COOK MEDICAL

Zenith® Alignment Stent

Suggested Instructions for Use

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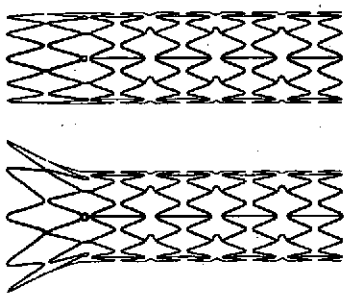


Zenith Alignment Stent Fig. 1

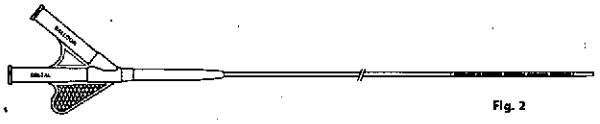
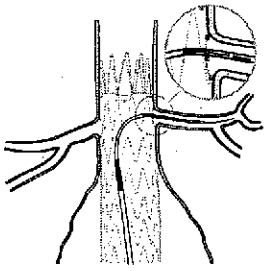


Fig. 2



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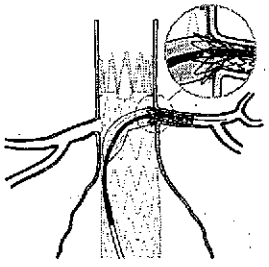

Fig. 4

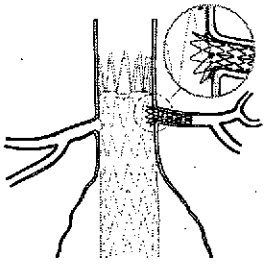

Fig. 5

ZENITH® ALIGNMENT STENT

SUGGESTED INSTRUCTIONS FOR USE

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

This document describes the suggested Instructions for Use for the Zenith Alignment Stent system. For information regarding the use of the Zenith Fenestrated AAA Endovascular Graft, please refer to the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot™ Introduction System Suggested Instructions for Use.

1 DEVICE DESCRIPTION

1.1 Zenith Alignment Stent

The Zenith Alignment Stent is a balloon-expandable stent (**Fig. 1**) that can be deployed through scallops or fenestrations in a Zenith Fenestrated AAA Endovascular Graft into branch vessels of the aorta. The stent is constructed of 316L stainless steel. The distal segment of the stent is designed to be expanded into the target vessel. The proximal segment of the stent, denoted by circumferential gold markers, is designed to extend into the lumen of a Zenith Fenestrated AAA Endovascular Graft already deployed in the aorta. This proximal segment that extends into the graft can be flared using a standard non-compliant balloon, to allow for ease in reintervention. The flarable portion of the Zenith Alignment Stent is denoted by circumferentially arranged gold markers located on the stent. The Zenith Alignment Stent is available in lengths of 18 and 26 mm, and nominal expanded diameters of 3, 4, 5, 6, 7, and 8 mm.

1.2 Zenith Alignment Stent Balloon Delivery System

The Zenith Alignment Stent is pre-mounted and positioned between two radiopaque (platinum) marker bands on the balloon catheter, which serves as the delivery system. (**Fig. 2**) The delivery system is 80 cm in length and its profile permits vascular access via 6.0 or 7.0 French introducer sheaths (dependent on the selected Zenith Alignment Stent size).

2 INDICATIONS FOR USE

The Zenith Alignment Stent is indicated for use as an adjunct to the Zenith Fenestrated AAA Endovascular Graft to assist alignment and patency at the orifice of aortic branch vessels with diameters ranging from 3 to 8 mm.

3 CONTRAINDICATIONS

The Zenith Alignment Stent and delivery system is contraindicated in the following:

- Patients with known sensitivities or allergies to stainless steel, polyester, nitinol, solder (tin, silver), polypropylene or gold.
- Patients with systemic or local infection that may increase the risk of endovascular graft infection.

4 WARNINGS AND PRECAUTIONS

4.1 General

- Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.
- The use of this device carries associated risks, including subacute thrombosis, vascular complications, and/or bleeding. Patients selected to receive this device must meet pre-determined selection criteria.
- Implantation of the Zenith Alignment Stent should be performed by physicians who have received adequate training in peripheral interventional techniques.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.
- It is necessary to appropriately size the stent to the vessel in order to reduce the possibility of stent migration.
- Pre-dilation may be required for patients with arterial stenosis.
- **The long-term performance of adjunctive flared stenting has not yet been established.** All patients receiving the Zenith Alignment Stent should receive enhanced follow-up. Specific follow-up guidelines are described in the **Zenith Fenestrated AAA Graft with the H&L-B One-Shot Introduction System Suggested Instructions for Use (Section 12, IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP).**
- Stenosis may require dilatation of the arterial segment containing the stent. The long-term outcome following repeated dilatation of a Zenith Alignment Stent is unknown.
- The Zenith Alignment Stent is not recommended in patients unable to undergo, or unwilling to comply with the necessary preoperative and postoperative imaging and implantation studies as described in the **Zenith Fenestrated AAA Graft with the H&L-B One-Shot Introduction System Suggested Instructions for Use (Section 12, IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP).**
- The Zenith Alignment Stent is pre-loaded onto the delivery system. Do not attempt to remove the Zenith Alignment Stent from its delivery system; damage to stent or delivery system may occur.

4.2 Patient Selection, Treatment and Follow-up

- The use of the Zenith Alignment Stent requires administration of intravascular contrast. The Zenith Alignment Stent is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and postoperative follow-up imaging.
- Patients with pre-existing renal insufficiency may have an increased risk of renal failure postoperatively. Care should be taken to limit the amount of contrast media used during the procedure.
- The Zenith Alignment Stent is not recommended in patients exceeding weight and/or size limits which compromise or prevent the necessary imaging requirements.
- The Zenith Alignment Stent is not recommended in patients with known sensitivities or allergies to stainless steel (316L) or gold.
- Patients with a systemic infection may be at increased risk of stent infection.

4.3 Implant Procedure

4.3.1 Stent Placement

- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician-preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- To avoid disrupting the position of the stent on the balloon, special care must be taken when handling the device. This is particularly important when removing the device from its packaging, placing the device over the wire guide, and advancing the device through a large-bore Tuohy-Borst "Y" adapter, or hemostasis valve, and/or guiding catheter hub.
- Do not wipe or clean stent or catheter with organic solvent (i.e., isopropyl alcohol).
- Minimize handling of the delivery balloon system during preparation and insertion to decrease the risk of stent contamination and infection.
- The Zenith Alignment Stent balloon delivery system should not be pre-inflated prior to stent deployment.
- Always use fluoroscopy for guidance, delivery and observation of Zenith Alignment Stent within the vasculature.
- Deployment of the Zenith Alignment Stent should only be achieved using recommended balloon inflation medium. Never use air or any gaseous medium to inflate balloon.
- Balloon pressures should be monitored during inflation. Do not exceed the rated burst pressure indicated on the product label. Use of pressures higher than specified on the product label may result in a ruptured balloon and possible intimal damage and dissection.
- Inaccurate placement and/or incomplete apposition of the Zenith Alignment Stent within the vessel may result in increased risk of migration or inadvertent occlusion of the vessel in which it is deployed. Vessel patency must be maintained to prevent/reduce the risk of subsequent complications.
- Care should be taken not to damage a previously placed endograft or disturb its position while placing the Zenith Alignment Stent. In the event that reinstrumentation is necessary, extreme care should be taken to avoid disturbance of endograft and adjunctive stent.
- When placing a Zenith Alignment Stent, do not attempt to pull an unexpanded stent back through the guiding catheter as dislodgement of the stent from the balloon delivery system may occur.
- If resistance is felt during Zenith Alignment Stent balloon delivery system removal, remove the balloon delivery system and the guiding catheter / sheath as a single unit.

4.3.2 Stent Flaring

- For optimal stent placement, accurate positioning of the non-compliant balloon must be maintained as it is inflated to flare the stent.
- Only expand the non-compliant balloon in the flarable portion of the Zenith Alignment Stent (i.e., the portion of the stent proximal to the circumferentially arranged gold markers located on the stent).
- Do not inflate the non-compliant balloon in renal, celiac or superior mesenteric arteries.
- Complete deflation of the flaring balloon should be confirmed prior to repositioning it.

4.4 MRI Information

The Zenith Alignment Stent is used in conjunction with the Zenith Fenestrated AAA Endovascular Graft. For information on MRI compatibility of the Zenith Fenestrated AAA Endovascular Graft, please refer to the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System Suggested Instructions for Use (**Section 4.5, MRI SAFETY AND COMPATIBILITY**).

The Zenith Alignment Stent is made from the same metal as the Formula Renal stent. Non-clinical testing has demonstrated that the Formula Renal stent is **MR Conditional** according to ASTM F2503, Standard *Practice for Marking Medical Devices and Other Items for Safety in the Magnetic resonance Environment*. A patient with this stent can be scanned safely anytime after placement under the following conditions.

- Static magnetic field of 3.0 Tesla or 1.5 Tesla
- Maximum spatial magnetic gradient of 720 Gauss/cm or less
- Product of the spatial gradient and the static magnetic field of 21.6 T^2/m or less
- MR system reported whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg or less for 15 minutes of scanning
- Normal operating mode

Non-clinical evaluation was conducted in an MR system (Excite, General Electric Healthcare) with a maximum spatial magnetic gradient field of 720 Gauss/cm as measured with a gaussmeter in the position of the static magnetic field pertinent to the patient (i.e., outside of scanner covering, accessible to a patient or individual). In non-clinical testing, a single and two overlapped Formula Renal stents produced a maximum temperature rise of 2.6 °C and 3.3 °C, respectively, during 15 minutes of MRI (i.e., for one scanning sequence) performed in a 3.0 Tesla MR system (3.0 Tesla/128 MHz, Excite, Software G3.0-052B, General Electric Healthcare) at an MR system reported whole-body-averaged SAR of 3.0 W/kg (associated with a calorimetry measured whole-body-averaged value of 2.8 W/kg).

The effect of heating in the MRI environment for stents with fractured struts is unknown.

Image Artifact

MR image quality may be compromised if the area of interest is within the lumen or within approximately 15 mm of the Formula Renal stent. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic stent.

5

MedicAlert Foundation

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

Mail: MedicAlert Foundation International
2323 Colorado Avenue
Turlock, CA 95382
Phone: 888-633-4298 (toll free)
209-668-3333 from outside the US
Fax: 209-669-2450
Web: www.medicalert.org

5 POTENTIAL ADVERSE EVENTS

Potential adverse events that may occur and/or require intervention include, but are not limited to:

- Aneurysm enlargement
- Aneurysm rupture and death
- Aortic damage, including perforation, dissection, bleeding, rupture and death
- Arterial or venous thrombosis and/or pseudoaneurysm
- Bleeding, hematoma or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Death
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Endoprosthesis: improper component placement; incomplete component deployment; component migration; suture break, occlusion; infection; stent fracture; graft material wear; dilatation; erosion; puncture; pericraft flow; and corrosion
- Fever and localized inflammation
- Fistula (e.g., aortoenteric, arteriovenous)
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- Hepatic failure
- Infection of the aneurysm, device or access site, including abscess formation, transient fever and pain
- Neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis)
- Occlusion of device or native vessel
- Organ impairment/loss due to side-branch vessel occlusion (in particular, renal and/or gastrointestinal impairment/loss)
- Renal complications and subsequent attendant problems (e.g., artery stenosis or occlusion, contrast toxicity, infarct, insufficiency, failure)
- Surgical conversion to open repair
- Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection
- Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death)
- Vessel damage
- Wound complications and subsequent attendant problems (e.g., dehiscence, infection, hematoma, seroma, cellulitis)

6 SUMMARY OF CLINICAL STUDIES

For information on clinical experience with Zenith Alignment Stents, please refer to the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System Suggested Instructions for Use (**Section 8, SUMMARY OF CLINICAL STUDIES**).

7 PATIENT SELECTION AND TREATMENT

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

7.1 Individualization of Treatment

Cook recommends that the Zenith Alignment Stent diameters be selected as described in **Section 9.4, ZENITH ALIGNMENT STENT DIAMETER SIZING GUIDELINES**. All lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when preoperative case planning measurements (treatment diameters/lengths) are not certain. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes.

8 HOW SUPPLIED

- The Zenith Alignment Stent is pre-loaded onto the balloon delivery system and is supplied sterilized by ethylene oxide gas in peel-open packages.
- The devices are intended for single use only. Do not re-sterilize the devices.
- Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product and return 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.
- Do not use after the "USE BY" (expiration) date printed on the label.
- Store in a dark, dry, cool place. Avoid extended exposure to light.

9 CLINICAL USE INFORMATION

9.1 Inspection Prior to Use

Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damaged, do not use the product and return to Cook. Prior to use, verify correct devices (quantity and size) are available.

9.2 Materials Required

- Fluoroscope with digital angiography capabilities (C-arm or fixed unit)
- Contrast media
- Syringe
- Heparinized saline solution
- Inflation device

9.3 Product Recommendations

The Zenith Alignment Stent is used in conjunction with equipment required for a conventional endovascular intervention procedure including, but not limited to, vascular access sets, arterial sheaths, guiding catheters/sheaths, wire guides, non-compliant balloon, and inflation devices.

The following products are recommended for implantation of the Zenith Alignment Stent. For information on the use of these products, refer to the individual product's suggested instructions for use.

- .035 inch (0.89 mm) standard wire guide; for example:
- Cook .035 inch wire guides
- Cook HiWire™ Hydrophilic Wire Guides
- Cook Rosen Curved Wire Guides
- Guiding Sheaths/Catheters; for example:
- Cook Flexor® Introducers
- Angiographic radiopaque tip catheters; for example:
- Cook Slip-Cath® Beacon® Tip Catheters
- Cook Beacon Tip Royal Flush® Plus High-Flow Catheters
- Cook Beacon Tip Torcon NB® Advantage Catheters
- Entry needles; for example:
- Cook Percutaneous Entry Needles
- Non-compliant balloon

9.3.1 Wire Guide Use and Selection

The Zenith Alignment Stent system is compatible with .035 inch wire guides.

9.3.2 Guiding Catheter/Introducer Selection

Appropriate guiding catheter/introducer selection is necessary to assure that the inside lumen is sufficient for unobstructed passage of the delivery system. Refer to **Table 9.3.2** for suggested minimum guiding catheter/introducer sizes.

NOTE: For successful placement, standard renal catheter curves should be selected to provide adequate guiding catheter/introducer support.

Table 9.3.2 Zenith Alignment Stent Sizes and Suggested Guiding Catheter/Introducer Sizes

Stent Size (Diameter x Length) (mm)	Guiding Catheter/Introducer Compatibility
3 x 18	6 Fr
3 x 26	6 Fr
4 x 18	6 Fr
4 x 26	6 Fr
5 x 18	6 Fr
5 x 26	6 Fr
6 x 18	6 Fr
6 x 26	6 Fr
7 x18	6 Fr
7 x26	6 Fr
8 x 18	7 Fr
8 x 26	7 Fr

9.4 Zenith Alignment Stent Diameter Sizing Guidelines

Stent diameters should be chosen carefully. Undersizing or oversizing may result in incomplete apposition or compromised flow. The length of the stent should be chosen to allow adequate flaring within the Zenith Fenestrated AAA Endovascular Graft and positioning within the branch vessel proximal to any bifurcation. Refer to Table 9.3.2 for stent dimensions. Table 9.4.1 exhibits stent/balloon compliance information.

Table 9.4.1 Zenith Alignment Stent and Balloon Delivery System Compliance Table
Stent Inner Diameter (mm) versus Inflation Pressure (atm)
(Average stent diameter following deployment with in vitro testing at 37 degrees C)

	Inflation Pressure (atm)											
Nominal Stent Inner Diameter (mm)	*2 atm*	*3 atm*	*4 atm*	*5 atm*	*6 atm*	*7 atm*	*8 atm*	*9 atm*	*10 atm*	*11 atm*	*12 atm*
3	N/A	N/A	2.75	2.82	2.89	2.95	3.03	3.09	3.11	3.15	3.20
4	N/A	N/A	3.54	3.64	3.74	3.83	3.96	4.02	4.07	4.12	4.17
5	4.42	4.56	4.72	4.89	5.02	5.10	5.19	5.27	5.32	5.36	5.44
6	5.38	5.56	5.71	5.88	6.03	6.17	6.25	6.31	6.37	6.45	6.50
7	N/A	6.11	6.28	6.48	6.64	6.82	6.97	7.05	7.13	7.17	7.23
8	6.79	7.00	7.22	7.40	7.55	7.86	7.99	8.09	8.17	8.25	8.34
							ANP=8 atm				RBP=12 atm

* NIP: Nominal Inflation Pressure

** RBP: Rated Burst Pressure

10 INSTRUCTIONS FOR USE

Prior to use of the Zenith Alignment Stent, review this Suggested Instructions for Use booklet and the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System Suggested Instructions for Use booklet. The following instructions embody a basic guideline for device placement. Variations in the following procedures may be necessary. These instructions are intended to help guide the physician and do not take the place of physician judgment.

10.1 General Use Information

This product is intended for use by physicians trained and experienced in interventional techniques. Standard techniques for placement of arterial access sheaths, guiding catheters/sheaths, angiographic catheters and wire guides should be employed during use of the Zenith Alignment Stent.

10.2 Pre-Implant Determinants

Proximal atherosclerotic plaque, which may inhibit advancement of the stent, and atherosclerotic plaque beyond the target segment, which may prevent advancement of the device into the targeted segment, must be taken into consideration during stent placement. Any lesions that may inhibit deployment of the Zenith Alignment Stent should be pre-dilated before implanting the Zenith Alignment Stent.

10.3 Patient Preparation

Refer to the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System Suggested Instructions for Use (**Section 11, INSTRUCTIONS FOR USE: Patient Preparation**).

10.4 Delivery Catheter Preparation/Flush

1. Remove the Zenith Alignment Stent system from the package and remove the protective sleeve from the distal tip of catheter. Visually inspect the balloon delivery system and stent to ensure they have not been damaged.
2. Attach syringe with saline (or a heparin-saline mixture) to the lumen labeled "Distal." Flush until fluid exits the end of the catheter.

CAUTION: Do not attempt pre-inflation technique to purge balloon lumen. Do not use air or any gaseous medium to inflate the balloon.

3. Using a 20 ml syringe containing 5 ml of 1:1 contrast-saline mixture, attach syringe to balloon lumen and apply negative pressure for 20-30 seconds.
4. Release syringe plunger, allowing negative pressure to draw mixture into balloon lumen.
5. Detach syringe, leaving a meniscus of mixture on the hub of the balloon lumen.
6. Prepare inflation device in standard manner and purge to remove all air from syringe and tubing.
7. Directly attach inflation device to balloon lumen while ensuring no air bubbles remain at connection.
8. Pull negative pressure on inflation device.

CAUTION: Significant amounts of air in the balloon may cause uneven expansion of the stent and difficulty in deployment of the stent.

9. Use a syringe with a solution of heparinized saline to moisten the stent and balloon.

CAUTION: Do not wipe device; doing so may dislodge the stent.

10.5 Introduction of Zenith Alignment Stent System

1. Advance a .035 inch wire guide of appropriate length across target vessel site.
2. Insert the appropriate guiding catheter/introducer and advance into position at the ostium of the target artery.
3. Advance the premounted stent/balloon catheter over the wire into either the introducer valve or Tuohy-Borst "Y" adapter.
   a. If using an introducer with a valve, make sure the flared end of the insertion tool (provided in the package) is loaded over the premounted stent on the balloon catheter. Pass the insertion tool loaded with the premounted stent through the introducer valve. Push the stent/balloon catheter into the body of the introducer. Slide the insertion tool proximally up the catheter shaft away from the guiding catheter/introducer. A slight contact of the stent with the introducer may be felt, but there must be no resistance.
   b. If using a Tuohy-Borst "Y" adapter, advance the premounted stent/balloon catheter over the wire and into the fully opened Tuohy-Borst "Y" adapter. Gently advance the stent/balloon catheter completely through the Tuohy-Borst "Y" adapter and into the guiding catheter/introducer. A slight contact of the stent with the guiding catheter/introducer may be felt, but there must be no resistance.

CAUTION: If resistance is encountered, do not force passage. Resistance may indicate damage to the stent.

10.6 Positioning and Deployment of the Zenith Alignment Stent

1. Advance the balloon delivery system to the distal end of the guiding catheter/introducer into the target artery while ensuring stability of guiding catheter/introducer.

CAUTION: If initial guiding catheter/introducer position is lost, do not pull or push the guiding catheter/introducer over the stent. Damage or dislodgement of the stent may occur.

2. While maintaining position of the delivery system, withdraw the sheath to fully expose the premounted stent and balloon.

