular graft and then advance the proximal endovascular graft.

2. Make sure the black safety-lock knob is in the unlocked position. Prior to complete unsheathing of the graft, check the configuration of the distal endovascular graft at the entry site before advancing the introducer sheath. (Fig. 12)

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 black rotation handle will remain engageable in 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 the barbs to perforate the introducer sheath.

3. Check the graft position by angiography and adjust if necessary.

4. Ensure the Captor Hemostatic Valve is on the Fluoroscopy Introducer Sheath is turned to the open position. (Fig. 7)

5. Stabilize the grey positioner (introduction system shaft) and begin withdrawing the stent graft.

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: As the sheath is withdrawn, 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 care must be taken to avoid wall damage.

14. Remove the introducer system, leave the wire guide in the graft.

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

NOTE: Inaccuracies in device size selection or placement, changes or anatomical variants necessitate placement of additional endovascular grafts and extensions to achieve the minimum length of proximal and distal seal and length of overlap between components.

10.6 Device Length Sizing Guidelines

• Femoral access vessel and anatomy (minimal thrombus, calcium and/or tortuosity) should be compatible with vascular access techniques and stent systems. Adequate control technique is 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.

• Aortic neck diameter that is 4 mm or more than the distal neck diameter requires the use of a proximal tapered component.

• No localized angulation (in aneurysms and tortuosity) should be compatible with vascular access techniques and stent systems in the summary of clinical data from the aneurysm/ulcer study).

• In aneurysms the graft may settle into the greater curve of the aneurysm, plus a minimum 20 mm sealing zones at both ends when positioned in the proximal and distal end components (so that the proximal end of the graft is not released from the introduction system when you introduce it) (Fig. 4)

NOTE: If the anatomy is difficult, consider using a brachial-femoral approach.

6. Remove the pigtail 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 fully hydrated endovascular system over the wire guide and advance to achieve configuration (Fig. 13)

CAUTION: To avoid inadvertent deployment of the graft during withdrawal, make sure the appropriate amount of overlap is maintained. Decrease the patient's mean arterial pressure to approximately 80 mm Hg (at the discretion of the physician).

CAUTION: Avoid entangling any catheters left in situ, rotate the introducer system when you introduce it. Allow the device to decrease the patient's mean arterial pressure to approximately 80 mm Hg (at the discretion of the physician).

NOTE: Care should be taken to avoid landing the bent stent in regions of localized angulation > 45 degrees. If the bent 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

1. Remove the yellow-hubbed inner stylet from the dilator tip. Verify that the correct device has been selected.

2. Expose the femoral artery using standard surgical technique.

CAUTION: To avoid entangling any catheters left in situ, rotate the introducer system when you introduce it. Allow the device to decrease the patient's mean arterial pressure to approximately 80 mm Hg (at the discretion of the physician).

NOTE: Extreme care should be taken with the catheter that the stent graft is still within it. Advancing the sheath at this stage may cause the stent to deploy prematurely.

9. Ensure that the Captor Hemostatic Valve on the Fluoroscopy Introducer Sheath is turned to the open position. (Fig. 7)

10. Stabilize the grey positioner (introduction system shaft) and withdraw the sheath until the graft is fully expanded and the valve assembly with the Captor Sleeve locks 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 maximal overlap. (so that the proximal end of the graft is not released from the introduction system when you introduce it).

NOTE: Use of a stiff .035 inch, 260/300 cm, LESDC wire guide is recommended.

NOTE: Make sure the black safety-lock knob is in the unlocked position.

NOTE: Verify that the introducer sheath has been turned clockwise to the unlocked position, the blue rotation handgrip is set to the open position. (so that the proximal end of the graft is not released from the introduction system when you introduce it). Verify that the device has been flushed 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 to achieve configuration.

4. Give systemic heparin. Flush all catheters and wet all wire guides with heparinized saline. Reflush catheters and rewet wire guides after each exchange.

