Zenith Alpha™ Thoracic Endovascular Graft

Instructions for Use
TABLE OF CONTENTS

1 DEVICE DESCRIPTION ................................................. 9
  1.1 Zenith Alpha Thoracic Endovascular Graft ........................................ 9
  1.2 Introduction System .............................................................................. 9
  1.3 Zenith Alpha Thoracic Endovascular Graft Ancillary Component ................. 9

2 INDICATIONS FOR USE ............................................. 9

3 CONTRAINDICATIONS ............................................... 9

4 WARNINGS AND PRECAUTIONS .................................. 9
  4.1 General ........................................................................................................ 9
  4.2 Patient Selection, Treatment and Follow-Up ............................................. 9
  4.3 Pre-Procedural Measurement Techniques and Imaging ............................ 9
  4.4 Device Selection ......................................................................................... 10
  4.5 Implant Procedure ...................................................................................... 10
  4.6 Molding Balloon Use – Optional ............................................................... 10
  4.7 MRI Safety Information ............................................................................. 10

5 POTENTIAL ADVERSE EVENTS .............................................. 10
  Device Related Adverse Event Reporting .................................................... 11

6 SUMMARY OF CLINICAL DATA .............................................. 11

7 PATIENT SELECTION AND TREATMENT ......................... 11
  7.1 Individualization of Treatment ................................................................. 11

8 PATIENT COUNSELING INFORMATION ................................. 11

9 HOW SUPPLIED ......................................................... 11

10 CLINICAL USE INFORMATION ........................................ 11
  10.1 Physician Training ................................................................................... 11
  10.2 Patient Selection ........................................................................................ 11
  10.3 Inspection Prior to Use .............................................................................. 11
  10.4 Materials Recommended ......................................................................... 11
  10.5 Device Diameter Sizing Guidelines ........................................................ 11
  Table 1 – Proximal, Distal and Proximal Tapered Component (PT, PT) Graft Diameter Sizing Guide ......................................................... 12
  Table 2 – Distal Extension (DE) Graft Diameter Sizing Guide ....................... 12
  Table 3 – Recommended Imaging Schedule for ......................................... 14
  Table 4 – Acceptable Imaging Protocols ...................................................... 14

11 DIRECTIONS FOR USE .............................................. 13
  11.1 Proximal and Distal Component Overlap ................................................ 13
  11.2 Pre-Implant Determinants ....................................................................... 13
  11.3 Device Preparation .................................................................................... 13
  11.4 Main Body Molding Balloon Insertion – Optional ................................... 14
  11.5 Final Angiogram ...................................................................................... 14
  11.6 Distal Extension Preparation/Flush .......................................................... 14
  11.7 Distal Extension Placement ....................................................................... 14
  11.8 Distal Extension Molding Balloon Insertion – Optional ......................... 14
  11.9 Final Angiogram ...................................................................................... 14

12 IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP .... 14
  12.1 General ...................................................................................................... 14
  12.2 Thoracic Device Radiographs .................................................................. 15
  12.3 MRI Safety Information ........................................................................... 15
  12.4 Pre-Implant Determinants ....................................................................... 15
  12.5 Additional Surveillance and Treatment .................................................... 15

13 RELEASE TROUBLESHOOTING ...................................... 15
  13.1 General ...................................................................................................... 15
  13.2 Distal Component - Bare Stent Deployment ............................................ 15
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
The Zenith Alpha Thoracic Endovascular Graft is contraindicated in:

- having vascular morphology suitable for endovascular repair (treatment of patients with aneurysms or ulcers of the descending thoracic aorta
- patients experiencing enlarging aneurysms or ulcer\n- if occlusion of the left subclavian artery ostium is required to obtain access into the thoracic aorta, 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 the Zenith Thoracic Endovascular Graft has been established in young patients and patients performing extreme sports.

- the structural integrity of the device.

- the Zenith Alpha Thoracic Endovascular Graft is not recommended for patients who cannot tolerate the procedure for intraprocedural and postoperative follow-up imaging, or who are unable to undergo, or will not be compliant with, the necessary preoperative and postoperative imaging needed to achieve optimal procedural outcomes.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure 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 lifelong follow-up and should be informed of the indications and the performance of their endovascular graft.

- patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or ulcers, or intimal hyperplasia) or who are at high risk for reflux or dissection.

- the structural integrity of the device.

- the procedure may increase the risk of paraplegia or paraparesis where graft exclusion covers the origins of dominant spinal cord or intercostal arteries.
enhanced spiral CT with 3D reconstruction is not available, the patient may change. Constantly monitor graft position and perform angiography to check the position as necessary.