CAUTION: Ensure that both the stent and balloon are completely clear of the guiding catheter/introducer.

3. Align the gold markers of the stent with the gold markers designating the fenestration or scallop of the Zenith Fenestrated AAA Endovascular Graft. Position the stent so that the flarable portion extends proximally from the ostium of the selected targeted vessel into the lumen of the Zenith Fenestrated AAA Endovascular Graft (Fig. 3).

CAUTION: If the Zenith Alignment Stent delivery system does not readily advance through the vessel, do not force. If unable to adequately position the stent, do not attempt to pull the unexpanded stent back into the guiding catheter/introducer. Withdraw the Zenith Alignment Stent delivery system until the proximal end of the stent aligns with the distal tip of the guiding catheter/sheath introducer, then remove the Zenith Alignment Stent delivery system and guiding catheter/sheath as a single unit, leaving the wire guide in place.

WARNING: If the stent is removed, do not attempt to reuse the device. Damage to the stent may occur upon removal.

4. Using high-resolution fluoroscopy, verify the stent has not been dislodged during positioning.

CAUTION: If the stent is dislodged, do not attempt to deploy or pull the unexpanded stent back into the guiding catheter/introducer. Withdraw the Zenith Alignment Stent delivery system until the proximal end of the stent aligns with the distal tip of the guiding catheter/sheath introducer, then remove the Zenith Alignment Stent delivery system and guiding catheter/sheath as a single unit, leaving the wire guide in place.

WARNING: If the stent is removed, do not attempt to reuse the device. Damage to the stent may occur upon removal.

5. Deploy the stent by inflating the balloon to the recommended expansion pressure (nominal inflation pressure) as indicated on the product label.

CAUTION: For accurate stent placement, maintain the position of the Zenith Alignment Stent system during balloon inflation.

CAUTION: Complete expansion and apposition of the stent against the vessel wall is necessary for clinical success. Do not under-expand the stent.

CAUTION: Do not exceed rated burst pressure of the balloon as indicated on the product label.

NOTE: After initial stent deployment, post-deployment inflation is at the discretion of the operator to achieve optimum angiographic appearance. The inflated diameter of the post-dilatation balloon should not exceed the reference vessel diameter by more than 10%.

10.7 Balloon Deflation and Removal

1. Completely deflate the balloon by pulling negative pressure on the inflation device or a 20 ml syringe. This usually requires 10-20 seconds.

CAUTION: Confirm complete deflation of balloon using fluoroscopy.

2. Slowly withdraw the balloon catheter from the stent while maintaining negative pressure on the balloon. Maintain position of the sheath introducer or guiding catheter. Observe this process using fluoroscopy to ensure that the balloon disengages from the stent.
3. Continue to withdraw the balloon catheter while maintaining position of wire guide and sheath introducer or guiding catheter.

10.8 Stent Flaring

1. Advance a 10 mm non-compliant balloon catheter through the guiding catheter and position the distal end of balloon within the flarable portion of the Zenith Alignment Stent (proximal to gold stent markers) making sure the distal end of the balloon does not extend past the gold stent markers.

CAUTION: When advancing the balloon catheter, be careful not to dislodge the newly placed stent.

NOTE: For optimal stent flaring, accurate positioning of the non-compliant balloon must be maintained as it is inflated to flare the stent.

2. Expand the flarable portion of the stent by inflating the balloon to the recommended expansion pressure (**Figs. 4** and **5**), as indicated on the product label.

CAUTION: Only expand the flarable portion of the Zenith Alignment Stent (e.g., the portion of the stent proximal to the circumferentially arranged gold markers located on the stent)

11 Imaging Guidelines and Postoperative Follow-up

For information on imaging guidelines and postoperative follow-up in patients receiving the Zenith Alignment Stent, please refer to the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System Suggested Instructions for Use, **Section 12, IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP.**

[redacted]

Keep dry

Keep away from sunlight

MANUFACTURER
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750 Daniels Way
Bloomington, IN 47404 U.S.A.

www.cookmedical.com

EC REPRESENTATIVE
WILLIAM COOK EUROPE ApS
Sandet 6, DK-4632
Bjaeverskov, DENMARK

September 2011

ZENITH® FENESTRATED AAA ENDOVASCULAR GRAFT WITH THE H&L-B ONE-SHOT™ INTRODUCTION SYSTEM

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

CAUTION: U.S Federal law restricts this device to sale by or on the order of a physician.

1 DEVICE DESCRIPTION

The Zenith Fenestrated AAA Endovascular Graft is a modular system consisting of three components, a proximal body graft, a distal bifurcated body graft and one iliac leg. (Figure 1) The graft modules are constructed of full-thickness woven polyester fabric sewn to self-expanding stainless steel Cook-Z® stents with braided polyester and monofilament polypropylene suture. The modules are fully stented to provide stability and the expansile force necessary to open the lumen of the graft during deployment. Additionally, the Cook-Z stents provide the necessary attachment and seal of the graft to the vessel wall. Ancillary devices such as main body extensions, iliac leg extensions, converters, and iliac plugs may also be required. Each individual device has its own separate delivery system. Each component comes in a range of lengths and diameters which allows the physician to tailor the device to individual patient anatomies and select the best proximal and distal fixation sites.

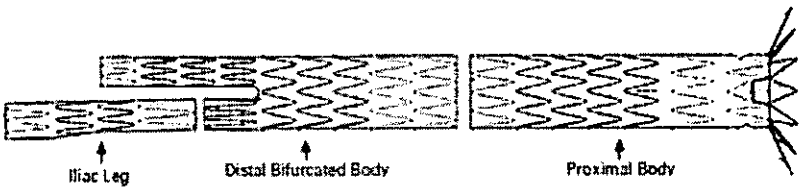


Fig. 1 The Zenith Fenestrated AAA Endovascular Graft

1.1 Proximal Body Graft

The bare suprarenal stent at the proximal end of the proximal body graft contains barbs that are placed at 3 mm increments for additional fixation of the device. This graft contains up to three precisely located holes (fenestration(s)), and cut-outs from the proximal margin (scallop(s)) of the graft material. (Figure 2) The fenestrations are either small (fit entirely between struts of the seal stent) or large (cross struts of the seal stent). The purpose of these scallops and fenestrations is to allow the proximal margin of the device to sit higher than standard AAA devices and allow uninterrupted blood flow to branch vessels of the aorta such as the renal and superior mesenteric arteries. It is recommended that all vessels accommodated by a small fenestration be stented in order to secure positive alignment of the graft fenestration with the vessel origin. Stenting is optional for vessels accommodated by a scallop and not recommended for vessels accommodated by a large fenestration. To facilitate fluoroscopic visualization of the stent graft, gold radiopaque markers are positioned as follows; one on the lateral aspect of the most distal stent and four in a circumferential orientation within 1 mm of the most superior aspect of the graft material. The proximal body graft also has vertically-aligned gold markers on the anterior side (at the 12:00 o'clock position) that should form a cross (+) with the horizontally-aligned gold markers on the posterior side (180 degrees opposite the vertical markers) when the device is properly oriented.

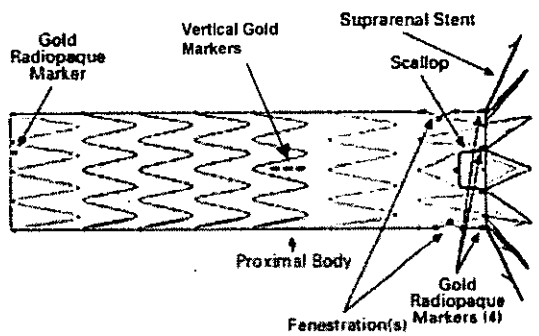


Fig. 2 Zenith Fenestrated AAA Endovascular Graft (Proximal Body)

1.2 Proximal Body Graft Delivery System

The Zenith Fenestrated AAA Endovascular Proximal Body Graft is shipped preloaded onto the H&L-B One-Shot Introduction System. (Figure 3) It has a sequential deployment method with built-in features to provide continuous control of the graft throughout the deployment procedure. The graft is reduced in diameter by an independent wire tied to diameter reducing ties, which allows the graft to be manipulated within the aorta to allow accurate positioning of the graft, which enables the fenestration(s) to line up with the desired arteries. The bare suprarenal stent is constrained within a top cap and held by a trigger-wire. The distal end of the graft is also attached to the delivery system and held by an independent wire. The H&L-B One-Shot Introduction System enables precise positioning and allows readjustment of the final graft position before deployment of the bare barbed suprarenal stent. The delivery system uses a 20 French H&L-B One-Shot Introduction System. All Systems are compatible with a .035 inch wire guide. For added hemostasis, the Captor™ Hemostatic Valve can be loosened or tightened for the introduction and/or removal of accessory/ancillary devices into and out of the sheath.

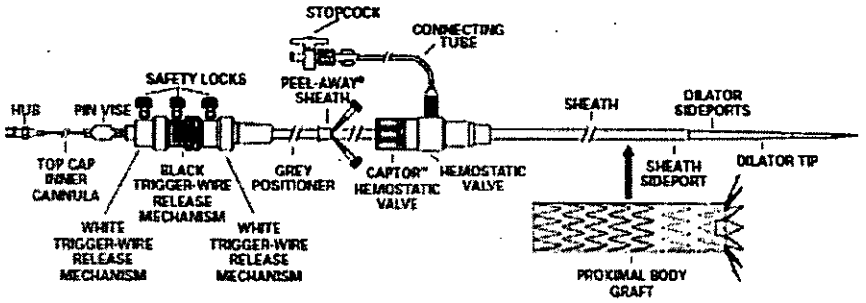


Fig. 3 H&L-B One-Shot Introduction System. (Proximal Body)

1.3 Distal Bifurcated Body Graft

The Zenith Fenestrated AAA Endovascular Distal Bifurcated Body Graft has one long ipsilateral iliac limb and one short contralateral limb. To facilitate fluoroscopic visualization of the stent graft, there is a radiopaque marker at the graft bifurcation, at the distal end of the contralateral limb, and at the proximal end (contralateral side) of the graft. (Figure 4)

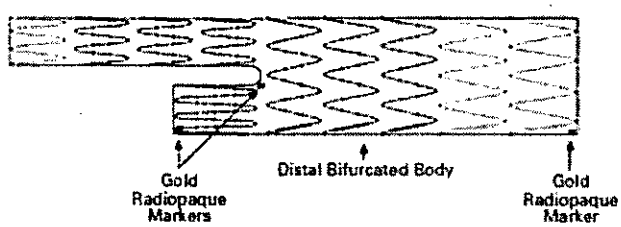


Fig. 4 Zenith Fenestrated AAA Endovascular Graft (Distal Body)

1.4 Distal Bifurcated Body Graft Delivery System

The Zenith Fenestrated AAA Endovascular Distal Bifurcated Body Graft is shipped preloaded onto the H&L-B One-Shot Introduction System. (Figure 5) It has a sequential deployment method with built-in features to provide continuous control of the graft throughout the deployment procedure. Both the proximal and distal segments of the graft are attached to the delivery system and held by independent wires. The H&L-B One Shot Introduction System enables precise positioning and allows readjustment of the graft position before deployment of the graft. The delivery system uses a 20 French H&L-B One-Shot Introduction System. All systems are compatible with a .035 inch wire guide. For added hemostasis, the Captor Hemostatic Valve can be loosened or tightened for the introduction and/or removal of accessory/ancillary devices into and out of the sheath.

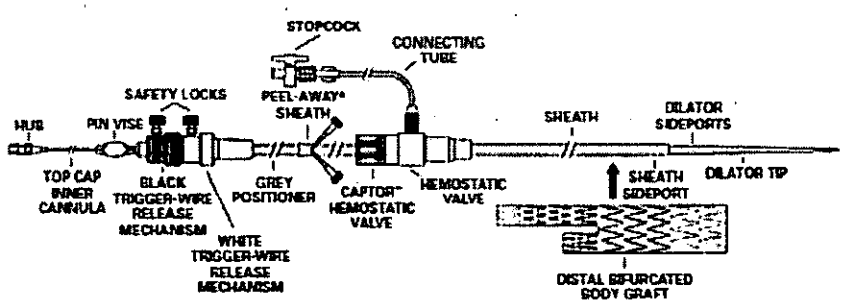


Fig. 5 H&L-B One-Shot Introduction System. (Distal Body)

1.5 Iliac Leg Graft and Delivery System

The Zenith Fenestrated AAA Endovascular Graft utilizes the same iliac leg graft as is available for the standard Zenith Flex AAA Endovascular Graft. Zenith iliac leg grafts are constructed from polyester fabric, self-expanding stainless steel and nitinol Z-stents, and polypropylene suture. Refer to the iliac leg graft Instructions for Use enclosed in device packaging for more information.

1.6 Ancillary Components and Delivery System

The Zenith Fenestrated AAA Endovascular Graft utilizes the same ancillary components (main body extensions, iliac leg extensions, converters, and iliac plugs) as are available for the standard Zenith Flex AAA Endovascular Graft.

Zenith ancillary components are constructed from the same polyester fabric, self-expanding stainless steel Z-stents, and polypropylene suture. Refer to the ancillary component Instructions for Use enclosed in device packaging for more information.

1.7 Adjunctive Zenith Alignment Stent and Delivery System

It is recommended that all vessels accommodated by a small fenestration be stented in order to secure positive alignment of the graft fenestration with the vessel origin (stenting optional for scallops and not recommended for large fenestrations). The Zenith Alignment Stent is available for this purpose. The Zenith Alignment Stent is a balloon-expandable stent that can be deployed through scallops or fenestrations in a Zenith Fenestrated AAA Endovascular Graft into branch vessels of the aorta. Refer to the Zenith Alignment Stent Instructions for Use for more information.

2 INTENDED USE

The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is indicated for the endovascular treatment of patients with abdominal aortic or aorto-iliac aneurysms having morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with the required introduction systems,
- Non-aneurysmal infrarenal aortic segment (neck) proximal to the aneurysm:
  - with a length that is at least 4 mm and unsuitable for a non-fenestrated graft,
  - with a diameter measured outer wall to outer wall of no greater than 31 mm and no less than 19 mm,
  - with an angle less than 45 degrees relative to the long axis of the aneurysm, and
  - with an angle less than 45 degrees relative to the axis of the suprarenal aorta.
- Ipsilateral iliac artery distal fixation site greater than 30 mm in length and 9-21 mm in diameter (measured outer wall to outer wall).
- Contralateral iliac artery distal fixation site greater than 30 mm in length and 7-21 mm in diameter (measured outer wall to outer wall).

3 CONTRAINDICATIONS

The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is contraindicated in the following:

- Patients with known sensitivities or allergies to stainless steel, polyester, nitinol, solder (tin, silver), polypropylene or gold.
- Patients with systemic or local infection that may increase the risk of endovascular graft infection.

4 WARNINGS AND PRECAUTIONS

4.1 General Use Information

- Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.
- Fenestrated grafts are made to a customized design to a specification requested by the responsible Physician, and are tailored to a specific patient's anatomy.
- The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device, which requires precise planning/sizing as well as accurate longitudinal positioning and rotational orientation during placement.
- Lack of non-contrast CT imaging may result in failure to appreciate iliac or aortic calcification, which may preclude access or reliable device fixation and seal.
- Preprocedure imaging reconstruction thickness > 3 mm may result in sub-optimal device sizing, or in failure to appreciate focal stenosis from CT
- Implantation of the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System requires high quality imaging. Some types of mobile image intensifiers may not provide adequate imaging quality.
- **The long-term performance of fenestrated endovascular grafts, including the stents placed in fenestrations/scallops, has not yet been established.** All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, changes in the structure or position of the endovascular graft, or stenosis/occlusion of vessels accommodated by fenestrations) should receive enhanced follow-up. Specific follow-up guidelines are described in Section 12.
- After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth, patency of vessels accommodated by a fenestration/scallop, or changes in the structure or position of the endovascular graft. At a minimum, annual imaging is recommended, including: 1) abdominal radiographs to examine device integrity (separation between components, stent fracture or barb separation) and 2) contrast and non-contrast CT to examine aneurysm changes, perigraft flow, patency, tortuosity and progressive disease. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs and duplex ultrasound may provide similar information.
- The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is not recommended in patients unable to undergo, or who will not be compliant with the necessary preoperative and post-operative imaging and implantation studies as described in **Section 12, Imaging Guidelines and Post-Operative Follow-Up.**
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms, unacceptable decrease in fixation length (vessel and component overlap) and/or endoleak. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture.
- Patients experiencing reduced blood flow through the graft limb/fenestration and/or leaks may be required to undergo secondary interventions or surgical procedures.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

4.2 Patient Selection, Treatment and Follow-Up

- Inappropriate patient selection may result in poor performance of the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System.
- Access vessel diameter (measured inner wall to inner wall) and morphology (minimal tortuosity, occlusive disease, and/or calcification) should be compatible with vascular access techniques and delivery systems of the profile of a 14 French to 20 French vascular introducer sheath. Iliac conduits may be used to ensure the safe insertion of the introduction system. Vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude placement of the endovascular graft and/or may increase the risk of embolization/trauma.
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (> 45 degrees for infrarenal neck to axis of AAA or > 45 degrees for suprarenal neck relative to the immediate infrarenal neck); short proximal aortic neck (<4 mm); greater than 10%

increase in diameter over 15 mm of proximal aortic neck length; and circumferential thrombus and/or calcification at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. Irregular calcification and/or plaque may compromise the fixation and sealing of the implantation sites. Necks exhibiting these key anatomic elements may be more conducive to graft migration.

- The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging.
- The use of this device requires administration of radiographic agents. Patients with pre-existing renal insufficiency may have an increased risk of post-operative renal failure.
- The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System is not recommended in patients of excessive weight and/or size that would limit, compromise, or prevent the necessary imaging requirements.
- Inability to maintain patency of at least one internal iliac artery or occlusion of an indispensable inferior mesenteric artery may increase the risk of pelvic/bowel ischemia.
- Multiple large, patent lumbar arteries, mural thrombus and a patent inferior mesenteric artery may all predispose a patient to Type II endoleaks. Patients with uncorrectable coagulopathy may also have an increased risk of Type II endoleak or bleeding complications.
- Patients with recurrent aortic aneurysmal disease or with disease above the renal arteries may be prone to further aortic dilation in the renal/visceral segment, which could compromise device integrity/fixation
- The Zenith Fenestrated AAA Endovascular Graft has not been evaluated in the following patient populations:
  - Less than 18 years of age
  - Females who are pregnant or breast-feeding
  - Leaking/ruptured or symptomatic aneurysms
  - Patients with connective tissue disorders
  - Patients with previous stent placement in vessels to be accommodated by fenestrations

4.3 Implant Procedure

- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- Maintain wire guide position during delivery system insertion.
- Do not bend or kink the delivery system. Doing so may cause damage to the delivery system and the Zenith Fenestrated AAA Endovascular Graft.
- Always use fluoroscopy for guidance, delivery and observation of any Zenith Fenestrated AAA Endovascular Graft components within the vasculature.
- The use of the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure post-operatively. Care should be taken to limit the amount of contrast media used during the procedure.
- To avoid any twist in the endovascular graft, during any rotation of the delivery system, be careful to rotate all of the components of the system together (from outer sheath to inner cannula).
- Inaccurate placement and/or incomplete sealing of the Zenith Fenestrated AAA Endovascular Graft within the vessel may result in increased risk of endoleak, migration or inadvertent occlusion of the renal or internal iliac arteries. Renal artery patency must be maintained to prevent/reduce the risk of renal failure and subsequent complications. It is recommended that all vessels accommodated by a small fenestration be stented in order to secure positive alignment of the graft fenestration with the vessel origin.
- Inadequate fixation of the Zenith Fenestrated AAA Endovascular Graft may result in increased risk of migration of the stent graft. Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
- The Zenith Fenestrated AAA Endovascular Graft incorporates a suprarenal stent with fixation barbs. Exercise extreme caution when manipulating interventional devices in the region of the suprarenal stent.
- Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the wire guide or delivery system. Stop and assess the cause of resistance. Vessel or catheter damage may occur. Exercise particular care in areas of stenosis, intravascular thrombosis or in calcified or tortuous vessels.
- Unless medically indicated, do not deploy the Zenith Fenestrated AAA Endovascular Graft in a location that will occlude arteries necessary to supply blood flow to organs or extremities. Do not cover significant renal or mesenteric arteries (exception is the inferior mesenteric artery) with the endoprosthesis.
- Take care during manipulation of catheters, wires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus, which can cause distal embolization.
- Care should be taken not to damage the graft or disturb graft positioning after graft placement in the event reinstrumentation of the graft is necessary.

4.4 Molding Balloon Use

- Prior to molding in the vicinity of any fenestration stent(s) confirm that the aortic section of the stent has been flared.
- Confirm complete deflation of balloon prior to repositioning.
- Do not inflate balloon in the vessel outside of graft, as doing so could result in damage to the vessel (e.g., rupture).