3. Expose the femoral artery using standard surgical technique.

2. Perform angiography at the appropriate level. If using radiopaque markers, mark the aorta, aneurysm, and angiography, as observed in the clinical study (refer to the Device Performance sections in the summary of clinical data from the aneurysm/ulcer study).

1. Refer to institutional protocols relating to anesthesia, anticoagulation, and sedation.

NOTE: Extreme care should be taken with the catheter that the stent graft is still within it. Advancing the sheath at this stage may cause the stent to deploy prematurely.

NOTE: CAUTION: To avoid entangling any catheters left in situ, rotate the introducer system when you introduce it. Allow the device to decrease the patient's mean arterial pressure to approximately 80 mm Hg (at the discretion of the physician).

NOTE: Extreme care should be taken with the catheter that the stent graft is still within it. Advancing the sheath at this stage may cause the stent to deploy prematurely.

NOTE: To avoid entangling any catheters left in situ, rotate the introducer system when you introduce it. Allow the device to decrease the patient's mean arterial pressure to approximately 80 mm Hg (at the discretion of the physician).

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11.2 Ancillary Devices: Distal Extension

11.2.1 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 below procedure provides specific instructions for the maintenance of the graft and previously in this document. It is vital to maintain wire guide access. Standard technique for the maintenance of the guiding catheter, angio catheters, and wire guides is employed using the Zenith Alpha Thoracic Endovascular Graft ancillary devices. The Zenith Alpha Thoracic Endovascular Graft ancillary devices are compatible with 0.35 inch diameter wire guides. Proximal main body components may overlap an extra-graft coverage proximally. Distal extensions are used to extend the distal end of an endovascular graft or to increase the length of overlap between graft components.

11.2.1.1 Distal Extension Preparation/Flush

1. Remove the yellow and white sheath over the dilator tip. Verify that the Captor Sleeve is within the Captor Hemostatic Valve; do not remove the Captor Sleeve.
2. Elevate distal tip of system and flush through the hemostatic valve until fluid exits the tip of the introducer sheath. (Fig. 8) Continue to inject a full 60 mL of flushing solution through the dilator. Discontinue injection and close the stopcock on the connecting tube.

NOTE: Graft flushing solution of heparinized saline is often used.

3. Attach a vacuum system to the black telescoping gripper on the hub of the blue rotation handle. (Fig. 6) Flush until fluid exits the distal sideports and dilator tip.
4. Suck out any gauze pads with saline and use the sterile saline free Fluoroscopic Sheath to achive a hydraulic locking back over both sheath and dilator liberally.

11.2.2 Placement of the Distal Extension

1. Perform the selected distal extension technique with an 18 gauge access needle. Alternatively, use the in situ wire guide that was used previously for introduction system/graft mainteance. Upon vessel entry, insert:
   - Wire guide (standard 0.035 inch, 260/300 cm, 15 mm J tip or Bentzon).
   - Appropriate-sized dilation balloon (if balloon has not turned over, 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, rotate the wire guide and advance the stent into the new proximal fixation seal site. Maintain proper sheath positioning.

15. Close the Captor Hemostatic Valve on the Flexor Introducer Sheath by turning it to the closed position.

CAUTION: Do not inflate balloon in the aorta outside of the graft. EXP: If endoleaks or other problems are observed (e.g., inadequate seal length or overlap length), refer to 11.2.4 Final Angiogram.

6. Remove the pigtail flush catheter and sheath.

7. Loosen the Captor Hemostatic Valve, remove the molding balloon guide in place.


9. Ensure the Captor Hemostatic Valve on the Flexor Introducer Sheath is turned counterclockwise to the unlock position. (Fig. 7) Stabilize black gray stopcock in the introducer sheath and withdraw the sheath until the graft is fully expanded and the valve assembly with the Captor Sleeve doks with the black gripper. (Fig. 8)

CAUTION: The sheath tip is not radioscopy, anatomy and graft feature may change. Constantly monitor graft position and perform angiography to check position.