- During sheath withdrawal, the uncovered proximal stent and covered portion of the endovascular graft should be in contact with the vessel wall. At this stage it may be possible to advance the device, but retraction may cause aortic wall injury or migration of the stent graft.

- Inadequate placement and/or incomplete sealing of the Zenith Alpha Thoracic Endovascular Graft within the vessel may result in increased risk of endoleak or migration of the unsubtained portion of the self-expanding stent, left common carotid, and/or carotid arteries.

- Inadequate fixation of the Zenith Alpha Thoracic Endovascular Graft may result in slipped stent grafting of the migration of the stent graft, incorrect deployment or migration of the stent graft may require surgical removal.

- Land the proximal and the distal ends of the device in parallel aortic neck segments without acute angulation (i.e., < 45 degrees) or circumferential thrombus/calcification to ensure fixation and seal.

- Be sure to land the proximal and distal ends of the device in the aortic neck segment with a diameter that matches the initial sizing of the device. Landling 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 bars, and an uncovered distal stent (on the distal component) with fixation bars. 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 stent, 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 where the proximal stent would be placed 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 stent graft. There may be a risk that the stent graft may be unable to be covered to the device, the clinician should be aware of the possibility of compromising the cerebral or 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 plug at a rate which may cause the barbs to perforate the introducer sheath.

- Do not attempt to redeploy 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. To avoid this, if any catheters are 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 stent grafts are in correct position and 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 (i.e., inadequate seal length), refer to Section 11.2, Ancillary Devices: Distal Extension.

In the event that reintervention (accompanies complication) 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 calcifications. Do not exceed maximum recommended pressure. Confirm complete deflation of the balloon prior to repositioning.

- For added hemostasis, the Captor Hemostatic Valve can be Koshered or tightly taped in place to immediately occlude the distal end of the endovascular graft.

4.7 MRI Safety Information

The use of the Zenith Alpha Thoracic Endovascular Graft as described in Section 12.3, MRI Safety Information is not contraindicated. Several clinical studies have demonstrated that the Zenith Alpha Thoracic Endovascular Graft as described in Section 12.3, MRI Safety Information is not contraindicated. Several clinical studies have demonstrated that the Zenith Alpha Thoracic 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 reactions that may occur with 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
- Aortic valve disease
- Atero-ecophagial fistula
- Arterial or venous thrombosis and/or pseudoaneurysm
- Arteriovenous fistula
- Bleeding, hemostasis, or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infection, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., pulmonary embolus, myocardial infarction, congestive heart failure, hypertension, hyperotension)
- Claudication (e.g., buttock, lower limb)
- Death
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak

MR
• Endovascular graft: improper component placement, incomplete component deployment, component migration or separation, suture break, occlusion, infection, stent fracture, stent corrosion, graft material wear, dilatation, erosion, puncture, peri-graft flow, barbed suture
• Femoral neurology
• Fever and localized inflammation
• General 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., stroke, stroke, transient ischemic attack, paraplegia, paraparesis, spinal cord shock, paralysis)
• Occlusion of coronary artery
• Pulmonary embolus
• Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory distress syndrome)
• Renal complications and subsequent attendant problems (e.g., acute oliguria, acute renal 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., femoral vessel dissection, bleeding, rupture, death)
• 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. For 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 Patient Selection

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 must be available to the physician, especially when preoperative case planning measurements (treatment diameters and lengths) are not certain. This approach minimizes 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:

• Age and patient’s life expectancy
• Comorbidities (e.g., cardiac, pulmonary, or renal insufficiency related to surgery, morbidity expectancy)
• Device 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 general, regional, or local anesthesia
• Ability and willingness to undergo and comply with the required follow-up
• Biomechanical aneurysm size and morphology (thrombus, calcification and/or tortuosity) should be considered to determine aneurysm access techniques and accessories of the delivery profile of a 16 French (6 mm OD) to 20 French system (4 mm OD) vascular interventional devices
• Vascular anatomy adequate for endovascular repair, including:
  • radius of curvature greater than or equal to 20 mm along the entire length of the aorta intended for treatment
  • Nonaneurysmal aortic segments (fixation sites) proximal and distal to the thoracic aneurysm or ulcer:
    • with a diameter 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 member) 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 associated with endovascular repair
• Potential advantages of endovascular repair
• The possibility that subsequent interventional or open surgical repair of the thoracic aneurysm or ulcer may be necessary

In addition to the risks and benefits of an endovascular repair, the physician should assess the patient’s commitment to and compliance with postoperative medical management necessary to improve and maintain graft function after implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

• 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 the card may be referenced with all future evaluations. 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 packed before 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 unopened. Inspect the integrity of the package to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterility of the device is in doubt. If damage has occurred, do not use the product, instead, return to the product to Cook. See to verify, use 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 an introducer sheath. The surface is treated with a hydrophilic coating that, when hydrated, enhances trackability. To activate the hydrophilic coating, the surface must be coated with a sterile glove 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 open surgical.