4.5 MRI Safety and Compatibility

Non-clinical testing has demonstrated that the Zenith Fenestrated AAA Endovascular Graft is MR Conditional. A patient with this endovascular graft in place for at least 6 months can be scanned safely under the following conditions:

- Static magnetic field of 3.0 Tesla or 1.5 Tesla
- Maximum spatial magnetic gradient of 720 Gauss/cm or less
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning or less (i.e., per scanning sequence)
- Normal operating mode

Static Magnetic Field

The static magnetic field for comparison to the above limits is the static magnetic field pertinent to the patient (i.e., outside of scanner covering, accessible to a patient or individual).

MRI-Related Heating

1.5 Tesla Systems:

In non-clinical testing, the Zenith AAA Endovascular Graft (similar construction as the Zenith Fenestrated AAA Endovascular Graft) produced a temperature rise of less than or equal to 1.4 °C at a maximum whole-body-averaged specific absorption rate (SAR) of 2.8 W.kg, for 15 minutes of MR scanning in a 1.5 Tesla Magnetom, Siemens Medical Magnetom, Numaris/4 Software, Version Syngo MR 2002B DHHS MR Scanner. The maximum whole-body-averaged specific absorption rate (SAR) was 2.8 W/kg, which corresponds to a calorimetry measured value of 1.5 W/kg.

3.0 Tesla Systems:

In non-clinical testing, the Zenith AAA Endovascular Graft (similar construction as the Zenith Fenestrated AAA Endovascular Graft) produced a temperature

rise of less than or equal to 1.9 °C at a maximum whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg, for 15 minutes of MR scanning in a 3.0 Tesla Excite, GE Electric Healthcare, G3.0-052B Software, MR Scanner. The maximum whole-body-averaged specific absorption rate (SAR) was 3.0 W/kg, which corresponds to a calorimetry measured value of 2.8 W/kg.

Image Artifact

The image artifact extends throughout the anatomical region containing the device, obscuring the view of immediately adjacent anatomical structures within approximately 20 cm of the device, as well as the entire device and its lumen, when scanned in nonclinical testing using the sequence: Fast spin echo, in a 3.0 Tesla, Excite, GE Electric Healthcare, with G3.0-052B Software, MR system with body radiofrequency coil.

For all scanners, the image artifact dissipates as the distance from the device to the area of interest increases. MR scans of the head and neck and lower extremities may be obtained without image artifact. Image artifact may be present in scans of the abdominal region and upper extremities, depending on distance from the device to the area of interest.

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

Mail: MedicAlert Foundation International
2323 Colorado Avenue
Turlock, CA 95382

Phone: 888-633-4298 (toll free)
209-668-3333 from outside the US

Fax: 209-669-2450

Web: www.medicalert.org

5 ADVERSE EVENTS

Potential adverse events that may occur and/or require intervention include, but are not limited to:

- Amputation
- Anesthetic complications and subsequent attendant problems (e.g., aspiration)
- Aneurysm enlargement
- Aneurysm rupture and death
- Aortic damage, including perforation, dissection, bleeding, rupture and death
- Arterial or venous thrombosis and/or pseudoaneurysm
- Bleeding, hematoma or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g. buttock, lower limb)
- Death
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Endoprosthesis: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft material wear; dilatation; erosion; puncture; perigraft flow; barb separation and corrosion
- Fever and localized inflammation
- Fistula (e.g., aortoenteric, arteriovenous)
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- Hepatic failure
- Impotence
- Infection of the aneurysm, device or access site, including abscess formation, transient fever and pain
- Lymphatic complications and subsequent attendant problems (e.g., lymph fistula)
- Neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis)
- Occlusion of device or native vessel
- Organ impairment/loss due to side-branch vessel occlusion (in particular, renal and/or gastrointestinal impairment/loss)
- Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent attendant problems (e.g., artery stenosis or occlusion, contrast toxicity, infarct, insufficiency, failure)
- Surgical conversion to open repair
- Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection
- Vascular spasm or vascular trauma (e.g.,iliofemoral vessel dissection, bleeding, rupture, death)
- Vessel damage
- Wound complications and subsequent attendant problems (e.g., dehiscence, infection, hematoma, seroma, cellulitis)

6 SUMMARY OF CLINICAL STUDIES

The Zenith Fenestrated AAA Endovascular Graft US clinical study is a non-randomized, multi-center study that was conducted to help evaluate the safety and effectiveness of the Zenith Fenestrated AAA Endovascular Graft in the treatment of abdominal aortic aneurysms in patients with short infrarenal neck lengths (≥4 mm and <15 mm). A total of 42 patients were enrolled among 7 investigational sites between January 6, 2005 and August 18, 2010. Each patient was treated with an individually tailored Fenestrated Graft. The study was initially approved for 30 patients and use of available balloon-expandable stents in combination with the Fenestrated Graft. Following completion of the initial 30 patient enrollment, the study hypothesis and requirements for approval were agreed upon. The study was then expanded to include the Zenith Alignment Stent and enrollment of 12 additional patients, thus providing 42 total patients, which was the pre-specified study sample size. The adjunctive Zenith Alignment Stent was used in 11 total patients.

The primary safety and effectiveness endpoint was based on treatment success, which was defined as technical success (i.e., successful access of the aneurysm site and deployment of the Zenith Fenestrated AAA Endovascular Graft in the intended location, with all vessels targeted by fenestrations patent at the completion of the procedure) plus freedom from the following at 6 months: Type I and III endoleak, aneurysm growth >0.5 cm, any AAA-related serious adverse event (death, rupture, conversion), and any AAA-related major complication (Q-wave MI; congestive heart failure; cardiac ischemia requiring intervention; renal failure requiring permanent dialysis; bowel obstruction, ischemia, or fistula; stroke with permanent deficit; paralysis). The study results for the primary endpoint, treatment success, were explored in patients treated with the Zenith Fenestrated AAA Endovascular Graft and in matched patients treated with the standard Zenith AAA Endovascular Graft. Propensity score methods with a pre-specified one-to-one global matching algorithm were used to select patients from the Zenith AAA Endovascular Graft multicenter study. The covariates for matching were pre-specified and included the following relevant demographic, comorbid, and anatomic characteristics, all of which were comparable between the two groups: age, gender, height, weight, arrhythmia, cancer, chronic heart failure, chronic obstructive pulmonary disease, cerebrovascular disease, diabetes, hypertension, previous diagnosis of systemic infection, previous myocardial infarction, peripheral vascular disease, previous surgeries at access site, thromboembolic event, maximum aneurysm diameter, minimum aneurysm diameter, and neck diameter.

Additional measures assessed in the cohort of patients treated with the Fenestrated Graft included mortality, pre-specified morbid events, change in aneurysm size, endoleak, migration, device integrity, and secondary interventions. The patients were to be seen for clinical and imaging (CT and X-ray) follow-up at pre-discharge, 1 month, 6 months, 12 months, and yearly thereafter through 5 years.

Table 6.1 reports the patient availability for follow-up. Of 42 patients enrolled in the clinical study, 95% (40) were evaluable for the primary endpoint analysis. The 42 patient cohort, combines patient data from the feasibility study (n = 30; implanted device between January 2005 – January 2006) with pivotal study data (n = 12).

Table 6.1. Follow-up availability

		Percent of Data Available[1]			Adequate Imaging to Assess the Parameter[2]				Events Occurring Before Next Interval				
Follow-up Visit	Patients Eligible for Follow-up[3]	Clinical	X-ray	CT	Size Increase	Endoleak	Migration	Fracture	Death	Conversion	Lost to Follow-up (LTF) or Withdrawal	Refused Consent for 3-5 Year Follow-up[4]	Not Due for Next Visit
Pre-discharge	42 (0)	100.0% (42/42)	95.2% (40/42)	95.2% (40/42)	95.2% (40/42)	92.9% (39/42)	95.2% (40/42)	100.0% (42/42)	0	0	0	0	0
30-day	42 (0)	97.6% (41/42)	88.1% (37/42)	97.6% (41/42)	97.6% (41/42)	92.9% (39/42)	95.2% (40/42)	97.6% (41/42)	1	0	1	0	0
6-month	40 (0)	97.5% (39/40)	95.0% (38/40)	95.0% (38/40)	95.0% (38/40)	87.5% (35/40)	95.0% (38/40)	97.5% (39/40)	0	0	1	0	4
12-month	35 (3)	91.4% (32/35)	82.9% (29/35)	88.6% (31/35)	82.9% (29/35)	80.0% (28/35)	82.9% (29/35)	82.9% (29/35)	1	0	0	0	7
24-month	27 (0)	96.3% (26/27)	85.2% (23/27)	96.3% (26/27)	96.3% (26/27)	81.5% (22/27)	96.3% (26/27)	96.3% (26/27)	1	0	0	6	0
3-year	20 (0)	90.0% (18/20)	70.0% (14/20)	90.0% (18/20)	75.0% (15/20)	70.0% (14/20)	80.0% (16/20)	75.0% (15/20)	0	0	1	0	0
4-year	19 (0)	94.7% (18/19)	73.7% (14/19)	89.5% (17/19)	84.2% (16/19)	63.2% (12/19)	84.2% (16/19)	89.5% (17/19)	0	0	2	0	0
5-year	17 (0)	100.0% (17/17)	70.6% (12/17)	82.4% (14/17)	64.7% (11/17)	52.9% (9/17)	64.7% (11/17)	64.7% (11/17)	0	0	0	0	0

[1]Site submitted data.
[2]Based on core lab analysis – does not include imaging exams received by the core lab for analysis, but that have not yet been analyzed.
[3]Number in parenthesis indicates the number of patients without submitted data who are still eligible for follow-up.
[4]Initial cohort of 30 patients consented only for 2-year follow-up and therefore were asked to reconsent for 3-5 year follow-up.

Table 6.2 summarizes the demographics and patient characteristics of patients implanted with the Zenith Fenestrated AAA Endovascular Graft.

Table 6.2. Demographics and patient characteristics

Demographic	Result[1]
Age (years)	75.3 ± 7.4 (58 - 86), 42
Gender	
Male	78.6% (33/42)
Female	21.4% (9/42)
Ethnicity	
White	92.9% (39/42)
Hispanic or Latino	2.4% (1/42)
Black or African American	0.0% (0/42)
American Indian or Alaska Native	2.4% (1/42)
Asian	2.4% (1/42)
Native Hawaiian or other Pacific Islander	0.0% (0/42)
Other	0.0% (0/42)
Height (in)	67.5 ± 4.4 (51 - 74), 41
Weight (lbs)	190.6 ± 46.9 (110 - 342), 42
Body mass index	28.7 ± 4.8 (19.5 - 40.8), 41

[1] Mean values +/- the standard deviation, with the range of values shown in parentheses, followed by the number of patients evaluated

Table 6.3 presents the medical history.

Table 6.3. Pre-existing comorbid medical conditions

Medical History	Percent Patients (number/total number)
Cardiovascular	
Previous myocardial infarction	23.8% (10/42)
Previous diagnosis of symptomatic congestive heart failure	9.5% (4/42)
Previous diagnosis of coronary artery disease	52.4% (22/42)
Previous diagnosis of cardiac arrhythmia	40.5% (17/42)
Vascular	
Thromboembolic event	11.9% (5/42)
Peripheral vascular disease	23.8% (10/42)
Family history of aneurysmal disease	14.3% (6/42)[1]
Hypertension	92.9% (39/42)
Pulmonary	
Chronic obstructive pulmonary disease	33.3% (14/42)
Renal	
Diagnosis of renal failure requiring dialysis	0.0% (0/42)
Renal insufficiency	9.5% (4/42)
GFR ≤ 60 ml/min/1.73 m^2	21.4% (9/42)
Endocrine	
Diabetes	26.2% (11/42)
Infectious disease	
Previous diagnosis of sepsis	7.1% (3/42)
Gastrointestinal	
Gastrointestinal disease	40.5% (17/42)
Hepatobiliary	
Previous diagnosis of liver disease	2.4% (1/42)
Neoplasms	
Previous diagnosis of cancer	35.7% (15/42)
Neurologic	
Previous diagnosis of cerebrovascular disease	16.7% (7/42)
Previous endarterectomy	2.4% (1/42)
Substance use	
Excessive alcohol use	0.0% (0/42)
Tobacco use: currently smokes	28.6% (12/42)
quit smoking	57.1% (24/42)
never smoked	14.3% (6/42)
Access site	
Previous surgery at the intended access site	11.9% (5/42)[2]
Previous radiation at the intended access site	0.0% (0/42)

[1] In 11.9% (5/42) of patients family history of aneurysmal disease was reported as unknown.
[2] In 2.4% (1/42) of patients previous surgery at intended access site was reported as unknown.

Table 6.4 lists the anatomical characteristics of the subject population for this study, as assessed by the core lab.

Table 6.4. Presenting anatomical dimensions, as assessed by core lab

Measure	Mean ± S.D. (range), N=42
Aortic diameters (mm)	
Diameter at celiac artery	28.2 ± 3.2 (21.2 - 35.9)
Diameter at SMA	28 ± 3.5 (22.3 - 39.8)
Diameter at lowest patent renal artery	25.7 ± 3.2 (19.2 - 33.2)
Diameter at midpoint of renal arteries	25.5 ± 5.1 (0.0 - 32.2)
Maximum aneurysm diameter – long axis	61.1 ± 10.9 (45.2 - 94.2)
Maximum aneurysm diameter – short axis	56.8 ± 10.3 (43.4 - 90.4)
Proximal neck length (mm)	9.7 ± 3.5 (2.4 - 19.1)
Angles (°)	
Angle between immediate suprarenal neck and immediate infrarenal neck	15.9 ± 9.6 (2 - 40)
Angle between the proximal neck and the longitudinal axis of the aneurysm	34 ± 14.2 (7 - 57)
Diameter of renal artery ostia (mm)	
Right renal artery	6.5 ± 1.2 (4.6 - 8.9)
Left renal artery	6.8 ± 1.3 (4.0 - 9.4)

Table 6.5 reports the type of stent-graft components that were deployed during the index procedure. All but one patient received the standard 3-piece system (proximal graft, distal graft, contralateral leg) – one patient received only a proximal graft, which landed in a previous open surgical graft and thus did not require a distal graft or contralateral leg.

Table 6.5. Stent-graft components deployed

Type	Percent Patients (number/total number)
Proximal graft	100% (42/42)
Distal graft	97.6% (41/42)*
Contralateral leg	97.6% (41/42)*
Ancillary components	
Main body extension	0.0% (0/42)
Additional iliac leg	7.1% (3/42)
Ipsilateral iliac leg extension	2.4% (1/42)
Contralateral iliac leg extension	7.1% (3/42)
Occluder	0.0% (0/42)
Converter	0.0% (0/42)

*One patient that had undergone prior open surgical AAA repair received only the proximal fenestrated component

Table 6.6 reports the sizes (diameters and lengths) of the proximal grafts used during the initial implant procedure. The full range of available graft diameters and lengths was utilized.

Table 6.6. Proximal graft sizes used

Diameter (mm)	Length (mm)					Total
	97	107	109	122	124	
24	0	0	0	0	2	2
26	0	0	4	0	0	4
28	1	0	7	0	4	12
30	1	0	6	0	9	16
32	0	0	1	0	2	3
34	0	2	0	2	0	4
36	0	0	0	1	0	1
Total	2	2	18	3	17	42

Table 6.7 reports the sizes (diameters and lengths) of the distal grafts used during the initial implant procedure. The full range of available graft diameters and lengths was utilized.

Table 6.7. Distal graft sizes used

Diameter (mm)	Length (mm)							Total
	119	121	136	138	151	153	168	
12	0	2	2	1	0	3	0	8
16	0	2	3	4	2	2	4	17
20	1	0	1	3	1	5	3	14
24	0	0	1	0	1	0	0	2
Total	1	4	7	8	4	10	7	41

Table 6.8 reports the sizes (diameters and lengths) of the contralateral leg grafts used during the initial implant procedure.

Table 6.8. Contralateral leg sizes used

Diameter (mm)	Length (mm)						Total
	54	56	71	73	88	90	
12	3	1	2	0	0	0	6
14	1	0	10	0	1	0	12
16	3	0	3	1	0	0	7
18	6	0	3	0	1	0	10
20	0	0	3	0	0	1	4
22	0	0	1	0	0	0	1
24	0	0	1	0	0	0	1
Total	13	1	23	1	2	1	41

The location of the most proximal graft margin relative to the renal arteries, SMA, and celiac artery is provided in Table 6.9. The proximal margin of the graft was above the renal arteries in all patients.

Table 6.9. Graft location

Location of proximal graft margin relative to specified vessel		Percent Patients (number/total number)
Renal arteries	Above	100.0% (42/42)
	Below	0.0% (0/42)
SMA	Above	66.7% (28/42)
	Below	33.3% (14/42)
Celiac	Above	0.0% (0/42)
	Below	100.0% (42/42)

The specific graft fenestration/scallop configurations that were utilized to accommodate the vessels intended to remain patent are provided in Table 6.10. The most commonly used configuration was 2 fenestrations and 1 scallop.

Table 6.10. Fenestrated configurations used

Configurations	% (n/N)
1 scallop	9.5% (4/42)
1 small fenestration and 1 scallop	11.9% (5/42)
2 small fenestrations	4.8% (2/42)
2 small fenestrations and 1 scallop	69.0% (29/42)
2 small fenestrations and 1 large fenestration	4.8% (2/42)

Table 6.11 provides the total number of each stent type used during the initial implant procedure. Eleven (11) patients received a Zenith Alignment Stent.

Table 6.11. Type and number of fenestration stents used

Stent type/description	(n)
Zenith Alignment Stent (uncovered, balloon-expandable, 316 L stainless steel)	22
Uncovered, balloon-expandable, 316L stainless steel biliary stent	28
Uncovered, balloon-expandable, 316L stainless steel biliary/iliac stent	20
Uncovered, balloon-expandable, 316L stainless steel biliary/renal stent	8
Covered, balloon-expandable, 316L stainless steel tracheobronchial stent	2

Table 6.12 indicates which vessels were targeted by either a fenestration or scallop and were either stented or unstented. All vessels accommodated by a small fenestration were stented.

Table 6.12. Fenestration and vessel stenting

Vessel	Small fenestration		Large fenestration		Scallop		Total
	Stented	Unstented	Stented	Unstented	Stented	Unstented	
Celiac	0	0	0	0	0	0	0
SMA	0	0	0	2	0	29	31
Right renal	35	0	0	0	3	0	38
Left renal	36	0	0	0	4	2	42
Accessory	0	0	0	0	0	0	0
Total	71	0	0	2	7	31	111

Primary Endpoint

Table 6.13 reports the 6-month treatment success for the Zenith Fenestrated AAA Endovascular Graft, as compared to the matched patients treated with the standard Zenith AAA Endovascular Graft. Of 42 patients enrolled in the clinical study, 40 were evaluable for the primary endpoint analysis (two patients were lost to follow-up). The 6-month treatment success rate was 97.5% in the Fenestrated endovascular treatment group compared to 95% in the matched Zenith AAA cohort.

Table 6.13. Results for 6-month treatment success

Measure	Zenith Fenestrated	Zenith AAA
Treatment success	97.5% (39/40)[1]	95.0% (38/40)[2]

[1]Failure due to bowel ischemia
[2]Failure due to congestive heart failure in one and congestive heart failure as well as cardiac ischemia requiring intervention in another.

Safety Data

Table 6.14 reports the technical success results for the Zenith Fenestrated AAA Endovascular Graft, which was defined as successful access of the aneurysm site and deployment of the Zenith Fenestrated AAA Endovascular Graft in the intended location, with all vessels targeted by fenestrations patent at the completion of the procedure. Technical success was 100%.

Table 6.14. Technical success

Measure	Percent (n/N)
Technical success	100.0% (42/42)

Table 6.15 reports the Kaplan-Meier survival estimates for freedom from major adverse events (MAE) within 30 days (death, Q-wave MI, bowel ischemia, paralysis, stroke, reintubation, renal failure requiring dialysis). There were no MAEs in the Zenith AAA group within 30 days.