11.2.2.1 Final Angiogram

1. Position angiographic catheter just above the level of the endovascular graft. (Fig. 7) Perform an angiogram to verify correct position and confirmation of the proximal fixation seal site. Maintain proper sheath positioning.

2. Advance the molding balloon over the wire guide and through the hemostatic valve of the introducer system to the level of the proximal fixation seal site. Maintain proper sheath positioning.

3. Tighten the Captor Hemostatic Valve around the angiographic catheter with gentle pressure by turning it clockwise.

4. Remove or replace all stiff wire guides to allow the aorta to resume its natural position.

11.2.2.2 Distal Extension Molding Balloon Insertion – Optional

1. Position angiographic catheter just above the level of the endovascular graft. (Fig. 7) Perform an angiogram to verify correct position and confirmation of the proximal fixation seal site. Maintain proper sheath positioning.

4. Repair vessels and close in standard surgical fashion.

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 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 introducer system to the level of the proximal fixation seal site. Maintain proper sheath positioning.

4. Tighten the Captor Hemostatic Valve around the angiographic catheter with gentle pressure by turning it clockwise.

5. Make sure that the blue rotation handle is clockwise and the black telescoping gripper is locked in the blue rotation handle. (Fig. 10) This indicates that the proximal end of the graft has been opened and that the distal attachment to the introducer has been released.

6. If the blue rotation handle stops before completing the rotation, verify the orientation of the black gray stopcock in the introducer sheath. If the black gray stopcock has not been turned counterclockwise to the unlocked position, the blue rotation handle will remain engaged. Continue with the procedure.

7. Once the Captor Hemostatic Valve is turned clockwise, the black gray stopcock in the introducer sheath is turned counterclockwise to the unlocked position.

8. Remove all air from the balloon.

9. In preparation for insertion of the molding balloon, open the Captor Hemostatic Valve by turning it counterclockwise. (Fig. 7)

3. Advane the molding balloon over the wire guide and through the Captor Hemostatic Valve by turning it clockwise. (Fig. 7)

4. Remove the pigtail flush catheter and sheath.

5. Loosen the Captor Hemostatic Valve, remove the molding balloon guide in place.

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

15. Close the Captor Hemostatic Valve on the Flexor Introducer Sheath by turning it to the closed position directly, without rotating it clockwise.

11.2.4 Final Angiogram

1. Position angiographic catheter just above the level of the endovascular graft. (Fig. 7) Perform an angiogram to verify correct position and confirmation of the proximal fixation seal site. Maintain proper sheath positioning.

2. Tighten the Captor Hemostatic Valve around the angiographic catheter with gentle pressure by turning it clockwise.

3. Remove or replace all stiff wire guides to allow the aorta to resume its natural position.

11.2.4.1 Final Angiogram

1. Position angiographic catheter just above the level of the endovascular graft. (Fig. 7) Perform an angiogram to verify correct position and confirmation of the proximal fixation seal site. Maintain proper sheath positioning.

2. Tighten the Captor Hemostatic Valve around the angiographic catheter with gentle pressure by turning it clockwise.

3. Remove or replace all stiff wire guides to allow the aorta to resume its natural position.

12.1 General

The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or changes in the structure and appearance of the endovascular graft) should have 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 or aneurysm. A second opinion can also be sought at any time.

Physicians should evaluate patients on an individual basis and prescribe follow-up visits according to circumstances of each individual patient. The recommended imaging schedule is presented in Table 3.

The schedule continues to be the minimum requirement for patient follow-up.

12.1.2 Imaging Guidelines and Postoperative Follow-Up

1. General

The importance of follow-up for endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or changes in the structure and appearance of the endovascular graft) should have follow-up.

Patients should be informed of 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 or aneurysm. A second opinion can also be sought at any time.

Physicians should evaluate patients on an individual basis and prescribe follow-up visits according to 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.
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 recent interventions 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 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.

12.5 Additional Surveillance and Treatment
(Relate to Section 4. WARNINGS AND PRECAUTIONS)
Additional surveillance and possible treatment is recommended for:

- Type I endoleak
- Type II 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
  - stem fracture
  - relative component migration

Consideration for reintervention or conversion to open repair should include the 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 conversions, 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.