A multidisciplinary team that has combined procedural experience with:

• Femoral and brachial cutdown, arteriotomy, and repair or conduit technique

• Endovascular stent and stent-graft deployment

• Surgical conversion to open repair

• Techniques to minimize radiation exposure

• Embolization

• Angioplasty

• Aneurysm stent placement

• Radiation safety

• Appropriate use of radiographic contrast material

Any adverse event (clinical incident) involving the Zenith Alpha Thoracic Endovascular Graft should be reported to Cook immediately. For an incident, call the Customer Relations Department at 800-457-4500 (24 hour) or 812.339.2235.

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 sterility of the device is in doubt. 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

• Endovascular dilators

• The Zenith Alpha Thoracic Endovascular Graft is sterilized by ethylene oxide gas.

• A selection of Zenith Alpha Thoracic Endovascular Graft distal ancillary components in diameters compatible with the proximal and distal components

• Fluorescope with digital angiography capabilities (C-arm or fixed unit)

• Contrast media

• .035 inch (0.89 mm) extra stiff wire guide, 260/300 cm:

• Cook single-wall entry needles

• Cook .035 inch wire guides

• Cook Introducer Sets

• Cook Check® Flo® Introducer Sets

• Cook Aurora® Cimeter Sizing Cather

• Cook Amplatz Ultra Stiff Wire Guides (AUS)

• Cook Aurocath® Wire gooseck

• Femoral and brachial cutdown, arteriotomy, and repair or conduit technique

Cook .035 inch (0.89 mm) extra stiff wire guide, 260/300 cm:

• Cook Amplatz Ultra Stiff Wire Guides (AUS)

• Cook Aurocath® Wire gooseck

• Cook Aurora® Cimeter Sizing Cather

• Cook Amplatz Ultra Stiff Wire Guides (AUS)

• Cook Aurocath® Wire gooseck

• Cook Aurora® Cimeter Sizing Cather

• Cook Amplatz Ultra Stiff Wire Guides (AUS)

• Cook Aurocath® Wire gooseck

• Cook Aurora® Cimeter Sizing Cather

• Cook Amplatz Ultra Stiff Wire Guides (AUS)

• Cook Aurocath® Wire gooseck

• Cook Aurora® Cimeter Sizing Cather

• Cook Amplatz Ultra Stiff Wire Guides (AUS)

• Cook Aurocath® Wire gooseck

• Cook Aurora® Cimeter Sizing Cather

• Cook Amplatz Ultra Stiff Wire Guides (AUS)

• Cook Aurocath® Wire gooseck

• Cook Aurora® Cimeter Sizing Cather

• Cook Amplatz Ultra Stiff Wire Guides (AUS)

• Cook Aurocath® Wire gooseck

• Cook Aurora® Cimeter Sizing Cather

• Cook Amplatz Ultra Stiff Wire Guides (AUS)

• Cook Aurocath® Wire gooseck

• Cook Aurora® Cimeter Sizing Cather

• Cook Amplatz Ultra Stiff Wire Guides (AUS)

• Cook Aurocath® Wire gooseck

• Cook Aurora® Cimeter Sizing Cather

• Cook Amplatz Ultra Stiff Wire Guides (AUS)

• Cook Aurocath® Wire gooseck

10.4 Materials Recommended

The following products are recommended for implantation of any component in the Zenith Alpha Thoracic Endovascular Graft. If any of these products are not included or provide endovascular dilator kit

• Endovascular dilators

10.5 Device Diameter Sizing Guidelines

The device should be determined from the outer-wall-to-out-wall vessel diameter and not the lumen diameter. Undersizing (as observed during the Device Performance sections in the summary of clinical data) or oversizing may result in incomplete sealing or compromised flow in the aneurysm neck. In the choice of graft sizing, particularly when in curved segments of the aorta, measure the