Table 6.15. Results from Kaplan-Meier analysis for freedom from 30-day MAE

Event	Parameter	Zenith Fenestrated
Any MAE	Number at risk	41
	Cumulative events	1
	Cumulative censored	0
	Kaplan-Meier estimate	0.976
	Standard error	0.024
Death	Number at risk	42
	Cumulative events	0
	Cumulative censored	0
	Kaplan-Meier estimate	1.000
	Standard error	0.000
Q-wave MI	Number at risk	42
	Cumulative events	0
	Cumulative censored	0
	Kaplan-Meier estimate	1.000
	Standard error	0.000
Bowel ischemia	Number at risk	41
	Cumulative events	1
	Cumulative censored	0
	Kaplan-Meier estimate	0.976
	Standard error	0.024
Paralysis	Number at risk	42
	Cumulative events	0
	Cumulative censored	0
	Kaplan-Meier estimate	1.000
	Standard error	0.000
Stroke	Number at risk	42
	Cumulative events	0
	Cumulative censored	0
	Kaplan-Meier estimate	1.000
	Standard error	0.000
Re-intubation	Number at risk	42
	Cumulative events	0
	Cumulative censored	0
	Kaplan-Meier estimate	1.000
	Standard error	0.000
Renal failure requiring dialysis	Number at risk	42
	Cumulative events	0
	Cumulative censored	0
	Kaplan-Meier estimate	1.000
	Standard error	0.000

Table 6.16 provides the Kaplan-Meier estimates for freedom from serious adverse events (death [all-cause and AAA-related], rupture, and conversion), as compared to Zenith AAA. AAA-related death was defined as any death occurring within 30 days of the initial implant procedure (or secondary intervention) or any death determined by the independent clinical events to be related. The cause of death was unknown in one patient from the Zenith Fenestrated group, which the CEC was therefore unable to adjudicate – this was the only patient death counted as AAA-related in the Zenith Fenestrated group. No aneurysm ruptures or conversions to open repair where reported in the Zenith Fenestrated group.

Table 6.16. Results from Kaplan-Meier analysis for serious adverse events (death, rupture, conversion)

Event	Group	Parameter	30 Days	365 Days	730 Days	1095 Days	1460 Days	1825 Days
All-cause mortality	Zenith Fenestrated	Number at risk	42	36	27	20	19	14
		Cumulative events	0	1	2	4	4	4
		Cumulative censored	0	5	13	18	19	24
		Kaplan-Meier estimate	1.000	0.976	0.943	0.861	0.861	0.861
		Standard error	0.000	0.024	0.040	0.066	0.066	0.066
	Zenith AAA	Number at risk	33	32	30	30	28	17
		Cumulative events	0	0	2	2	2	2
		Cumulative censored	0	1	1	1	3	14
		Kaplan-Meier estimate	1.000	1.000	0.938	0.938	0.938	0.938
		Standard error	0.000	0.000	0.043	0.043	0.043	0.043
AAA-related mortality	Zenith Fenestrated	Number at risk	42	36	27	20	19	14
		Cumulative events	0	0	0	1*	1	1
		Cumulative censored	0	6	15	21	22	27
		Kaplan-Meier estimate	1.000	1.000	1.000	0.955	0.955	0.955
		Standard error	0.000	0.000	0.000	0.044	0.044	0.044
	Zenith AAA	Number at risk	33	32	30	30	28	17
		Cumulative events	0	0	0	0	0	0
		Cumulative censored	0	1	3	3	5	16
		Kaplan-Meier estimate	1.000 0.000	1.000 0.000	1.000 0.000	1.000 0.000	1.000 0.000	1.000 0.000
		Standard error						
Rupture	Zenith Fenestrated	Number at risk	42	37	28	21	21	18
		Cumulative events	0	0	0	0	0	0
		Cumulative censored	0	5	14	21	21	24
		Kaplan-Meier estimate	1.000	1.000	1.000	1.000	1.000	1.000
		Standard error	0.000	0.000	0.000	0.000	0.000	0.000
	Zenith AAA	Number at risk	33	32	30	30	28	17
		Cumulative events	0	1	1	1	1	1
		Cumulative censored	0	0	2	2	4	15
		Kaplan-Meier estimate	1.000	0.970	0.970	0.970	0.970	0.970
		Standard error	0.000	0.030	0.030	0.030	0.030	0.030
Conversion	Zenith Fenestrated	Number at risk	42	37	28	21	21	18
		Cumulative events	0	0	0	0	0	0
		Cumulative censored	0	5	14	21	21	24
		Kaplan-Meier estimate	1.000	1.000	1.000	1.000	1.000	1.000
		Standard error	0.000	0.000	0.000	0.000	0.000	0.000
	Zenith AAA	Number at risk	33	32	30	30	28	17
		Cumulative events	0	1	1	1	1	1
		Cumulative censored	0	0	2	2	4	15
		Kaplan-Meier estimate	1.000	0.970	0.970	0.970	0.970	0.970
		Standard error	0.000	0.030	0.030	0.030	0.030	0.030

*1 case of death that the CEC was unable to adjudicate, which was conservatively counted as AAA-related for the purpose of analysis.

Table 6.17 reports the Kaplan-Meier survival estimates for freedom from any pre-specified cardiovascular, pulmonary, renal, GI, wound, neurologic, and vascular event reported by the investigative sites, as compared to Zenith AAA. The procedure-related incidence (i.e., within 30 days) of cardiovascular, pulmonary, gastrointestinal, wound, and neurologic events appeared comparable between Zenith Fenestrated and Zenith AAA, and the occurrence of events in these categories beyond 30 days was not surprising given the pre-existing comorbid conditions of the patient populations. The percent of patients experiencing renal events or vascular events within 30 days trended higher for Zenith Fenestrated compared to Zenith AAA patients, the details of which are provided in Tables 6.18 and 6.19, respectively.

Table 6.17. Kaplan-Meier estimates (freedom from morbidity, by category)

Category	Group	Parameter	30 Days	365 Days	730 Days	1095 Days	1460 Days	1825 Days
Cardiovascular[a]	Zenith Fenestrated	Number at risk	40	30	21	15	15	10
		Cumulative events	2	6	7	8	8	10
		Cumulative censored	0	6	14	19	19	22
		Kaplan-Meier estimate	0.952	0.854	0.817	0.766	0.766	0.656
		Standard error	0.033	0.055	0.064	0.078	0.078	0.098
	Zenith AAA	Number at risk	29	27	24	24	23	14
		Cumulative events	4	5	6	6	6	6
		Cumulative censored	0	1	3	3	4	13
		Kaplan-Meier estimate	0.879	0.848	0.817	0.817	0.817	0.817
		Standard error	0.057	0.062	0.068	0.068	0.068	0.068
Pulmonary[b]	Zenith Fenestrated	Number at risk	41	32	24	18	17	12
		Cumulative events	1	4	4	5	5	6
		Cumulative censored	0	6	14	19	20	24
		Kaplan-Meier estimate	0.976	0.903	0.903	0.855	0.855	0.798
		Standard error	0.024	0.046	0.046	0.064	0.064	0.081
	Zenith AAA	Number at risk	33	32	29	29	28	17
		Cumulative events	0	0	1	1	1	1
		Cumulative censored	0	1	3	3	4	15
		Kaplan-Meier estimate	1.000	1.000	0.969	0.969	0.969	0.969
		Standard error	0.000	0.000	0.031	0.031	0.031	0.031
Renal[c]	Zenith Fenestrated	Number at risk	37	30	21	15	14	10
		Cumulative events	5	6	8	9	10	10
		Cumulative censored	0	6	13	18	18	22
		Kaplan-Meier estimate	0.881	0.856	0.791	0.742	0.692	0.692
		Standard error	0.050	0.054	0.067	0.079	0.088	0.088
	Zenith AAA	Number at risk	33	31	29	29	27	16
		Cumulative events	0	1	1	1	1	1
		Cumulative censored	0	1	3	3	5	16
		Kaplan-Meier estimate	1.000	0.970	0.970	0.970	0.970	0.970
		Standard error	0.000	0.030	0.030	0.030	0.030	0.030

Category	Group	Parameter	30 Days	365 Days	730 Days	1095 Days	1460 Days	1825 Days
GI[d]	Zenith Fenestrated	Number at risk	40	33	25	20	19	14
		Cumulative events	2	2	2	2	2	2
		Cumulative censored	0	7	15	20	21	26
		Kaplan-Meier estimate	0.952	0.952	0.952	0.952	0.952	0.952
		Standard error	0.033	0.033	0.033	0.033	0.033	0.033
	Zenith AAA	Number at risk	33	32	30	30	28	17
		Cumulative events	0	0	0	0	0	0
		Cumulative censored	0	1	3	3	5	16
		Kaplan-Meier estimate	1.000	1.000	1.000	1.000	1.000	1.000
		Standard error	0.000	0.000	0.000	0.000	0.000	0.000
Wound[e]	Zenith Fenestrated	Number at risk	41	32	24	19	18	13
		Cumulative events	1	3	3	3	3	3
		Cumulative censored	0	7	15	20	21	26
		Kaplan-Meier estimate	0.976	0.927	0.927	0.927	0.927	0.927
		Standard error	0.024	0.041	0.041	0.041	0.041	0.041
	Zenith AAA	Number at risk	32	31	29	29	26	15
		Cumulative events	1	1	1	1	2	2
		Cumulative censored	0	1	3	3	5	16
		Kaplan-Meier estimate	0.970	0.970	0.970	0.970	0.936	0.936
		Standard error	0.030	0.030	0.030	0.030	0.044	0.044
Neurologic[f]	Zenith Fenestrated	Number at risk	42	35	26	19	18	13
		Cumulative events	0	0	0	1	1	1
		Cumulative censored	0	7	16	22	23	28
		Kaplan-Meier estimate	1.000	1.000	1.000	0.950	0.950	0.950
		Standard error	0.000	0.000	0.000	0.049	0.049	0.049
	Zenith AAA	Number at risk	33	32	28	28	26	15
		Cumulative events	0	0	2	2	2	2
		Cumulative censored	0	1	3	3	5	16
		Kaplan-Meier estimate	1.000	1.000	0.934	0.934	0.934	0.934
		Standard error	0.000	0.000	0.045	0.045	0.045	0.045
Vascular[g]	Zenith Fenestrated	Number at risk	34	28	20	17	16	10
		Cumulative events	8	8	8	8	8	9
		Cumulative censored	0	6	14	17	18	23
		Kaplan-Meier estimate	0.810	0.810	0.810	0.810	0.810	0.759
		Standard error	0.061	0.061	0.061	0.061	0.061	0.075
	Zenith AAA	Number at risk	30	28	26	26	23	13
		Cumulative events	3	4	4	4	5	5
		Cumulative censored	0	1	3	3	5	15
		Kaplan-Meier estimate	0.909	0.879	0.879	0.879	0.845	0.845
		Standard error	0.050	0.057	0.057	0.057	0.064	0.064

[a]Cardiovascular pre-specified events: cardiac ischemia requiring intervention, inotropic support, Q-wave MI, non-Q-wave MI, congestive heart failure (CHF), arrhythmia requiring intervention or new treatment, and medically intractable hypertension.
[b]Pulmonary pre-specified events: pneumonia requiring antibiotics, supplemental oxygen at discharge, ventilation (>24 hours and >72 hours), and re-intubation.
[c]Renal pre-specified events: renal failure requiring dialysis, renal insufficiency, renal infarct, and occlusion of fenestrated renal vessel.
[d]GI pre-specified events: bowel obstruction, bowel ischemia/mesenteric ischemia, paralytic ileus >4 days, and aorto-enteric fistula.
[e]Wound pre-specified events: incisional hernia, wound infection requiring antibiotic treatment, wound complication requiring return to the operating room (OR), seroma requiring treatment, lymph fistula, and wound breakdown requiring debridement.
[f]Neurologic pre-specified events: transient ischemic attack (TIA)/reversible ischemic neurological deficit (RIND), stroke, spinal cord ischemia/paralysis.
[g]Vascular pre-specified events: embolization resulting in tissue loss or requiring intervention; limb thrombosis, aneurysm leak/rupture, pseudoaneurysm, increase in aneurysm size by >0.5 cm, vascular injury, and post-procedure transfusion.

Given the involvement of the renal arteries in the repair with a fenestrated graft, there is an expected higher risk for renal adverse events as compared to use of a standard, non-fenestrated endograft. Renal morbidity was therefore closely monitored during the study by evaluating several pre-specified events (renal infarct, renal insufficiency, renal failure requiring dialysis, renal artery occlusion). Table 6.18 reports the Kaplan-Meier estimates for freedom from the individual pre-specified renal morbid events, as compared to Zenith AAA. Also included in Table 6.18 is the Kaplan-Meier estimate for freedom from stenosis/compression events that required reintervention, as also counted (as device/renal stenosis) in Table 6.24 (Reasons for Secondary Intervention).

There were five incidental findings of renal infarct on imaging (without an associated clinical event). Each occurred in a patient from the Zenith Fenestrated group that had some degree of calcification/thrombus in the seating zone (one also with a history of infarct and coverage of an accessory renal artery at the time of the procedure).

Renal insufficiency was observed in Zenith Fenestrated (n=3) as well as Zenith AAA (n=1) patients. One of the Zenith Fenestrated patients with renal insufficiency was also the only patient in either group to require dialysis, which the CEC judged to be unrelated to AAA repair due to underlying renal dysfunction. Renal insufficiency in one of the other patients from the Zenith Fenestrated group was also judged unrelated to AAA repair by the CEC due to underlying renal dysfunction.

There were two reports of renal occlusion in the Zenith Fenestrated group, neither of which was associated with graft migration. One required reintervention and occurred in a patient with suboptimal placement of the renal stent in the middle/upper portion of the fenestration.

There were seven patients with stenosis/compression events requiring secondary intervention (one associated with migration), four of which had a peak systolic velocity <280 cm/s prior to reintervention.

Table 6.18. Kaplan-Meier estimates for freedom from pre-specified renal events (regardless of whether determined by the clinical events committee to be related or unrelated to AAA repair)

Category	Group	Parameter	30 Days	365 Days	730 Days	1095 Days	1460 Days	1825 Days
Renal infarct*	Zenith Fenestrated	Number at risk	37	31	24	19	18	14
		Cumulative events	5[a,b,c,d,e]	5	5	5	5	5
		Cumulative censored	0	6	13	18	19	23
		Kaplan-Meier estimate	0.881	0.881	0.881	0.881	0.881	0.881
		Standard error	0.050	0.050	0.050	0.050	0.050	0.050
	Zenith AAA	Number at risk	33	32	30	30	28	17
		Cumulative events	0	0	0	0	0	0
		Cumulative censored	0	1	3	3	5	16
		Kaplan-Meier estimate	1.000	1.000	1.000	1.000	1.000	1.000
		Standard error	0.000	0.000	0.000	0.000	0.000	0.000
Renal insufficiency** (on two or more follow-up tests)	Zenith Fenestrated	Number at risk	42	35	25	18	16	11
		Cumulative events	0	0	1[f]	2[g]	3[h]	3
		Cumulative censored	0	7	16	22	23	28
		Kaplan-Meier estimate	1.000	1.000	0.963	0.912	0.862	0.862
		Standard error	0.000	0.000	0.036	0.060	0.075	0.075

	Zenith AAA	Number at risk	33	31	29	29	27	16
		Cumulative events	0	1	1	1	1	1
		Cumulative censored	0	1	3	3	5	16
		Kaplan-Meier estimate	1.000	0.970	0.970	0.970	0.970	0.970
		Standard error	0.000	0.030	0.030	0.030	0.030	0.030
Dialysis***	Zenith Fenestrated	Number at risk	42	35	26	20	18	13
		Cumulative events	0	0	0	0	1[g]	1
		Cumulative censored	0	7	16	22	23	28
		Kaplan-Meier estimate	1.000	1.000	1.000	1.000	0.947	0.947
		Standard error	0.000	0.000	0.000	0.000	0.051	0.051
	Zenith AAA	Number at risk	33	32	30	30	28	17
		Cumulative events	0	0	0	0	0	0
		Cumulative censored	0	1	3	3	5	16
		Kaplan-Meier estimate	1.000	1.000	1.000	1.000	1.000	1.000
		Standard error	0.000	0.000	0.000	0.000	0.000	0.000
Renal occlusion	Zenith Fenestrated	Number at risk	42	34	24	18	18	13
		Cumulative events	0	1[l]	2[l]	2	2	2
		Cumulative censored	0	7	16	22	22	27
		Kaplan-Meier estimate	1.000	0.975	0.945	0.945	0.945	0.945
		Standard error	0.000	0.025	0.038	0.038	0.038	0.038
	Zenith AAA	Number at risk	33	32	30	30	28	17
		Cumulative events	0	0	0	0	0	0
		Cumulative censored	0	1	3	3	5	16
		Kaplan-Meier estimate	1.000	1.000	1.000	1.000	1.000	1.000
		Standard error	0.000	0.000	0.000	0.000	0.000	0.000
Stenosis/compression requiring reintervention	Zenith Fenestrated	Number at risk	41	33	24	18	16	11
		Cumulative events	1[k]	3[l,m]	4[n]	5[o]	6[p]	7[p]
		Cumulative censored	0	6	14	19	20	24
		Kaplan-Meier estimate	0.976	0.927	0.897	0.850	0.800	0.747
		Standard error	0.024	0.040	0.049	0.065	0.078	0.089

*As reported by sites, regardless of whether confirmed by core lab.
**Creatinine rise >2 mg/dl and >30% from baseline.
***Although dialysis in patients with a normal pre-operative renal function was pre-specified, the analysis was performed with consideration to dialysis in any patient.
[a](0111011) Incidental finding on imaging without an associated clinical event at the time of reporting; patient noted to have (mild) thrombus and calcification in the seal zone on pre-procedure imaging.
[b](0511009) Incidental finding on imaging without an associated clinical event at the time of reporting; patient noted to have (mild) thrombus and calcification in the seal zone on pre-procedure imaging; patient also with bilateral renal artery stenosis (uncovered, balloon-expandable 316L stainless steel biliary stent) treated with bilateral angioplasty and stenting. No evidence of graft migration or stent deformation, suggesting the stenosis may have resulted from local thrombus formation or intimal hyperplasia within the stented segment.
[c](0511010) Incidental finding on imaging without an associated clinical event at the time of reporting; patient noted to have (moderate) thrombus and (mild) calcification in the seal zone on pre-procedure imaging; patient also with hydronephrosis on POD# 237.
[d](1111002) Incidental finding on imaging without an associated clinical event at the time of reporting; patient noted to have (moderate) calcification in the seal zone as well as renal infarct on pre-procedure imaging, and also underwent intentional coverage of an accessory renal artery at the time of aneurysm repair.
[e](1111007) Incidental finding on imaging without an associated clinical event at the time of reporting; patient noted to have (mild) calcification in the seal zone on pre-procedure imaging; patient also with renal insufficiency (creatinine rise >2 mg/dl and >30% from baseline) on a single follow-up (at POD# 424).
[f](0211010) Patient with a decrease in GFR >30% at the 24-month follow-up, but not on subsequent follow-up at 36 months. The patient underwent secondary intervention to treat a Type II endoleak (on POD# 239) and hospitalization for congestive heart failure treated with Lasix (on POD# 314), but there were no reports of renal artery stenosis or occlusion at any time point.
[g](0111006) Patient also with renal calculi noted on POD# 214; all events (renal calculi, renal insufficiency, and dialysis) were determined un-related to AAA repair by the CEC.
[h](0421001) Patient also with stenosis of an unstented renal artery proximal to the graft margin, which underwent stenting on POD# 1221; all events (renal insufficiency and stenosis) were determined un-related to AAA repair by the CEC.
[i](0211008) No evidence of graft migration, but with compression of the fenestration stent (uncovered, balloon-expandable 316L stainless steel biliary/renal stent), due likely to suboptimal deployment of the renal stent into the middle/upper portion of the fenestration; patient underwent secondary intervention (ilio-renal bypass).
[j](0611003) No evidence of graft migration or fenestration stent compression (uncovered, balloon-expandable 316L stainless steel biliary/iliac stent), suggesting occlusion likely resulted from the development and progression of thrombus or intimal hyperplasia within the stented vessel; patient did not undergo secondary intervention; patient also with site-reported atrophy of kidney (on POD# 177).
[k] (0211011) Angiography revealed that the right renal artery was severely stenosed. Attempted cannulation was unsuccessful, as the fenestration stent (Zenith® Alignment Stent) was not flared at the time of the initial implant procedure. No evidence of graft migration or stent deformation, suggesting the stenosis may have resulted from local thrombus formation or intimal hyperplasia within the stented segment.
[l] (0111008) Right renal artery stenosis (uncovered, balloon-expandable 316L stainless steel biliary stent) was treated by angioplasty and additional stent placement. No evidence of graft migration or stent deformation, suggesting the stenosis may have resulted from local thrombus formation or intimal hyperplasia within the stented segment.
[m] (0111014) Bilateral renal artery stenoses (uncovered, balloon-expandable 316L stainless steel biliary stent) were treated by angioplasty and additional stent placement. No evidence of graft migration or stent deformation, suggesting the stenosis may have resulted from local thrombus formation or intimal hyperplasia within the stented segment.
[n] (0211007) Right renal artery stenosis (uncovered, balloon-expandable 316L stainless steel biliary/renal stent) was treated by angioplasty and additional stent placement. No evidence of graft migration or stent deformation, suggesting the stenosis may have resulted from local thrombus formation or intimal hyperplasia within the stented segment.
[o] (0511006) Right renal artery stent compression and subsequent stenosis (uncovered, balloon-expandable 316L stainless steel biliary stent) treated by angioplasty and stent placement. Compression of fenestration stent associated with graft migration (approximately 12 mm by 24 months) due likely to longitudinal progression of disease with further aortic neck dilatation.
[p] (0511003) Left renal artery stenosis (uncovered, balloon-expandable 316L stainless steel biliary stent) from slight compression of fenestration stent (with no measurable graft movement > 5 mm) treated by angioplasty and stent placement.