1.3 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-cap (cap, Fig. 19).
2. Stabilize the gray positioning and slide the blue rotation handle backward to pull the release wires out until 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 will still be inside the sheath. Withdraw the sheath slowly with a rotating movement (Fig. 27).

Table 3 – Recommended Imaging Schedule for Endograft Patients

<table>
<thead>
<tr>
<th>CT (contrast and non-contrast)</th>
<th>Thoracic Device Radiographs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-procedure</td>
<td>X¹</td>
</tr>
<tr>
<td>Procedural</td>
<td>X</td>
</tr>
<tr>
<td>1 month</td>
<td>X²</td>
</tr>
<tr>
<td>6 month</td>
<td>X</td>
</tr>
<tr>
<td>12 months (annually thereafter)</td>
<td>X</td>
</tr>
</tbody>
</table>

¹ Imaging should be performed within 6 months before the procedure.
² 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 II endoleak, prompt intervention and additional follow-up post-intervention is recommended. See Section 12.3, Additional Surveillance and Treatment.

Table 4 – Acceptable Imaging Protocols

<table>
<thead>
<tr>
<th>Acceptable Imaging Protocols</th>
<th>Non-contrast</th>
<th>Contrast</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptable machines</td>
<td>Spiral CT or high performance MDCT</td>
<td>Spiral CT or high performance MDCT</td>
</tr>
<tr>
<td>Injection volume</td>
<td>mL</td>
<td>mL</td>
</tr>
<tr>
<td>Injection rate</td>
<td>mL/sec</td>
<td>&gt; 2.5 mL/sec</td>
</tr>
<tr>
<td>Injection mode</td>
<td>Power</td>
<td>Power</td>
</tr>
<tr>
<td>Bolus timing</td>
<td>Test bolus: Smart Prep, C.A.R.E or equivalent</td>
<td></td>
</tr>
<tr>
<td>Coverage - start</td>
<td>Neck</td>
<td>Subclavian artery</td>
</tr>
<tr>
<td>Coverage - finish</td>
<td>Daphnioma</td>
<td>Profunda femoris origin</td>
</tr>
<tr>
<td>Collimation</td>
<td>≤ 3 mm</td>
<td>≤ 3 mm</td>
</tr>
<tr>
<td>Reconstruction</td>
<td>2.5 mm throughout - soft algorithm</td>
<td>2.5 mm throughout - soft algorithm</td>
</tr>
<tr>
<td>Axial DFOV</td>
<td>62 cm</td>
<td>62 cm</td>
</tr>
</tbody>
</table>

Table 3

1.2 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 MRI safe for a patient with this endovascular graft can be scanned safely after placement under the following conditions:

- Static magnetic field of 1.5 to 3.0 tesla
- Maximum spatial magnetic field of 1600 gauss/cm (160 T/m) or less
- Maximum MR system reported, sinus 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.

The combination of contrast and non-contrast CT imaging provides an important tool for assessing device integrity, especially in the event of a suboptimal MR imaging. For Type I or II endoleak, prompt intervention and additional follow-up post-intervention is recommended. See Section 12.3, Additional Surveillance and Treatment.

Fig. 26
1.2 Contrast and Non-Contrast CT Recommendations
- Image sets should include all sequential images at lowest possible slice thickness (≤ 3 mm) and/or omit consecutive CT image sets, as it presumes pristine 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 or--coordinates while endoleak, patency, tortuosity, progressive disease, fixation length, and other morphological changes.
- 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.

Mail: MedicAlert Foundation International
2523 Colorado Avenue
Turlock, CA 95382
Phone: 800.668.3333 from outside the US
Fax: 200.669.2450
Web: www.medicalert.org

Table 4

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:

1.3.1 Difficulty Removing Release Wires
Turning the blue rotation handle pulls the release wire back, lifting 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-cap (cap, Fig. 19).
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Until the bare stent is outside the sheath.