11
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*

<table>
<thead>
<tr>
<th>Intended Aortic Vessel Diameter (mm)</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>
</tr>
</thead>
<tbody>
<tr>
<td>20 24</td>
<td>105/127**</td>
<td>n/a</td>
<td>n/a</td>
<td>160/229**</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>21 24</td>
<td>105/127**</td>
<td>n/a</td>
<td>n/a</td>
<td>160/229**</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>22 26</td>
<td>105/149**</td>
<td>n/a</td>
<td>n/a</td>
<td>160/229**</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>23 26</td>
<td>105/149**</td>
<td>n/a</td>
<td>n/a</td>
<td>160/229**</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>24 28</td>
<td>109/132**/155/201</td>
<td>160/229**</td>
<td>n/a</td>
<td>160/229**</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>25 28</td>
<td>109/132**/155/201</td>
<td>160/229**</td>
<td>n/a</td>
<td>160/229**</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>26 30</td>
<td>109/132**/155/201</td>
<td>160/229**</td>
<td>108</td>
<td>160/229**</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>27 30</td>
<td>109/132**/155/201</td>
<td>160/229**</td>
<td>108</td>
<td>160/229**</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>28 32</td>
<td>109/132**/155/201</td>
<td>160/229**</td>
<td>178/201</td>
<td>160/229**</td>
<td>7.1</td>
<td>7.1</td>
</tr>
<tr>
<td>29 32</td>
<td>109/132**/155/201</td>
<td>160/229**</td>
<td>178/201</td>
<td>160/229**</td>
<td>7.1</td>
<td>7.1</td>
</tr>
<tr>
<td>30 34</td>
<td>113/137**/161/209</td>
<td>142/190</td>
<td>161/209</td>
<td>137/190</td>
<td>7.1</td>
<td>7.1</td>
</tr>
<tr>
<td>31 36</td>
<td>113/137**/161/209</td>
<td>142/190</td>
<td>161/209</td>
<td>137/190</td>
<td>7.1</td>
<td>7.1</td>
</tr>
<tr>
<td>32 36</td>
<td>113/137**/161/209</td>
<td>142/190</td>
<td>161/209</td>
<td>137/190</td>
<td>7.1</td>
<td>7.1</td>
</tr>
<tr>
<td>33 38</td>
<td>117/142**/167/217</td>
<td>147/197</td>
<td>167/217</td>
<td>142/197</td>
<td>7.1</td>
<td>7.1</td>
</tr>
<tr>
<td>34 38</td>
<td>117/142**/167/217</td>
<td>147/197</td>
<td>167/217</td>
<td>142/197</td>
<td>7.1</td>
<td>7.1</td>
</tr>
<tr>
<td>35 40</td>
<td>117/142**/167/217</td>
<td>147/197</td>
<td>167/217</td>
<td>142/197</td>
<td>7.7</td>
<td>7.7</td>
</tr>
<tr>
<td>36 40</td>
<td>117/142**/167/217</td>
<td>147/197</td>
<td>167/217</td>
<td>142/197</td>
<td>7.7</td>
<td>7.7</td>
</tr>
<tr>
<td>37 42</td>
<td>121/147**/173/225</td>
<td>152/204</td>
<td>173/225</td>
<td>147/204</td>
<td>7.7</td>
<td>7.7</td>
</tr>
<tr>
<td>38 42</td>
<td>121/147**/173/225</td>
<td>152/204</td>
<td>173/225</td>
<td>147/204</td>
<td>7.7</td>
<td>7.7</td>
</tr>
<tr>
<td>39 44</td>
<td>125/152**/179/233</td>
<td>157/211</td>
<td>179/233</td>
<td>152/211</td>
<td>7.7</td>
<td>7.7</td>
</tr>
<tr>
<td>40 46</td>
<td>125/152**/179/233</td>
<td>157/211</td>
<td>179/233</td>
<td>152/211</td>
<td>7.7</td>
<td>7.7</td>
</tr>
<tr>
<td>41 46</td>
<td>125/152**/179/233</td>
<td>157/211</td>
<td>179/233</td>
<td>152/211</td>
<td>7.7</td>
<td>7.7</td>
</tr>
<tr>
<td>42 46</td>
<td>125/152**/179/233</td>
<td>157/211</td>
<td>179/233</td>
<td>152/211</td>
<td>7.7</td>
<td>7.7</td>
</tr>
</tbody>
</table>

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

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

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

*All dimensions are nominal.
**Non stock items.
*Maximum diameter along the fixation site, measured outer-wall-to-outer-wall.
Round the measured aortic diameter to the nearest mm.
3Additional considerations may affect the choice of diameter.
11.1.1 Proximal and Distal Components Preparation/Flush

Verify from pre-implant planning that the correct device has been selected. In rare cases, incorrect device selection may occur, infrequently requiring intervention (including transfusion). 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 femoral anatomy. The Zenith Alpha Thoracic Endovascular Graft is equipped with angiographic catheters, and wire guides should be employed during use. Measurements to be taken during the pre-treatment assessment in Fig. 3.