Given the expected longer procedure times for Zenith Fenestrated compared to Zenith AAA (252.2 ± 75.5 minutes for Zenith Fenestrated vs. 160.6 ± 60.6 minutes for Zenith AAA) and correspondingly greater amount of procedural blood loss (537.4 ± 498.5 cc for Zenith Fenestrated vs. 281.2 ± 192.4 cc for Zenith AAA), the need for post-procedure transfusion was also greater, as shown in Table 6.19, which provides the Kaplan-Meier estimates for freedom from individual pre-specified vascular events occurring in either the Zenith Fenestrated or Zenith AAA groups.

Table 6.19. Kaplan-Meier estimates for freedom from pre-specified vascular events occurring in either Zenith Fenestrated or Zenith AAA

Event	Group	Parameter	30 Days	365 Days	730 Days	1095 Days	1460 Days	1825 Days
Embolization resulting in tissue loss or requiring intervention	Zenith Fenestrated	Number at risk	41	34	25	19	18	13
		Cumulative events	1	1	1	1	1	1
		Cumulative censored	0	7	16	22	23	28
		Kaplan-Meier estimate	0.976	0.976	0.976	0.976	0.976	0.976
		Standard error	0.024	0.024	0.024	0.024	0.024	0.024
	Zenith AAA	Number at risk	33	32	30	30	28	17
		Cumulative events	0	0	0	0	0	0
		Cumulative censored	0	1	3	3	5	16
		Kaplan-Meier estimate	1.000	1.000	1.000	1.000	1.000	1.000
		Standard error	0.000	0.000	0.000	0.000	0.000	0.000
Limb thrombosis	Zenith Fenestrated	Number at risk	42	35	26	20	19	14
		Cumulative events	0	0	0	0	0	0
		Cumulative censored	0	7	16	22	23	28
		Kaplan-Meier estimate	1.000	1.000	1.000	1.000	1.000	1.000
		Standard error	0.000	0.000	0.000	0.000	0.000	0.000
	Zenith AAA	Number at risk	33	31	29	29	27	16
		Cumulative events	0	1	1	1	1	1
		Cumulative censored	0	1	3	3	5	16

Event	Group	Parameter	30 Days	365 Days	730 Days	1095 Days	1460 Days	1825 Days
		Kaplan-Meier estimate	1.000	0.970	0.970	0.970	0.970	0.970
		Standard error	0.000	0.030	0.030	0.030	0.030	0.030
Post-procedure transfusion	Zenith Fenestrated	Number at risk	34	28	20	17	16	10
		Cumulative events	8	8	8	8	8	9
		Cumulative censored	0	6	14	17	18	23
		Kaplan-Meier estimate	0.810	0.810	0.810	0.810	0.810	0.759
		Standard error	0.061	0.061	0.061	0.061	0.061	0.075
	Zenith AAA	Number at risk	30	29	27	27	24	14
		Cumulative events	3	3	3	3	4	4
		Cumulative censored	0	1	3	3	5	15
		Kaplan-Meier estimate	0.909	0.909	0.909	0.909	0.875	0.875
		Standard error	0.050	0.050	0.050	0.050	0.058	0.058

Effectiveness Data

Table 6.20 reports the percent of patients with an increase (> 5 mm), decrease (> 5 mm), or no change (≤ 5 mm) in aneurysm size at each follow-up time point, as compared to pre-discharge based on the results from core lab analysis. There were two cases of aneurysm expansion, both of which occurred in patients with a persistent Type II endoleak.

Table 6.20. Change in aneurysm size based on results from core lab analysis

Item	1-month	6-month	12-month	24-month	36-month	48-month	60-month
Increase (>5mm)	0.0% (0/39)	0.0% (0/38)	0.0% (0/29)	0.0% (0/26)	6.7% (1/15)[1]	6.3% (1/16)[2]	0.0% (0/11)
Decrease (>5mm)	2.6% (1/39)	50.0% (19/38)	69.0% (20/29)	69.2% (18/26)	73.3% (11/15)	75.0% (12/16)	72.7% (8/11)
No change (≤5mm)	97.4% (38/39)	50.0% (19/38)	31.0% (9/29)	30.8% (8/26)	20.0% (3/15)	18.8% (3/16)	27.3% (3/11)

[1] Patient 0511004 had a persistent Type II endoleak requiring secondary intervention at 1393 days post-procedure.
[2] Patient 0211010 had a persistent Type II endoleak requiring secondary intervention at 239 days post-procedure, but the Type II endoleak was still evident on the 48-month exam.

Table 6.21 reports endoleaks by type, as assessed by the core lab at each exam period. Except for two endoleaks of unknown type, all other reported endoleaks were Type II.

Table 6.21. Endoleak based on results from core lab analysis

Type	Pre-discharge	1-month	6-month	12-month	24-month	36-month	48-month	60- month
Any (new only)	32.5% (13/40)	2.4% (1/41)	5.3% (2/38)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/16)	0.0% (0/11)
Any (new and persistent)	32.5% (13/40)	22.0% (9/41)	23.7% (9/38)	27.6% (8/29)	15.4% (4/26)	12.5% (2/16)	12.5% (2/16)	0.0% (0/11)
Multiple	0.0% (0/40)	0.0% (0/41)	0.0% (0/38)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/16)	0.0% (0/11)
Proximal Type I	0.0% (0/40)	0.0% (0/41)	0.0% (0/38)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/16)	0.0% (0/11)
Distal Type I	0.0% (0/40)	0.0% (0/41)	0.0% (0/38)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/16)	0.0% (0/11)
Type II	30.0% (12/40)	22.0% (9/41)	21.1% (8/38)	27.6% (8/29)	15.4% (4/26)	12.5% (2/16)	12.5% (2/16)	0.0% (0/11)
Type III	0.0% (0/40)	0.0% (0/41)	0.0% (0/38)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/16)	0.0% (0/11)
Type IV	0.0% (0/40)	0.0% (0/41)	0.0% (0/38)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/16)	0.0% (0/11)
Unknown	2.5% (1/40)	0.0% (0/41)	2.6% (1/38)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/16)	0.0% (0/11)

Table 6.22 reports the percent of patients with CEC-confirmed radiographic migration (≥10 mm) or clinically significant migration (measurable movement of the stent-graft >5 mm and that developed a type I endoleak or renal stenosis/occlusion with demonstrable deformation of the mating renal stent by core lab) at each follow-up time point (date of first occurrence). There were two reports of migration, one of which required secondary intervention (due to associated renal stenosis). Neither case was associated with aneurysm growth or endoleak. Both cases of migration occurred in patients with evidence of disease progression at follow-up (without aneurysm pressurization).

Table 6.22. CEC-confirmed migration (date of first occurrence)

Item	1-month	6-month	12-month	24-month	36-month	48-month	60- month
Radiographic migration	0.0% (0/40)	0.0% (0/38)	0.0% (0/30)	3.6%[1] (1/28)	0.0% (0/16)	0.0% (0/16)	9.1%[2] (1/11)
Clinically significant migration	0.0% (0/40)	0.0% (0/38)	0.0% (0/30)	3.6%[1] (1/28)	0.0% (0/16)	0.0% (0/16)	0.0% (0/11)

[1] Patient 0511006 with renal stenosis from associated stent compression (uncovered, balloon-expandable 316L stainless steel biliary stent) requiring secondary intervention. Longitudinal progression of disease with further aortic neck dilatation likely resulted in migration. There was no endoleak or increase in aneurysm size in this patient. The total amount of graft movement detected at the time of the clinically significant migration was approximately 12 mm (relative to the celiac).
[2] Patient 0511008 was without any associated renal stenosis requiring reintervention and additionally did not have any endoleak or increase in aneurysm size. Longitudinal progression of disease with further aortic neck dilatation likely resulted in migration. The total amount of graft movement was approximately 10 mm (relative to the celiac), which retrospectively occurred over 60 months. No interventions have been performed on this patient.

Device integrity observations are summarized in Table 6.23. Losses in device integrity included three patients with barb separation, one patient with possible fenestration stent fracture, and one patient with seal stent and fenestration stent fracture (who also had evidence of disease progression during follow-up in the absence of aneurysm pressurization). None of the integrity findings were associated with adverse clinical sequelae or the need for reintervention. Although not associated with a device integrity loss (i.e., fracture), other observations included 4 cases with fenestration stent deformation/compression (1 also with migration, 3 without migration), 2 of which underwent reintervention to treat stenosis.

Table 6.23. Device integrity findings by core lab (time of first occurrence)

Finding	Pre-discharge	1-month	6- month	12-month	24-month	36-month	48-month	60- month
Stent-graft								
Barb separation	0.0% (0/42)	0.0% (0/41)	2.6% (1/39)[1]	3.4% (1/29)[2]	3.8% (1/26)[3]	0.0% (0/16)	0.0% (0/17)	0.0% (0/11)
Stent fracture (single)	0.0% (0/42)	0.0% (0/41)	0.0% (0/39)	3.4% (1/29)[4]	0.0% (0/26)	0.0% (0/16)	0.0% (0/17)	0.0% (0/11)
Stent fracture (multiple)	0.0% (0/42)	0.0% (0/41)	0.0% (0/39)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/17)	0.0% (0/11)
Component separation	0.0% (0/42)	0.0% (0/41)	0.0% (0/39)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/17)	0.0% (0/11)
Limb separation	0.0% (0/42)	0.0% (0/41)	0.0% (0/39)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/17)	0.0% (0/11)
Stent-to-graft separation	0.0% (0/42)	0.0% (0/41)	0.0% (0/39)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/17)	0.0% (0/11)
Other	0.0% (0/42)	0.0% (0/41)	0.0% (0/39)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/17)	0.0% (0/11)
Fenestration stent								
Fracture	0.0% (0/42)	0.0% (0/41)	2.6% (1/39)[5]	3.4% (1/29)[6]	0.0% (0/26)	0.0% (0/16)	0.0% (0/17)	0.0% (0/11)
Separation	0.0% (0/42)	0.0% (0/41)	0.0% (0/39)	0.0% (0/29)	0.0% (0/26)	0.0% (0/16)	0.0% (0/17)	0.0% (0/11)
Other	0.0% (0/42)	0.0% (0/41)	7.7% (3/39)[5,7,8]	3.4% (1/29)[8]	0.0% (0/26)	0.0% (0/16)	0.0% (0/17)	0.0% (0/11)

[1] Patient 0421003: Separation of a single fixation barb. No clinical sequelae related to the barb separation have been reported.
[2] Patient 0111009: Separation of a single fixation barb. No clinical sequelae related to the barb separation have been reported.
[3] Patient 0511008: Separation of two barbs. No clinical sequelae related to the barb separation have been reported, although radiographic migration (approximately 10 mm over 5 years) was observed and was due likely to longitudinal progression of disease with further aortic neck dilatation.
[4] Patient 0411001: Fracture of sealing stent (at the distal edge of the scallop fenestration) and left renal fenestration stent (uncovered, balloon-expandable 316L stainless steel biliary/iliac stent), but in a patient with progressive aneurismal disease within and proximal to the treated segment, which likely resulted in uncharacteristic tension/loading of the stents. No subsequent renal events, endoleak, or secondary interventions reported in this patient.
[5] Patient 0511010: Fracture of left renal fenestration stent (Zenith® Alignment Stent) not readily confirmed based on subsequent bench top CT imaging studies that showed the same appearance of fracture, but in an entirely intact stent.
[6] Patient 1111011: Deformation of fenestration stent (Zenith® Alignment Stent) with no measurable graft movement > 5 mm and not requiring secondary intervention.
[7] Patient 0511003: Slight compression of fenestration stent (uncovered, balloon-expandable 316L stainless steel biliary stent) with no measurable graft movement > 5 mm. Angioplasty and stent placement was performed 1539 days post-procedure to treat stenosis.
[8] Patient 0511007: Slight compression of fenestration stent (uncovered, balloon-expandable 316L stainless steel biliary stent) with no measurable graft movement > 5 mm and not requiring secondary intervention.
[9] Patient 0511006: Compression of fenestration stent (uncovered, balloon-expandable 316L stainless steel biliary stent) associated with graft migration (approximately 12 mm by 24 months) due likely to longitudinal progression of disease with further aortic neck dilatation. Angioplasty and stent placement were performed 883 days post-procedure to treat stenosis.

Table 6.24 summarizes the site reported reasons for secondary intervention. Of the 11 patients who underwent a secondary intervention, 7 did so because of renal stenosis (1 associated with graft migration and stent deformation, 1 associated with stent deformation without migration). In 4 patients, the peak systolic velocity was <280 cm/s prior to reintervention. The other reported reasons for reintervention included renal occlusion in 1, Type II endoleak in 2, and suspected Type I endoleak in 1 (ruled out by angiogram).

Table 6.24. Reasons for secondary intervention (as reported by site)

Reason	0-30 Days	31-365 Days	366-730 Days	731-1095 Days	1096-1460 Days	1461-1825 Days
Aneurysm rupture	0	0	0	0	0	0
Symptoms	0	0	0	0	0	0
Device/renal stenosis	1[1]	2[5,9]	1[7]	1[6]	1[9]	1[11]
Device migration	0	0	0	0	0	0
Device separation	0	0	0	0	0	0
Occlusion	0	1[2]	0	0	0	0
Device kink	0	0	0	0	0	0
Infection	0	0	0	0	0	0
Endoleak						
Type I proximal	0	1[3]	0	0	0	0
Type I distal	0	0	0	0	0	0
Type IIA (vessel perfusion)	0	1[4]	0	0	1[10]	0
Type IIB (vessel perfusion)	0	0	0	0	0	0
Type III (graft overlap joint)	0	0	0	0	0	0
Type IV (through graft body)	0	0	0	0	0	0
unknown	0	0	0	0	0	0
Other	0	0	0	1[8]	1[10]	0

[1] Patient 0211011: Angiography revealed that the right renal artery was severely stenosed. Attempted cannulation was unsuccessful, as the fenestration stent (Zenith® Alignment Stent) was not flared at the time of the initial implant procedure. No evidence of graft migration or stent deformation, suggesting the stenosis may have resulted from local thrombus formation or intimal hyperplasia within the stented segment.
[2] Patient 0211008: Angiogram demonstrated occluded left renal artery with proximal compression of the left renal stent (uncovered, balloon-expandable 316L stainless steel biliary/renal stent), which was treated with iliorenal bypass. Compression without evidence of migration due likely to suboptimal deployment of the renal stent into the middle/upper portion of the fenestration
[3] Patient 0411004: Selective left renal angiography was performed for suspected Type I endoleak. No type I endoleak was identified; however, Type II endoleak was identified but not treated.
[4] Patient 0211010: Persistent Type II endoleak was treated by coil embolization.
[5] Patient 0111008: Right renal artery stenosis (uncovered, balloon-expandable 316L stainless steel biliary stent) was treated by angioplasty and additional stent placement. No evidence of graft migration or stent deformation, suggesting the stenosis may have resulted from local thrombus formation or intimal hyperplasia within the stented segment.
[6] Patient 0111014: Bilateral renal artery stenoses (uncovered, balloon-expandable 316L stainless steel biliary stent) were treated by angioplasty and additional stent placement. No evidence of graft migration or stent deformation, suggesting the stenosis may have resulted from local thrombus formation or intimal hyperplasia within the stented segment.
[7] Patient 0211007: Right renal artery stenosis (uncovered, balloon-expandable 316L stainless steel biliary/renal stent) was treated by angioplasty and additional stent placement. No evidence of graft migration or stent deformation, suggesting the stenosis may have resulted from local thrombus formation or intimal hyperplasia within the stented segment.
[8] Patient 0511006: Right renal artery stent compression and subsequent stenosis (uncovered, balloon-expandable 316L stainless steel biliary stent) treated by angioplasty and stent placement. Compression of fenestration stent associated with graft migration (approximately 12 mm by 24 months) due likely to longitudinal progression of disease with further aortic neck dilatation.
[9] Patient 0511009: Bilateral renal artery stenosis (uncovered, balloon-expandable 316L stainless steel biliary stent) was treated by bilateral angioplasty and stenting. No evidence of graft migration or stent deformation, suggesting the stenosis may have resulted from local thrombus formation or intimal hyperplasia within the stented segment.
[10] Patient 0511004: Underwent diagnostic angiogram for suspect Type IIa and Type III endoleak, which were not detected at 1137 days post-procedure; additional intervention performed 1393 days post-procedure, involving laparotomy, suture ligation of IMA, and exploration of aneurysm sac as treatment for Type II endoleak with aneurysm growth.
[11] Patient 0511003: Left renal artery stenosis (uncovered, balloon-expandable 316L stainless steel biliary stent) from slight compression of fenestration stent (with no measurable graft movement > 5 mm) treated by angioplasty and stent placement.

Summary

This study enrolled 42 patients treated with the Zenith Fenestrated AAA Endovascular Graft, a line extension of the Zenith AAA Endovascular Graft that is customized to the individual anatomy of patients having an infrarenal aortic neck length that is too short for the standard endograft. A variety of fenestration/scallop configurations were utilized, the most frequent of which was 2 small fenestrations and 1 scallop. A total of 111 vessels were targeted by either a fenestration or scallop, 78 of which received a fenestration stent (all stented vessels were main renal arteries accommodated by either a small fenestration or a scallop), including 21 vessels (11 patients) receiving 22 Zenith Alignment Stents. All devices deployed successfully in the intended location, and all graft components and vessels targeted by a fenestration were patent upon completion of deployment, yielding a technical success rate of 100%.

The primary safety and effectiveness data showed that the 6-month treatment success rate for Zenith Fenestrated (97.5%) was similar to that for matched patients treated with Zenith AAA (95%).

There were no ruptures or conversions following treatment with Zenith Fenestrated at any time point. Only one death was counted as AAA-related because the cause was unknown and the CEC was therefore unable to adjudicate it – all other deaths in the Zenith Fenestrated group (3) were determined unrelated to AAA-repair by the CEC.

Pre-specified renal adverse events included renal infarct, renal insufficiency, renal failure requiring dialysis, and occlusion of a fenestrated renal vessel. There were five patients with renal infarct (none were associated with a clinical event), each of which occurred in a patient with some degree of either thrombus or calcification in the seal zone (as well as a history of infarct and coverage of an accessory renal in one). Two of three patients with renal insufficiency in the Zenith Fenestrated group had renal dysfunction prior to treatment and were considered unrelated to AAA-repair by the CEC, one of which was also the only patient in the Zenith Fenestrated group requiring dialysis (also unrelated according to the CEC). Two patients developed occlusion of a fenestrated renal vessel (neither was associated with graft migration), one of which had evidence of fenestration stent compression (from suboptimal stent placement in the mid/upper portion of the fenestration) that required reintervention.

There were no reports of Type I or Type III endoleak, and the only reports of aneurysm growth (2) occurred in patients with a Type II endoleak. There were 2 reports of migration, both in patients with evidence of disease progression at follow-up (without aneurysm pressurization), one of which had associated

fenestration stent compression requiring secondary intervention. One patient was noted to have fracture of a fenestration stent as well as the seal stent on the Fenestrated Graft, neither of which resulted in endoleak, a clinical renal event, or the need for secondary intervention. This patient also exhibited disease progression at follow-up in the absence of aneurysm pressurization. A possible second patient with fenestration stent fracture was identified without a subsequent clinical renal event or need for reintervention.

The majority of patients who underwent reintervention following treatment with the Zenith Fenestrated Graft (7 of 11) did so for renal stenosis. There was evidence of fenestration stent deformation in 2 of 7 patients that underwent reintervention for renal stenosis (1 from suboptimal stent placement in the mid/upper portion of the fenestration, and 1 from migration due to progression of disease at follow-up in the absence of aneurysm pressurization).

7 PATIENT SELECTION AND TREATMENT

(See Warnings and Precautions)

7.1 Individualization of Treatment

Each patient must be evaluated on an individual basis to determine the specific location of the graft fenestrations (refer to Planning and Sizing Sheet), with careful consideration also given to both the potential benefits and specific risks associated with the procedure.

Considerations regarding the use of the Zenith Fenestrated AAA Endovascular Graft (see Warnings) include:

- Risk of aneurysm rupture
- Morbidity and mortality associated with conventional surgical repair
- Comorbidities
- Size of aneurysm
- History of renal failure
- Life expectancy
- Anesthetic risk
- Age of patient
- Iliofemoral access vessel size and morphology (minimal thrombus, calcification and/or tortuosity) should be compatible with vascular access techniques and accessories of the delivery profile of a 14 French to 20 French vascular introducer sheath. Note: Iliac conduits may be used to ensure the safe insertion of the delivery system.
- Non-aneurysmal infrarenal aortic segment (neck) proximal to the aneurysm:
  - with a length that is at least 4 mm and unsuitable for a non-fenestrated graft,
  - with a diameter measured outer wall to outer wall of no greater than 31 mm and no less than 19 mm,
  - with an angle less than 45 degrees relative to the long axis of the aneurysm, and
  - with an angle less than 45 degrees relative to the axis of the suprarenal aorta.
- Ipsilateral iliac artery distal fixation site greater than 30 mm in length and 9-21 mm in diameter (measured outer wall to outer wall).
- Contralateral iliac artery distal fixation site greater than 30 mm in length and 7-21 mm in diameter (measured outer wall to outer wall).
- Freedom from significant femoral/iliac artery occlusive disease that would impede flow through the endovascular graft.

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

8 PATIENT COUNSELING INFORMATION

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

- Risks and differences between endovascular repair (fenestrated and non-fenestrated) and surgical repair.
- Potential advantages of traditional open surgical repair.
- Potential advantages of fenestrated endovascular repair.
- The possibility that subsequent interventional or open surgical repair of the aneurysm may be required after initial endovascular repair.

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

- There have been limited numbers of patients treated with fenestrated endovascular grafts when compared to non-fenestrated endovascular grafts.
- Long-term performance of fenestrated endovascular grafts and stents in the fenestrations/scallops has not yet been established.
- All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft.
- Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, changes in the structure or position of the endovascular graft, or stenosis/occlusion of vessels accommodated by fenestrations) should receive enhanced follow-up.

Specific follow-up guidelines are described in **Section 12, IMAGING AND POST-OPERATIVE FOLLOW-UP.**

9 HOW SUPPLIED

The Zenith Fenestrated AAA Endovascular Graft is supplied sterile and pre-loaded in peel-open packages. The device is intended for single use only and the fenestration/scallop location is individually tailored for each patient. Do not re-sterilize the device. Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product and return to your Cook representative or your nearest Cook office. 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. Do not use after the expiration date printed on the label. Store in a cool dry place.

10 CLINICAL USE INFORMATION

10.1 Physician Training

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

CAUTION: The Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device, which requires precise planning/sizing as well as accurate longitudinal positioning and rotational orientation during placement. The recommended skill/knowledge requirements for physicians using the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System are outlined below:

Patient Selection:

- Knowledge of the natural history of abdominal aortic aneurysms (AAA) and co-morbidities associated with AAA repair.
- Knowledge of radiographic image interpretation, device/fenestration selection and sizing.

A multi-disciplinary team that has combined procedural experience with:

- Femoral cutdown, arteriotomy and repair
- Percutaneous access and closure techniques
- Non-selective and selective wire guide and catheter techniques, especially accessing visceral vessels (e.g., renal arteries)
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty
- Endovascular stent-graft placement
- Renal/visceral stent placement
- Snare techniques
- Appropriate use of radiographic contrast material
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

10.2 Inspection Prior to Use

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

10.3 Materials Required

(Not included in 3-piece modular system)

- Zenith AAA Endovascular Graft Ancillary Kit
- Fluoroscope with digital angiography capabilities (C-arm or fixed unit)
- Contrast media
- Syringe
- Heparinized saline solution

10.4 Materials Recommended

(Not included in 3-piece modular system)

The following products are recommended:

- .035 inch (0.89 mm) extra stiff wire guide, 260 cm; for example:
  - Cook Amplatz Ultra Stiff Wire Guides (AUS)
  - Cook Lunderquist Extra Stiff Wire Guides (LES)
- .035 inch (0.89 mm) standard wire guide; for example:
  - Cook .035 inch wire guides
  - Cook Nimble™ Wire Guides
  - Cook Rosen Wire Guide
- Molding Balloons (e.g., CODA)
- Zenith Alignment Stents
- Introducer sets; for example:
  - Cook Check-Flo® Introducer Sets
  - Cook Extra Large Check-Flo Introducer Sets
  - Cook Flexor® Balkin Up & Over® Contralateral Introducers
- Sizing catheter; for example:
  - Cook Aurous® Centimeter Sizing Catheters
- Angiographic radiopaque tip catheters; for example:
  - Cook Beacon® Tip Angiographic Catheters
  - Cook Beacon Tip Royal Flush Catheters
- Entry needles; for example:
  - Cook single wall entry needles

10.5 Device Diameter Sizing Guidelines

The choice of diameter should be determined from the outer wall to outer wall vessel diameter and not the lumen diameter. Undersizing or excessive oversizing may result in incomplete sealing or comprised flow.

Table 10.5.1 Proximal Body Graft Diameter Sizing

Intended Aortic Vessel Diameter	Main Body Diameter	Introducer Sheath
19	24	20 Fr
20	24	20 Fr
21	24	20 Fr
21	26	20 Fr
22	26	20 Fr
23	28	20 Fr
24	28	20 Fr
24	30	20 Fr
25	30	20 Fr
26	30	20 Fr

26	32	20 Fr
27	32	20 Fr
28	32	20 Fr
28	34	20 Fr
29	34	20 Fr
29	36	20 Fr
30	36	20 Fr
31	36	20 Fr

Table 10.5.2 Distal Body (Ipsilateral Limb) Graft Diameter Sizing

Intended Iliac Vessel Diameter	Ipsilateral Limb Diameter	Introducer Sheath
9	12	20 Fr
10	12	20 Fr
11	12	20 Fr
12	16	20 Fr
13	16	20 Fr
14	16	20 Fr
15	16	20 Fr
15	20	20 Fr
16	20	20 Fr
17	20	20 Fr
18	20	20 Fr
18	24	20 Fr
19	24	20 Fr
20	24	20 Fr
21	24	20 Fr

10.6 Device Length Sizing Guidelines

The proximal body graft and distal body graft are available in multiple lengths. The chosen lengths should provide a minimum two-stent overlap should the graft components align completely along the greater curve of the aorta/aneurysm over time. Planning for a longer overlap length initially (e.g., 3-4 stents) is therefore preferable.

10.6.1 Proximal Graft Lengths	
Diameter (mm)	Body length (mm)
24	76 / 91 / 94 / 106 / 109 / 121 / 124
26	76 / 91 / 94 / 106 / 109 / 121 / 124
28	76 / 91 / 94 / 106 / 109 / 121 / 124
30	76 / 91 / 94 / 106 / 109 / 121 / 124
32	76 / 91 / 94 / 106 / 109 / 121 / 124
34	84 / 99 / 114 / 129 / 107 / 122 / 137
36	84 / 99 / 114 / 129 / 107 / 122 / 137

10.6.2 Distal Graft Lengths		
Ipsilateral Limb Diameter (mm)	Body length (mm)	Ipsilateral Limb length (mm)
12	76 / 91 / 106 / 121	28 / 45 / 62
16	76 / 91 / 106 / 121	28 / 45 / 62
20	76 / 91 / 106 / 121	28 / 45 / 62
24	76 / 91 / 106 / 121	28 / 45 / 62

10.7 Graft Fenestration/Scallop Guidelines

The proximal body graft may contain up to three precisely located holes (fenestration(s)), and cut-outs from the proximal margin (scallop(s)) of the graft material. The fenestration and/or scallop locations are individualized to the patient anatomy based on measurements from high resolution pre-operative CT imaging. Refer to the Planning and Sizing Sheet for information regarding how these locations are determined.

11 INSTRUCTIONS FOR USE

General Use Information

Prior to use of the Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System, review this Suggested Instructions for Use booklet. The following instructions embody a basic guideline for device placement. Variations in the following procedures may be necessary.

These instructions are intended to help guide the physician and do not take the place of physician judgment.

Pre-Implant Determinants

Verify from pre-implant planning (refer to Planning and Sizing Sheet) that the correct device has been selected. Determinants include:

1. Femoral artery selection for introduction of the main body system, (i.e., define respective contralateral and ipsilateral iliac arteries).
2. Angulation of aortic neck, aneurysm and iliacs.
3. Quality of the aortic neck.
4. Diameters of infrarenal aortic neck and distal iliac vessels.
5. Distance from renal arteries to the aortic bifurcation.
6. Distance from the renal arteries to the hypogastric (internal iliac) arteries/attachment site(s).
7. Aneurysm(s) extending into the iliac arteries may require special consideration in selecting a suitable graft/artery interface site.
8. Consider the degree of vascular calcification.
9. Size and location/position of visceral vessel origins.

NOTE: Each respective vessel diameter and length (aorta, ipsilateral iliac and contralateral iliac) provides the necessary criteria for choosing the appropriate endovascular graft.

Patient Preparation

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

11.1 Fenestrated System

11.1.1 Proximal Body Graft Preparation/Flush

1. Remove black-hubbed shipping stylet (from the inner cannula), cannula protector tube (from the inner cannula) and dilator tip protector (from the dilator tip). Remove Peel-Away® sheath from back of the Captor hemostatic valve. **(Figure 8)** Elevate distal tip of system and flush through the stopcock on the hemostatic valve until fluid emerges from the sideport near the tip of the introduction sheath. **(Figure 9)** Continue to inject a full 20 cc of flushing solution through the device. Discontinue injection and close stopcock on connecting tube.

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

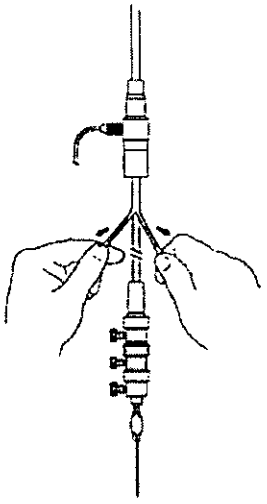


Fig.8

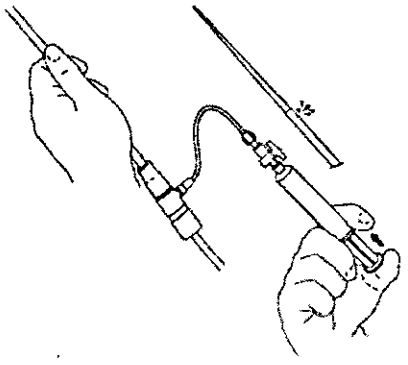


Fig. 9

2 .Attach syringe with normal heparinized saline to the hub on the inner cannula. Flush until fluid exits the distal tip. **(Figure 10)**

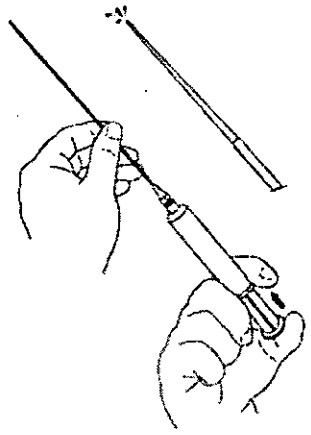


Fig. 10

NOTE: When flushing system, elevate distal end of system to facilitate removal of air.

11.1.2 Distal Bifurcated Body Graft Preparation/Flush

1. Remove black-hubbed shipping stylet (from the inner cannula), cannula protector tube (from the inner cannula) and dilator tip protector (from the dilator tip). Remove Peel-Away sheath from back of the Captor hemostatic valve. **(Figure 11)** Elevate distal tip of system and flush through the stopcock on the hemostatic valve until fluid emerges from the sideport near the tip of the introduction sheath. **(Figure 12)** Continue to inject a full 20 cc of flushing solution through the device. Discontinue injection and close stopcock on connecting tube.

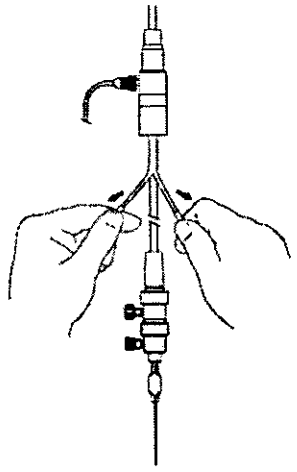


Fig. 11

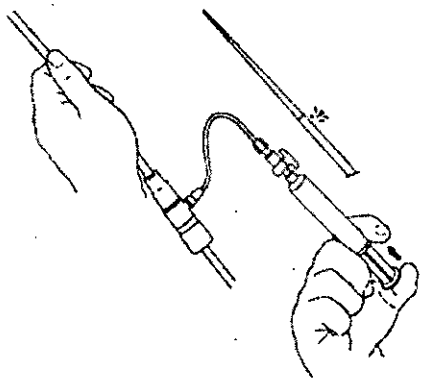


Fig. 12

11.1.3 Iliac Leg (Contralateral) Preparation/Flush

Refer to the Instructions for Use enclosed in the device packaging for the iliac leg graft for instruction on preparation/flush.

11.1.4 Vascular Access and Angiography

1. Puncture the selected common femoral arteries using standard technique with an 18 or 19UT gage arterial needle. Upon vessel entry, insert:
- Wire guides - standard .035 inch diameter, 145 cm long, J tip or Bentson Wire Guide
- Appropriate size sheaths (e.g., 6.0 or 8.0 French)
- Flush catheter (often radiopaque sizing catheters - e.g., Centimeter Sizing Catheter or straight flush catheter)

2. Perform angiography to identify level(s) of renals, aortic bifurcation and iliac bifurcations.

NOTE: If fluoroscope angulation is used with an angulated neck it may be necessary to perform angiograms using various projections.

NOTE: A previous planning exercise will have determined which side will be used to introduce the proximal and distal bodies.

11.1.5 Proximal Body Placement

CAUTION: Verify that the predetermined access site is chosen for the introduction and placement of the proximal body.

1. Ensure the delivery system has been flushed with heparinized saline and that all air is removed from the system.
2. Give systemic heparin and check flushing solutions. Flush after each catheter and/or wire guide exchange.

NOTE: Monitor the patient's coagulation status throughout the procedure.

3. On ipsilateral side, replace J wire with stiff wire guide (LES) .035 inch, 260 cm long and advance through catheter and up to the thoracic aorta. Remove flush catheter and sheath. Maintain wire guide position.

NOTE: A straight angiographic catheter should be inserted up the contralateral side to aid in placement of graft.

4. Before insertion, position proximal body delivery system on patient's abdomen under fluoroscopy to assist with orientation and positioning. Rotate to a position where the anterior markers are situated in the most anterior (12:00 o'clock) position. The sidearm of the hemostatic valve may serve as an external reference to the fenestration(s) and/or scallop(s), anterior and posterior markers and body side markers.

CAUTION: Maintain wire guide position during delivery system insertions.

CAUTION: To avoid any twist in the endovascular graft, during any rotation of the delivery system, be careful to rotate all of the components of the system together (from outer sheath to inner cannula).

5. Advance the delivery system until the radiopaque markers indicating the fenestration(s) and/or scallop(s) are at the level of the appropriate arteries. Check that the distal end of the graft is in a satisfactory position above the aortic bifurcation and that the anterior and posterior markers indicate that the graft is in satisfactory orientation. **(Figure 16)**

NOTE: Angiography should be performed as needed throughout deployment, to confirm correct placement of the graft.

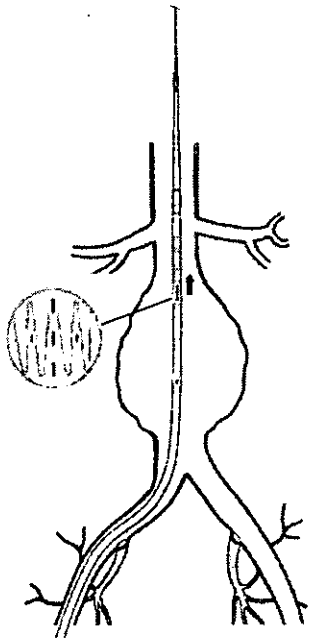


Fig. 16

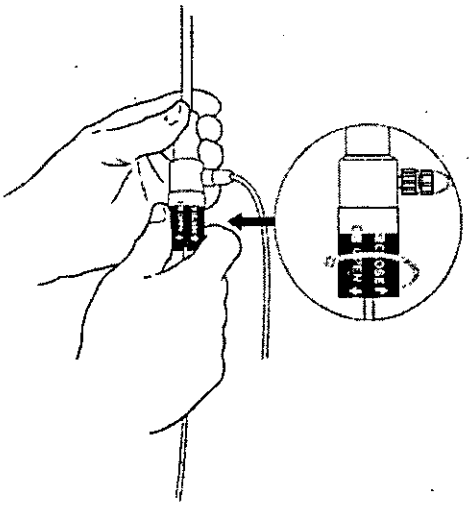


Fig. 17

6. Verify position of the wire guide in the thoracic aorta. Ensure that fenestration(s) and/or scallops are at the level of the appropriate arteries and the anterior markers are in the most anterior (12:00 o'clock) position.

NOTE: The vertical anterior markers, and the horizontal posterior markers should form a cross, on the fluoroscopic image, when correctly oriented **(Figure 16)**.

NOTE: The fenestration/scallop markers should be in close apposition to the appropriate side branch vessels.

Clear identification of fenestration position(s) may not be possible until the graft has been partially unsheathed.

NOTE: Ensure the Captor Hemostatic Valve on the introducer sheath is turned to the open position. **(Figure 17)**

7. Stabilize the grey positioner (the shaft of the delivery system) while withdrawing the sheath. Deploy the first two (2) covered stents by withdrawing the sheath while monitoring device location.

8. Perform angiography, and adjust graft placement as necessary. Continue to withdraw the sheath making positional adjustments as necessary.

NOTE: Techniques to ensure that the fenestration(s) and/or scallop(s) will accurately align with their respective vessels will vary, and will depend upon vessel anatomy, graft design, and physician preferences.

NOTE: If a small fenestration is being utilized, care should be taken to properly align the fenestration with the respective vessel.

9. Proceed with deployment until the graft has been fully unsheathed. **(Figure 18)**

10. When a satisfactory graft position has been achieved, exchange the contralateral angiographic catheter and wire guide with a selective wire guide/selective catheter positioned just below the level of the proximal body. Cannulate the partially deployed proximal main body. Advance the selective catheter over the selective wire guide into the renal artery. Exchange the selective wire with a Rosen wire or equivalent wire guide.

11. Utilizing contralateral access sheath and wire guide, advance a guiding catheter into each small fenestration and its respective vessel. **(Figure 19)**

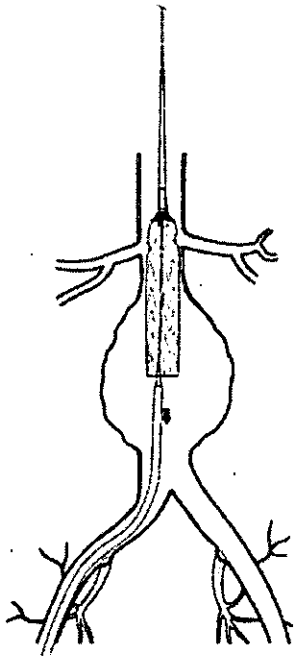


Fig. 18

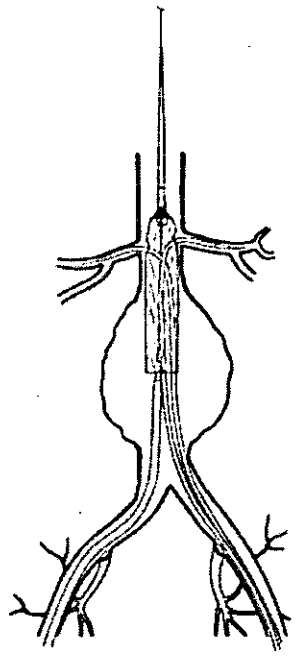


Fig. 19

NOTE: Non-compliant angioplasty balloons may be used as an alternative to guiding catheters.

NOTE: Cannulation of the scallop and its respective vessel may also be achieved using similar techniques.

NOTE: It is not recommended to use balloons or guiding catheters to guide final placement of large fenestrations as stent struts across fenestration may interfere.

NOTE: To ensure renal stent placement in the lower portion of the fenestration, it may be necessary to slightly advance the graft after catheter/sheath access to the renal vessels, before removal of the diameter reducing ties.

CAUTION: Before release of the diameter reducing ties, verify that the position of the ipsilateral access wire extends just distal to the aortic arch.