Proximal and Distal Component Overlap

A minimum overlap of the components should be ensured; however, the proximal sealing stent of the proximal component or distal sealing stent of the distal component should not 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 malposition to the vessel wall.

NOTE

Proximal and distal neck diameters should be monitored. Localized angulation > 45 degrees. If the bare stent is landed in localized angulation, angulation, and growth as observed in the clinical study (refer to the Device Selection Section in the summary of clinical data from the aneurysm/uterus study).

11.1.2 Proximal and Distal Components Preparation/Flush

NOTE

Position the imaging table to allow fluoroscopic visualization from the aortic arch to the femoral bifurcations. Failure to do so could result in migration, and proximal and distal sealing zones at both ends even when positioned in the graft are not possible. 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. However, no part of the distal component should overlap the proximal sealing stent of the proximal component.

NOTE

If an angiographic catheter is placed in the femoral artery, it should be advanced further. The black safety-lock knob should be turned counterclockwise to the unlocked position. The blue rotation handle will remain engaged. Continue with the procedure.

NOTE

If the anatomy is difficult, consider using a brachio-femoral approach to check position as necessary.

NOTE

If the anatomy is difficult, consider using a brachio-femoral approach to check position as necessary.
If extreme difficulty is encountered when attempting to withdraw .035 inch diameter wire guides. Additional proximal main body ancillary devices are compatible previously in this document. It is vital to maintain wire guide access. Additional endovascular grafts and extensions. Regardless of the device placed, in patient anatomy, or procedural complications can require placement of 13. Close the Captor Hemostatic Valve on the Flexor Introducer Sheath by turning it in a clockwise direction.

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

11.4.1 Main Body Molding Balloon Insertion – Optional
1. Prepare the molding balloon as follows and per the manufacturer’s instructions:
   - Flush the wire lumen with heparinized saline.
   - Remove all air from the sheath.
   - In preparation for insertion of the molding balloon, open the Captor Hemostatic Valve of the main body introduction system (Fig. 5).
   - 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.
   - Tighten the Captor Hemostatic Valve around the molding balloon with gentle pressure by turning it to the closed position.

CAUTION: Do not inflate the balloon outside of the graft.
- 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.
- If applicable, withdraw the molding balloon to the proximal component/ distal component overlap and expand.
- Withdraw the molding balloon to the distal fixation site and expand.
- Open the Captor Hemostatic Valve, remove the molding balloon and replace 3 with an angiographic catheter to perform completion angiography.
- Tighten the Captor Hemostatic Valve around the angiographic catheter with gentle pressure by turning it clockwise.
- Remove or replace all stiff wire guides to allow the aorta to assume its natural position.

11.5.1 Final Angiogram
1. Position angiographic catheter just above the level of the endovascular graft. Perform angiography to verify correct positioning of the graft.

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 the two 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
Guideline Use Information: Inaccuracies in device selection or place, changes or anamnoses in patient, or procedural complications can require placement of additional endovascular devices beyond the intended endovascular device model. Regardless of the device placed, the basic procedural sequence will be similar to the maneuvers required and described previously in the main body insertion.

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 all Zenith Thoracic Endovascular Graft components. The Zenith Thoracic Endovascular Graft main body components are 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.

11.2.1 Distal Extension Preparation/Flush
1. Remove the yellow-hubbed inner stylet from the dilator tip. Verify that the Captor Valve is open in the Captor Hemostatic Valve; do not remove the Captor Valve (Fig. 4).
2. Elevate distal tip of system and flush through the hemostatic valve until fluid exits the tip of the sheath and the device is fully expanded. (Fig. 6) Continue to inject a full 60 mL of flushing solution through the device. Discontinue injection and close the stopcock.

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. 7) Using the dilator, insert the distal endoprosthetics and dilatex.
4. Soak sterile gauze pads with saline and use to wipe the Flexor Introducer Sheath to achieve the hydraulic coating. Hydrate both sheath and dilatex catheters.