12. Verify proper position of proximal body. Remove the safety lock from the first (distal) white trigger-wire release mechanism. Withdraw and remove the trigger-wire by sliding the white trigger-wire release mechanism off the handle and then remove via its slot over the inner cannula. (Figure 20)

NOTE: At this point, the proximal main body graft should be fully expanded with the proximal bare stent contained within the top cap.

13. Remove the safety lock from the black trigger-wire release mechanism. Withdraw and remove the trigger-wire to unlock the suprarenal stent from the top cap by sliding the black trigger-wire release mechanism off the handle and then remove via its slot over the inner cannula. (Figure 21)

NOTE: The distal stent is still secured by the trigger-wire.

14. Loosen the pin vise. (Figure 22) Control the position of the graft by stabilizing the grey positioner of the introducer.

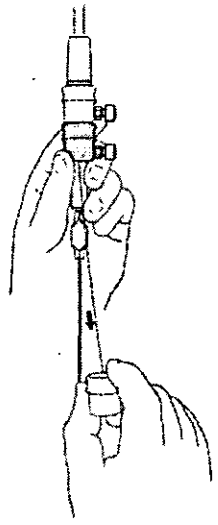


Fig. 20

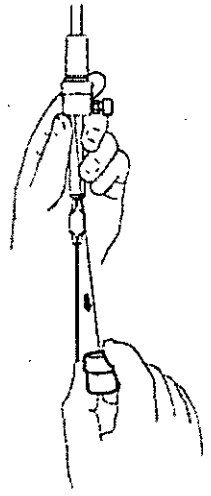


Fig. 21

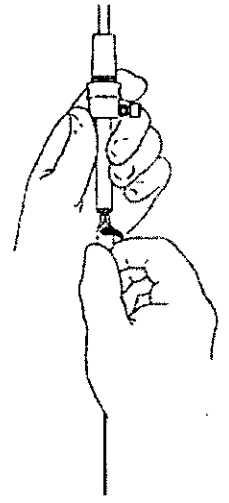


Fig. 22

15. Deploy the suprarenal stent by advancing the top cap inner cannula 1 to 2 mm at a time while controlling the position of the proximal body until the top stent is fully deployed. **(Figures 23a and 23b)** Advance the top cap cannula an additional 1 to 2 cm and then retighten the pin vise to avoid contact with the deployed suprarenal stent.

WARNING: The Zenith Fenestrated AAA Endovascular Graft incorporates a suprarenal stent with fixation barbs. Exercise extreme caution when manipulating interventional devices in the region of the suprarenal stent.

16. Remove the safety lock from the second (proximal) white trigger-wire release mechanism. Withdraw and remove the trigger-wire to detach the distal end of the endovascular graft from the delivery system by sliding the white trigger-wire release mechanism off the handle and then remove via its slot over the device inner cannula. **(Figure 24)**

NOTE: Check to make sure that all trigger-wires are removed prior to withdrawal of the delivery system.

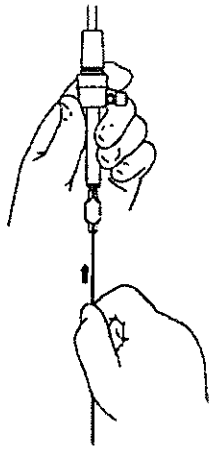


Fig. 23a

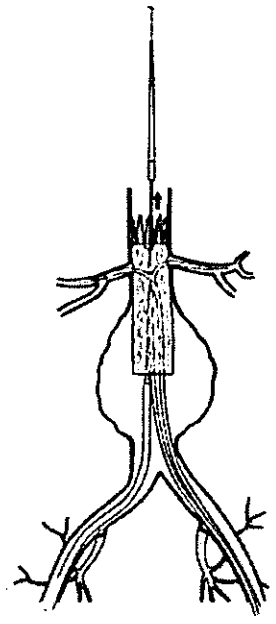


Fig. 23b

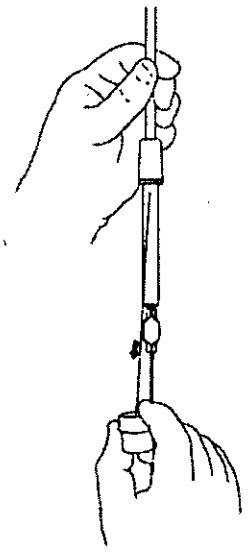


Fig. 24

11.1.6 Docking of Top Cap

1. Loosen the pin vise. **(Figure 25)**
2. Secure sheath and inner cannula to avoid any movement of these components.
3. Advance the grey positioner over the inner cannula until it docks with the top cap. **(Figures 26a, 26b and 26c)**

NOTE: If resistance occurs, slightly rotate grey positioner and continue to gently advance.

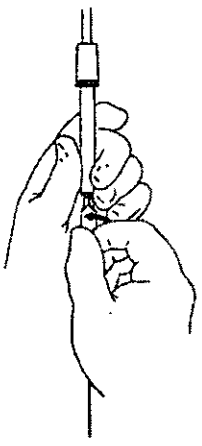


Fig. 25

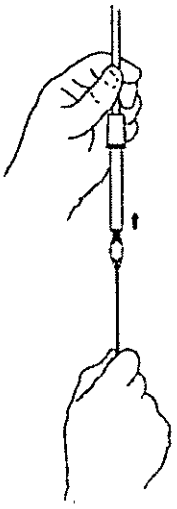


Fig. 26a

Fig. 26b

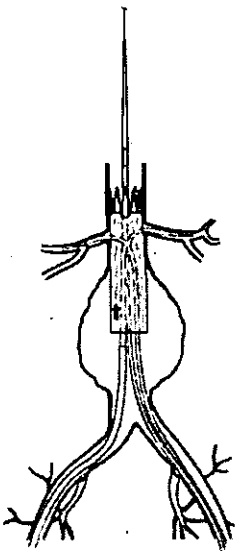


Fig. 26c

4. Retighten the pin vise and withdraw the entire top cap and grey positioner through the graft and through the sheath by pulling on the pink hub of the inner cannula. (Figure 27) Leave the sheath and wire guide in place.
5. Close the Captor Hemostatic Valve by turning it in a clockwise direction until it stops.

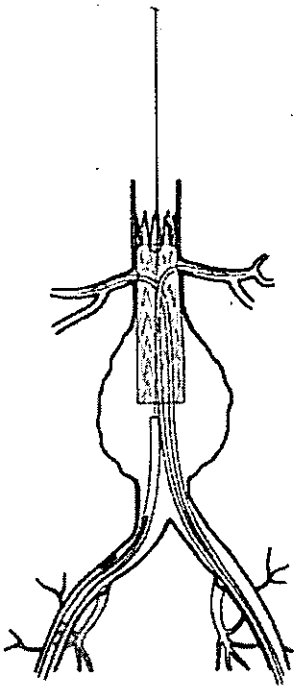


Fig. 27

11.1.7 Fenestration Stent Placement and Deployment

General Use Information

In the event that small fenestrations are being utilized, stents may be placed to secure positive alignment. Standard techniques for placement of arterial stents should be employed during use of stents. The Zenith Alignment Stent is available for this purpose. Refer to the Zenith Alignment Stent Suggested Instructions for Use for details.

1. Return to the guide catheter and wire guide which cannulate the small fenestration and respective vessel.
2. Introduce appropriately sized balloon expandable stent and advance to the ostium of the fenestration/vessel. Advance stent partially into the vessel, leaving approximately 4-5mm of stent in the aorta. (Figure 28)

NOTE: Fluoroscopic views tangential to the fenestration will optimize visualization of the stent position relative to the stent graft.

3. Expand stent.
4. Remove the balloon and replace with an oversized angioplasty balloon. Advance the balloon until the proximal tip is positioned at the ostium.
5. Inflate the balloon to flare the intra-aortic segment of the stent. **(Figure 29)**

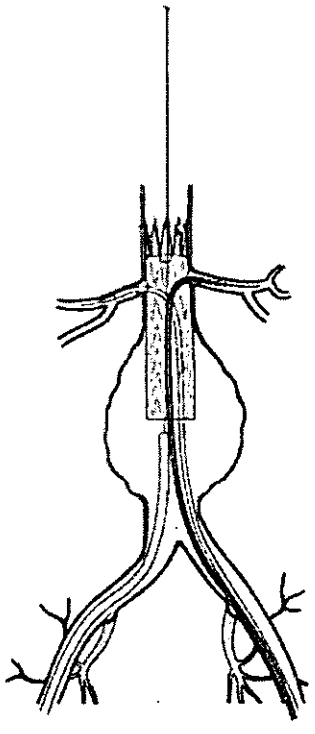


Fig. 28

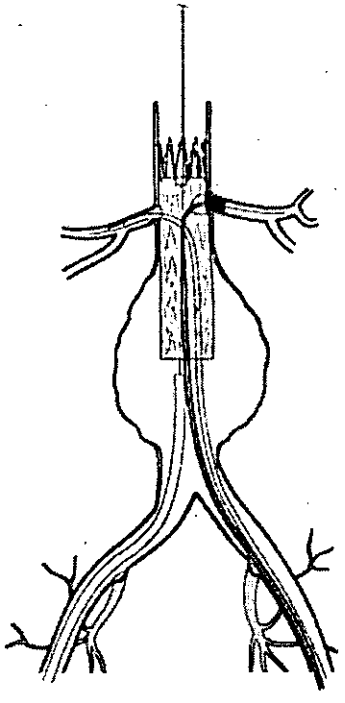


Fig. 29

CAUTION: This technique requires high quality imaging. Mobile image intensifiers may provide less than adequate imaging quality.

6. Remove the angioplasty balloon.
7. Withdraw renal access sheaths, catheters and wire guides in the contralateral side to a level just above the aortic bifurcation.

NOTE: In the event that there is more than one fenestration, repeat the preceding steps for each additional small fenestration.

11.1.8 Distal Bifurcated Body Placement

1. Ensure the delivery system has been flushed with heparinized saline and that all air is removed from the system.
2. Check flushing solutions. Flush after each catheter and/or wire guide exchange.
3. Before insertion, position distal bifurcated body delivery system on patient's abdomen under fluoroscopy to determine the orientation of the contralateral limb. The side arm of the hemostatic valve may serve as an external reference to the contralateral limb radiopaque marker.

NOTE: Distal bifurcated body delivery system will not pass through the sheath used to deliver the proximal body.

NOTE: The proximal body delivery sheath must be removed prior to insertion of the distal bifurcated body delivery system.

4. Insert Distal Bifurcated Body delivery system over the wire, into the femoral artery with attention to sidearm reference.

CAUTION: Maintain wire guide position during delivery system insertion.

CAUTION: To avoid any twist in the endovascular graft, during any rotation of the delivery, be careful to rotate all of the components of the system together (from outer sheath to inner cannula).

5. Advance delivery system until the contralateral limb is positioned in suitable orientation above and anterior to the origin of the contralateral iliac. **(Figure 30)** If the contralateral limb radiopaque marker is not properly aligned, rotate the entire system until it is.
6. Repeat angiogram to verify:
   - The degree of overlap with proximal body (no less than 2 stents)
   - The position of the contralateral limb
   - The position of the ipsilateral iliac limb with respect to the common iliac bifurcation.

Reposition distal bifurcated body as required.

CAUTION: When introducing distal bifurcated body, observe proximal body closely to avoid any disruption to its position.

NOTE: Ensure the Captor Hemostatic Valve on the introducer sheath is turned to the open position. **(Figure 31)**

7. Stabilize the grey positioner (the shaft of the delivery system) while withdrawing the sheath. Deploy the first two (2) covered stents by withdrawing the sheath while monitoring device location. Proceed with deployment until contralateral limb is fully deployed. **(Figure 32)**

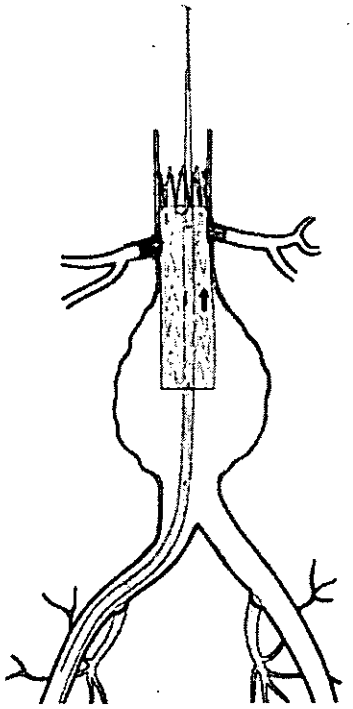


Fig. 30

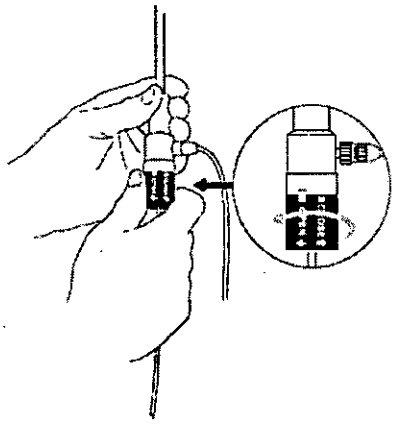


Fig. 31

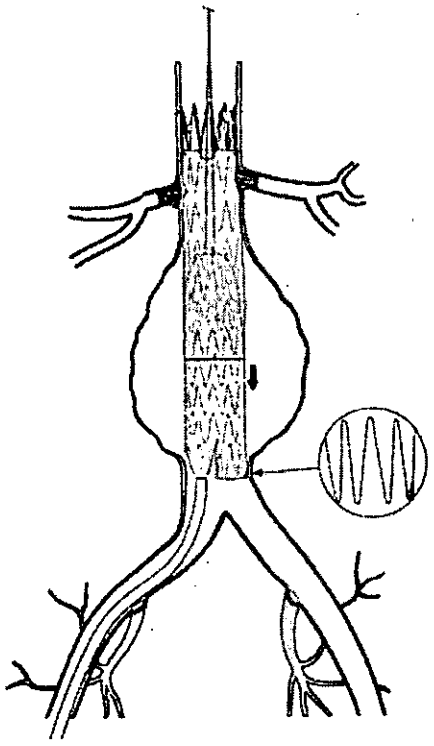


Fig. 32

11.1.9 Contralateral Iliac Wire Guide Placement

1. Manipulate the wire guide from the contralateral side and into the contralateral limb and into the Distal Bifurcated Body. **(Figure 33)** AP and oblique

fluoroscopic views can aid in verification of device cannulation.

2. Advance the angiographic catheter into the body of the graft to the level of the overlap between the proximal and distal graft components. Perform angiography to confirm correct position inside the Distal Bifurcated Body. Advance the catheter to where the proximal end of the Distal Bifurcated Body is attached to the introducer.

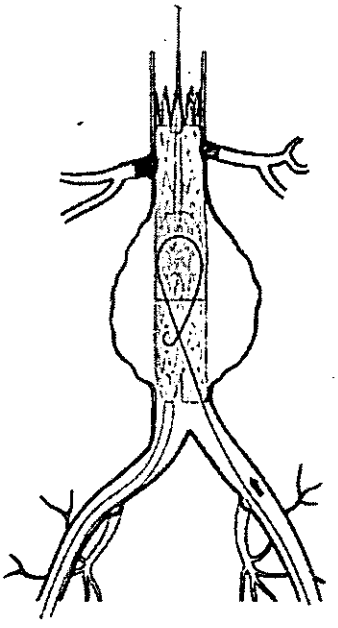


Fig. 33

11.1.10 Distal Bifurcated Body Deployment

1. Perform angiography to confirm proper position of the ipsilateral iliac leg with respect to the internal iliac (hypogastric) artery. Adjust position if necessary.
2. Withdraw sheath until the iliac leg is fully deployed.
3. Remove the safety lock from the black trigger-wire release mechanism. Withdraw and remove the trigger-wire by sliding the black trigger-wire release mechanism off the handle and then remove via its slot over the device inner cannula. (Figure 34) Stop withdrawing sheath.
4. Advance the contralateral catheter to above the level of the proximal graft, and pass a supportive wire guide (AUS or LES) through it to the level of the arch. Remove the catheter.

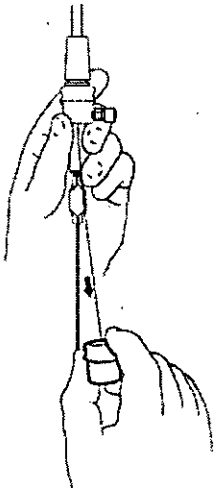


Fig. 34

11.1.11 Iliac Leg (Contralateral) Placement

Refer to the Instructions for Use enclosed in the device packaging for the iliac leg graft. Once placement of the contralateral iliac leg is complete, continue with deployment of the distal bifurcated body (11.1.12).

11.1.12 Distal Bifurcated Body Deployment (Continued)

1. Remove the safety lock from the white trigger-wire release mechanism. Withdraw and remove the trigger-wire by sliding the white trigger-wire release mechanism off the handle and then remove via its slot over the device inner cannula. **(Figure 38)**
2. Under fluoroscopy and after verification of iliac leg graft position, withdraw grey positioner with secured inner cannula.
3. Re-check the position of the wire guides. Leave sheath and wire guide in place.
4. Close the Captor Hemostatic Valve on the introducer sheath by turning in a clockwise direction until hemostasis is achieved. **(Figure 39)**

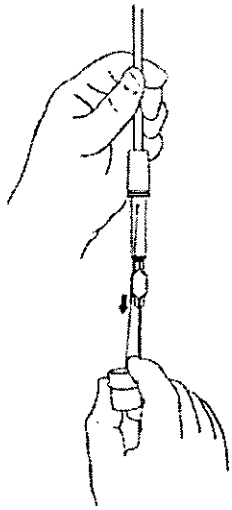


Fig. 38

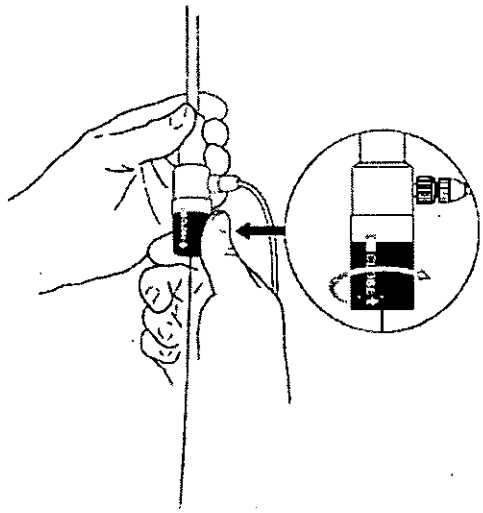


Fig. 39

11.1.13 Molding Balloon Insertion

1. Prepare Molding balloon as follows:
   - Flush wire lumen with heparinized saline.
   - Remove all air from balloon.
2. In preparation for the insertion of the molding balloon, open the Captor Hemostatic Valve by turning it counter-clockwise.
3. Advance the Molding balloon over the wire guide and through the Captor Hemostatic Valve of the distal bifurcated body introduction system to level of renal arteries. Maintain proper sheath positioning.

NOTE: Captor Hemostatic Valve may be utilized to assist with hemostasis by turning in a counter-clockwise rotation to the "close" position.

NOTE: Captor Hemostatic Valve should always be in the "open" position when repositioning of molding balloon.

4. Expand the molding balloon with diluted contrast media (as directed by the manufacturer) in the area of the suprarenal stent and the infrarenal neck, starting proximally and working in the distal direction. **(Figure 40)**

CAUTION: Prior to molding in the vicinity of any Fenestration stent(s) confirm that the aortic section of the stent has been flared.

CAUTION: Confirm complete deflation of balloon prior to repositioning.

5. Withdraw the Molding balloon to the ipsilateral limb distal fixation site and expand.

CAUTION: Do not inflate balloon in the vessel outside of graft, as doing so can result in vessel damage (e.g., rupture).

6. Deflate and remove molding balloon. Transfer the molding balloon onto the contralateral wire guide and into the contralateral iliac leg introduction system. Advance molding balloon to the contralateral limb overlap and expand.

CAUTION: Confirm complete deflation of balloon prior to repositioning.

7. Withdraw the molding balloon to the contralateral iliac leg/vessel distal fixation and expand. **(Figure 40)**

CAUTION: Do not inflate balloon in the vessel outside of graft, as doing so can result in vessel damage (e.g., rupture).

8. Remove molding balloon and replace it with an angiographic catheter to perform completion angiograms.
9. Remove or replace all stiff wire guides to allow iliac arteries to resume their natural position.