11.2.2 Placement of the Distal Extension
1. Puncture the selected artery using standard technique with an 18 gauge access. Alternatively, use the wire lumen that was used previously for introduction of the guiding catheter. Using the wire entry:
   - Wire guide: standard 0.035 inch, 260/300 cm, 15 mm J-tips or Bonestra.
   - Appropriate sheath size (e.g., 3 French).
   - Pigtail flush catheter (often radiopaque-banded sizing catheters; e.g., Cook Merit 0.035 inch, 260 cm, 15 mm J-tips).
   - Perform angiography at the appropriate level. If using radiopaque markers, adjust position as necessary and repeat angiography.

5. Replace the standard wire guide with a stiff 0.035 inch, 260/300 cm, LDS 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 introduction. Alternatively, the contralateral femoral artery can be used.

7. Introduce the freely hydrated introduction system over the wire guide and advance the dilator into the graft. Stress the importance of ensuring correct distal extension overlaps the distal component by a minimum of three stents.

NOTE: To avoid twisting the endovascular graft, never rotate the introduction system when you introduce it. Allow the device to conform correct positionally to the aortic anatomy and avoid rotation.


NOTE: Ensure that the Captor Hemostatic Valve on the Flexor Introducer Sheath is turned counterclockwise to the open position. (Fig. 7).

9. Stabilize the aorta immediately with the sheath by advancing the Captor Sleeve docks with the black gripper. (Fig. 8)

CAUTION: The sheath end is withdrawn, anatomy and graft position may change. Constantly monitor graft position and perform angiography to check position.

NOTE: If extreme difficulty is encountered when attempting to withdraw the sheath, place the device in a less tortuous position that allows the sheath to retract and return in a subsequent attempt. Do not rotate.

10. If the bare stent cannot be fully released from the cap, complete the release by turning the blue rotation handle. Refer to Section 13, RELEASE TROUBLESHOOTING for instructions on how to disassemble the blue rotation handle.

11. Remove the inner introduction system entirely, leaving the sheath and wire guide in place.

12. Close the Captor Hemostatic Valve on the Flexor Introducer Sheath by turning it in a clockwise direction.

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

11.2.3 Distal Extension Molding Balloon Insertion – Optional
1. Prepare the molding balloon as follows and per the manufacturer’s instructions:
   - Flush the wire lumen with heparinized saline.
   - Remove all air from the sheath.

2. In preparation for insertion of the molding balloon, open the Captor Hemostatic Valve of the introduction system (Fig. 6).
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 the balloon outside of the graft.
- 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.
- If applicable, withdraw the molding balloon to the proximal component/ distal component overlap and expand.
- Withdraw the molding balloon to the distal fixation site and expand.
- Open the Captor Hemostatic Valve, remove the molding balloon and replace 3 with an angiographic catheter to perform completion angiography.
- Tighten the Captor Hemostatic Valve around the angiographic catheter with gentle pressure by turning it clockwise.
- Remove or replace all stiff wire guides to allow the aorta to assume 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 of the graft.

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 the two 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. Patients who receive the Zenith Thoracic Endovascular Graft system 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, local aneurysms or ulcers; changes or anamnoses in patient structure or position of the endovascular graft) should receive additional follow-up. These patients should be seen more often than those who do not have any important changes. 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 is based on patient risks and may be shorter or longer for patient follow-up.
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.

Acceptable machines

<table>
<thead>
<tr>
<th>Non-contrast</th>
<th>Contrast</th>
</tr>
</thead>
</table>
| Acceptable machines | In addition to the above, all three views should be acquired using a gradient echo pulse sequence and a 3.0 T MR system. The image artifact caused by the device extends more than 2.1 °C after 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.

12.4 MRI Safety Information
Nonclinical testing has demonstrated that the Zenith Alpha Thoracic Endovascular Graft is MR Conditional according to ASTM F1505. A patient with this endovascular graft can be scanned safely after full placement and under the following conditions:

- Static magnetic field of 1.5 or 3.0 tesla
- Maximum static 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
- Maximum spatial magnetic field of 1600 gauss/cm (16.0 T/m) or less
- Static magnetic field of 1.5 or 3.0 tesla

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 II endoleak
- Aneurysm or ulcer enlargement ≥ 5 mm of maximum aneurysm diameter or ulcer depth (independent of endoleak status)
- Migration
- Inadequate seal length
- Graft thrombosis or occlusion
- Loss of device integrity
- Bar fracture
- Relative component migration

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

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

13.1 Difficulty Removing Release Wires
When 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 wire until the graft is released. Do not pull the release wire 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 forces (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) until the bare stent is outside the sheath.