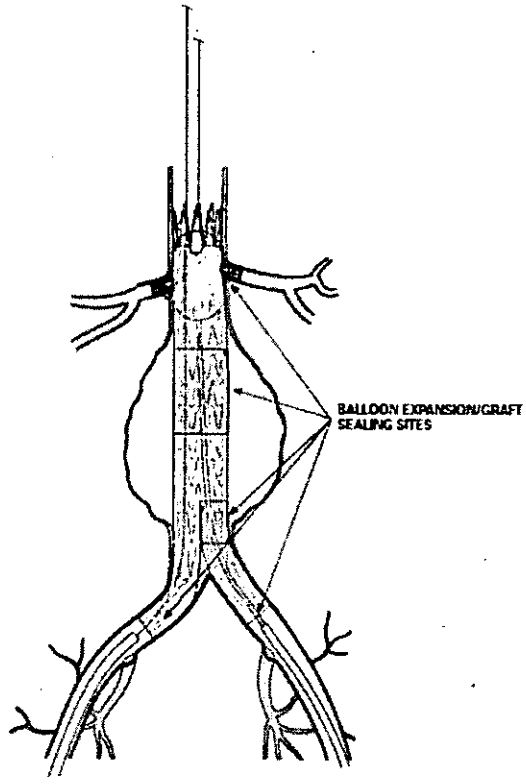


Fig. 40

Final Angiogram

1. Position angiographic catheter just above the level of the branch vessel(s) accommodated by a fenestration/scallop. Perform angiography to verify branch vessel (e.g., renal artery, superior mesenteric artery) patency and that there are no endoleaks. Verify patency of internal iliac arteries.
2. Confirm there are no endoleaks or kinks and verify position of proximal gold radiopaque markers. Remove the sheaths, wires and catheters.

NOTE: If endoleaks or other problems are observed, refer to **Section 1.6, Ancillary Components**.

3. Repair vessels and close in standard surgical fashion.

12 IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

12.1 General

All patients should be advised that endovascular treatment with this device requires lifelong, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, or changes in the structure or position of the endovascular graft) may require additional follow-up. Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be informed that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of abdominal aneurysms with this device. Physicians should evaluate patients on an individual basis and prescribe follow-up relative to the needs and circumstances of each individual patient.

Please refer to table 12.1 for recommended imaging and post-operative follow-up requirements. Precise planning and sizing of the Zenith Fenestrated AAA Endovascular Graft requires high resolution CT pre-procedure in order to obtain accurate measurements for determining graft size (diameter and length) and fenestration/scallop location. Regular follow-up imaging is important to monitor the performance of the device, allowing for timely reintervention if necessary. The imaging recommended at follow-up (CT/X-ray) is the same as for a non-fenestrated device and is intended to similarly provide for an assessment of device integrity, endoleak, change in aneurysm size, and device position (migration, component overlap). Following placement of a fenestrated graft, it is also important to evaluate the patency of vessels accommodated by fenestrations, which can also be supported by high resolution CT imaging. Duplex ultrasound may also be a useful screening tool in assessing the patency of vessels accommodated by a fenestration, provided the results are interpreted using appropriate criteria.

Table 12.1 - Recommended Imaging and Post-Operative Follow-up Schedule

	Pre-procedure	Procedure	30 Day	6 Month (optional)	12 Month[3]
Clinical exam	X		X	X	X
CT	X		X[1]	X[1]	X[1]
Device x-ray			X	X	X
Angiography	X[2]	X			
Renal Duplex Ultrasound	X		X	X	X
Blood Tests (Serum Creatinine, BUN)	X		X	X	X

1 Duplex ultrasound along with a non-contrast CT may be used to assess the aneurysm for those patients experiencing renal failure or who are otherwise unable to undergo contrast enhanced CT scan.

2 Pre-procedure angiography may be required at discretion of implanting physician or film reviewer.

3 Annually thereafter..

12.2 Angiography

Angiographic imaging is recommended during the procedure to evaluate anatomy and facilitate device placement. In addition, selective catheterization of the visceral vessels targeted by a fenestration is recommended. At the completion of the procedure, patency of the following arteries: aorta, celiac, superior mesenteric, right and left renals and/or accessory renals, and right and left internal external iliac arteries should be evaluated. Pre-procedural angiography may be required at the discretion of the implanting physician or film reviewer.

12.3 Computed Tomography (CT)

High resolution CT imaging is recommended pre-procedure in order to obtain accurate measurements for determining graft size (diameter and length) and fenestration/scallop location. CT images are also recommended at 30 days post-procedure, optionally at 6 months post-procedure and yearly thereafter to provide for an assessment of endoleak, change in aneurysm size, and device position (migration, component overlap). Following placement of a fenestrated graft, it is also important to evaluate the patency of vessels accommodated by fenestrations, which can also be supported by high resolution CT imaging.

Table 12.3.1 lists the general scan parameters for evaluation of patients with the Zenith Fenestrated AAA Endovascular Graft.

Table 12.3.1 Recommended CT imaging parameters

Scan Parameters	Recommendations for Optimal Imaging
Acceptable machines	Spiral CT or high performance MDCT capable of >40 seconds
Scan Parameters	Optimize the technique for body habitus and slice thickness
Superior Extent	Above diaphragm
Inferior Extent	Proximal femur
Slice Thickness	≤1.0 mm
Slice Spacing	At least 50% overlap
Field of View (FOV)	Adjust for body habitus (include all anatomy / soft tissue)
IV Contrast	100-200 cc, tailored to the needs or limitations of individual patient
Reconstruction Algorithm	1 mm throughout

12.4 Device X-Ray

X-rays are recommended at 30 days post-procedure, optionally at 6 months post-procedure and yearly thereafter as an adjunct to CT to assess device integrity. It is important to ensure that the entire device is captured on the images for device assessment. Recommended imaging parameters include:

- The patient be in the supine position
- 40 inch focal film distance (FFD)
- Obtain 4 views: AP, LAT, 30° RPO, and 30° LPO centered on umbilicus.
- In order to properly penetrate and expose the abdomen utilize lumbar spine technique, center photo cell or manual technique.

12.5 Renal Duplex Ultrasound

Duplex ultrasound may be used as a screening tool for assessing the patency of vessels to be accommodated by a fenestration both pre- and post-procedure. Duplex ultrasound can be an important adjunct to non-contrast enhanced CT in patients with renal failure or who are otherwise contraindicated to receive iodinated contrast. The following information should be included in the evaluation if duplex ultrasound is performed:

- Transverse and longitudinal imaging from the level of the proximal abdominal aorta - demonstrating celiac, mesenteric and renal arteries – to the iliac bifurcations to verify if endoleaks are present and vessels are patent utilizing color flow and color power Doppler (if accessible).
- Spectral analysis confirmation of any suspected endoleaks.
- Transverse and longitudinal imaging of the maximum aneurysm diameter.

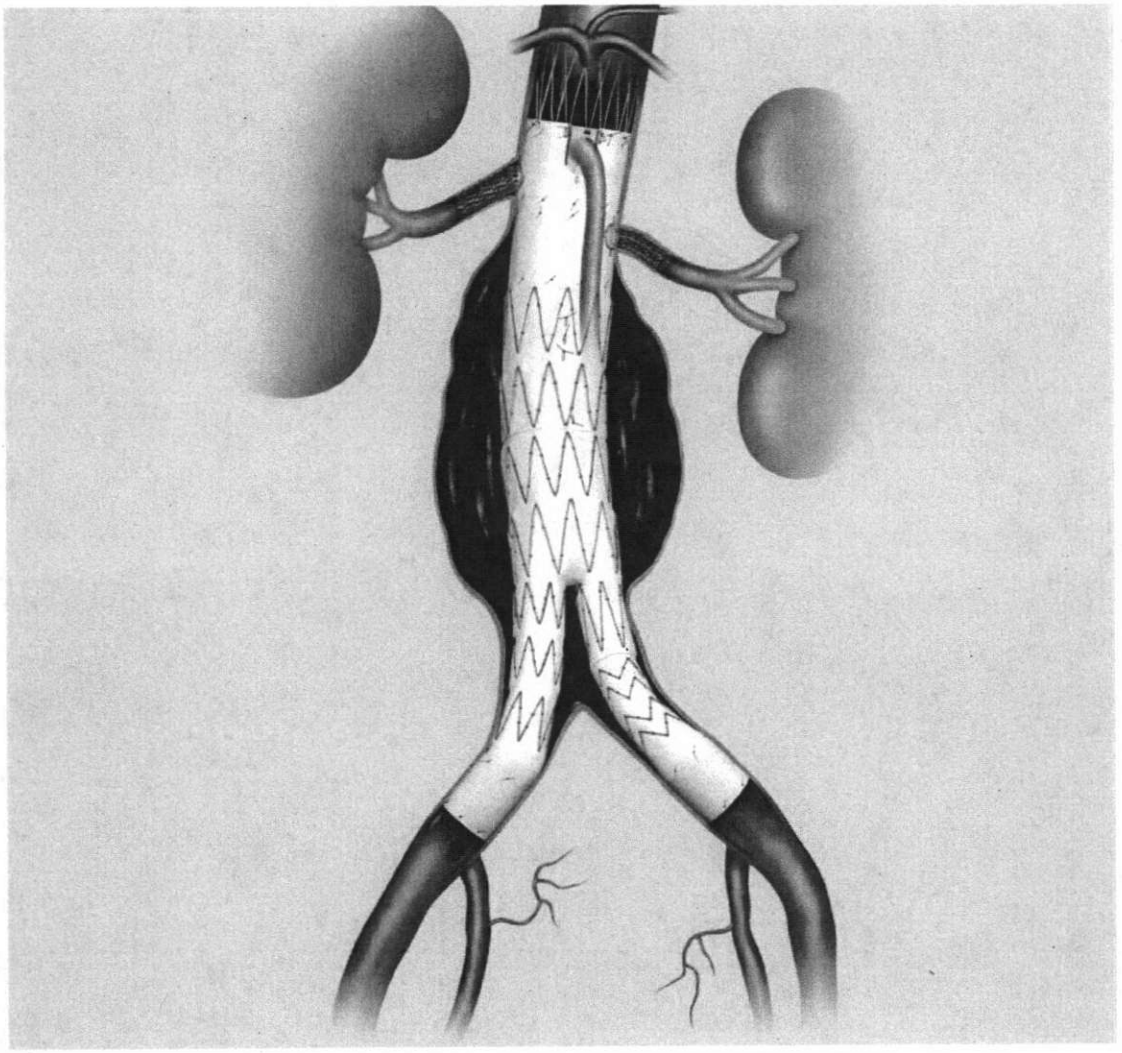
12.6 Supplemental Imaging

Additional radiological imaging may be necessary to further evaluate the endovascular graft *in situ* based on findings revealed by previous imaging assessments. The following recommendations may be considered.

- If there is evidence of poor or irregular position of the endovascular graft, severe angulation, kinking, or migration of the endovascular graft on X-rays, a spiral CT should be performed to assess aneurysm size and the presence or absence of an endoleak.
- If a new endoleak or increase in AAA size is observed by spiral CT, adjunctive studies such as 3-D reconstruction or angiographic assessment of the endovascular graft and native vasculature may be helpful in further evaluating any changes of the endovascular graft or aneurysm.
- Spiral CT without contrast or Renal Duplex Ultrasound may be considered in select patients who cannot tolerate contrast media or who have renal function impairment. For centers with appropriate expertise, gadolinium or CO2 angiography may be considered in patients with renal function impairment requiring angiographic assessment.

PATIENT GUIDE

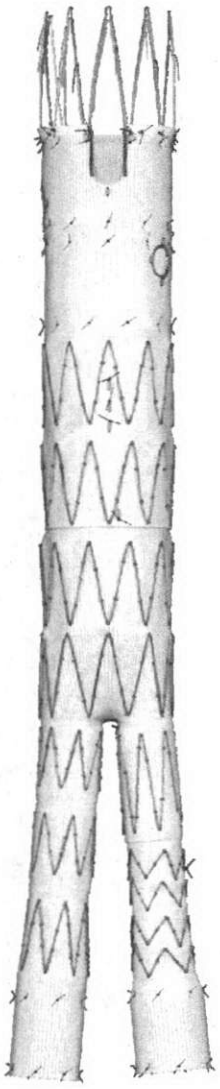
Treating Your Abdominal Aortic Aneurysm



COOK MEDICAL

Zenith® Fenestrated

AAA ENDOVASCULAR GRAFT



About This Patient Guide

This patient guide has been provided as a courtesy from Cook Medical Incorporated and is intended to help you learn more about an **abdominal aortic aneurysm** (AAA). We hope this information will be helpful to you and your family.

For your convenience, a glossary of medical terms is included on pages 4-6. Words in **bold** throughout this text are defined in the glossary.

This patient guide is only a guideline. It provides basic information about **abdominal aortic** and **aortoiliac aneurysms** and their treatment with the Cook **Zenith Fenestrated® AAA Endovascular Graft**. This information is not intended to diagnose a medical condition. The treatment of **abdominal aortic aneurysms** may vary according to an individual's unique needs and doctor assessments. As with any surgery or medical procedure, the best source of information and advice is your doctor.

CONTENTS

Glossary

Abdominal Aortic Aneurysm (AAA) – a bulge that occurs in the part of the aorta that passes through the abdomen (stomach area). The bulge (enlarging and thinning) of the aorta is due to a weakening in the arterial wall.

Aorta – the main artery that carries blood from the heart to the rest of the body.

Aortoiliac Aneurysm – an enlarging and thinning of a weakened area of the abdominal aorta that also extends down into the common iliac artery.

Aneurysm – a bulging or ballooning (enlarging and thinning) of a weakened area of a blood vessel.

Angiography – an x-ray method that uses contrast (dye) injected into the bloodstream to see blood flow through blood vessels.

Angiogram – the image taken during an angiography.

Branch Vessels – blood vessels that come off the aorta, such as the renal and superior mesenteric arteries

Contrast (dye) – a liquid dye injected into the bloodstream to show blood vessels under x-ray or CT scan.

CT Scan – a series of computerized x-rays that form a picture of your aneurysm. Formerly known as a CAT scan.

Embolization – the process of purposefully obstructing a blood vessel or organ with a material mass.

Endoleak – blood flow into the abdominal aortic aneurysm after placement of an endovascular graft.

Endovascular – inside or within a blood vessel.

Endovascular Graft – a graft placed inside a diseased vessel without the use of open surgical techniques. The graft makes a new path through which the blood flows.

Endovascular Repair – placement of an endovascular graft to seal off (exclude) an aneurysm. Instead of making a large incision in the abdomen, the doctor makes a small cut near each hip (near the crease between the abdomen and thigh) to get to the femoral arteries (blood vessels). Through these small cuts, a graft (fabric tube) is inserted through the femoral arteries. The graft makes a new path through which the blood flows.

Femoral Arteries – two blood vessels (one in each leg) that carry blood to the thigh region of each leg. Doctors can use the femoral arteries as a path to reach the iliac arteries and the aorta.

Fenestration – precisely placed hole in the graft material to permit blood flow to a **branch vessel**.

Fenestration Stents – surgical steel mesh tubes that are deployed through the scallops or fenestrations to help maintain blood flow into the **branch vessels**.

Iliac Arteries (Common) – the two large blood vessels that extend from the lower end of the aorta to the internal iliac, external iliac and femoral arteries in each leg.

Iliac Leg(s) – the parts of the Zenith Fenestrated AAA Endovascular Graft that extend from the main body (in the aorta) to the iliac arteries.

MRI (Magnetic Resonance Imaging) – a way of creating detailed pictures of the body. The MRI scanner uses magnetic fields and radio waves to create the pictures.

Occlusion – blockage of a blood vessel.

Open Surgical Repair – a type of surgery performed to repair an aneurysm. To reach the aneurysm, a doctor makes a cut through the abdomen or the side of the patient. The doctor repairs the aorta by replacing the aneurysm section with a fabric tube called a graft. The graft is sewn into place and acts as a replacement blood vessel.

Renal Arteries – two blood vessels that come off the aorta and carry blood to the kidneys.

Renal Infarct – loss of blood flow to a portion of the kidney.

Rupture – a tear in the blood vessel wall that causes serious internal bleeding.

Scallop – u-shaped opening or cutout from the proximal edge of the graft to permit blood flow to a **branch vessel**.

Sheath – a long plastic tube that contains the Zenith Fenestrated AAA Endovascular Graft. The sheath is advanced inside the blood vessel to the aneurysm site, and the graft is put in place.

Stents – surgical steel parts of the endovascular graft that provide support and hold it in place.

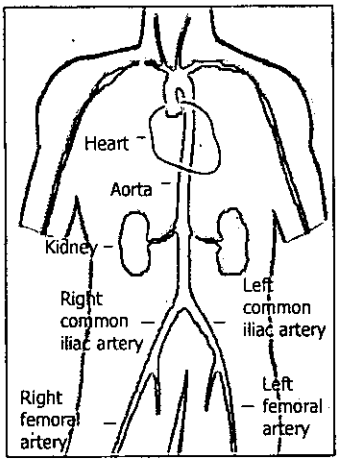
Superior Mesenteric Artery – blood vessel that comes off the aorta and carries blood to the intestine.

Ultrasound – a way to create pictures of parts of the body using high frequency sound waves.

Vascular – composed of, or pertaining to the vessels that convey blood.

Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System – a device placed within an abdominal aortic aneurysm to seal off the aneurysm. The graft is a tube made of polyester graft material (fabric) like that used in open surgical repair. Standard surgical suture is used to sew the graft material to a frame of stainless steel stents. These self-expanding stents provide support. The Zenith Fenestrated AAA Endovascular Graft is made of three parts: a proximal body, distal body and a leg. The proximal body is positioned in the aorta and has carefully positioned scallops (u-shaped openings/cutouts) or fenestrations (holes), so blood can continue to flow to the body's organs. The graft extends from the aorta around the renal arteries, which lead to the kidneys, into both iliac arteries. The Zenith Fenestrated AAA Endovascular Graft is placed within the aneurysm using the H&L-B One-Shot Introduction System.

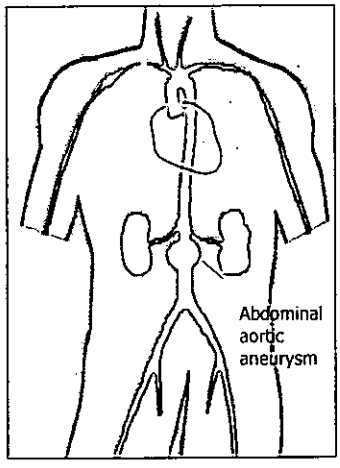
Introduction



What is an abdominal aortic aneurysm (AAA)?

The **aorta** is the main blood vessel that carries blood from the heart to the rest of the body. It extends from the chest to the abdomen, where it branches into the **iliac arteries**. The **iliac arteries** carry blood to lower parts of the body and to the legs. Sometimes, because of aging or other changes, a section of the **aorta** may weaken and begin to bulge.

This bulge can enlarge over time as the walls of the **aorta** become thinner and stretch (like a balloon). This bulge in the **aorta** is called an **aneurysm**. Sometimes an **aneurysm** occurs in the part of the **aorta** that runs through the abdomen (the stomach). This is called an **abdominal aortic aneurysm (AAA).** Sometimes an **aneurysm** that occurs in the part of the **aorta** that runs through the abdomen (the stomach) can extend into the **iliac arteries**. This is called an **aortoiliac aneurysm**.



Are these serious conditions?

In its early stages, when an **AAA** is small, it may not pose an immediate health risk. However, your doctor will want to check the condition of the **aneurysm** regularly.

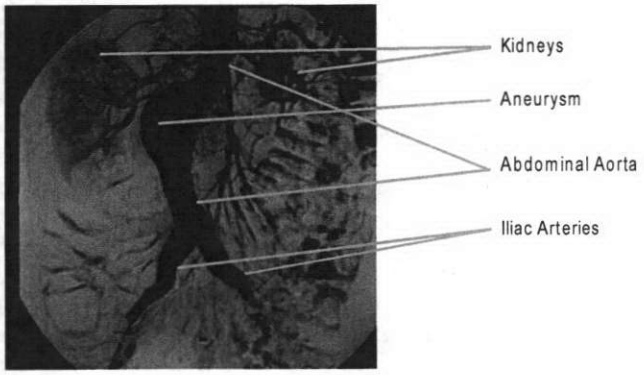
In later stages, if the **AAA** continues to grow, the walls of the **aorta** can become thin and lose their ability to stretch. The weakened sections of wall may become unable to support the force of blood flow. Such an **aneurysm** could **rupture**, causing serious internal bleeding and death.

What are some of the symptoms of an AAA?

In most cases patients have no symptoms of an **AAA**. For people who do have symptoms, the most common one is pain. The pain can be in the abdomen, back or chest. It could be anything from a mild pain to a severe pain or tenderness in the mid to upper abdomen or lower back. Some patients feel the **aneurysm** as a pulsating or throbbing mass in their abdomen. Many patients feel none of these symptoms yet may still have an **AAA**.

An **AAA** is often discovered during an examination being done for other medical reasons. Your doctor may feel a bulge or pulsation (throbbing) in your abdomen. Most often, **aneurysms** are found during a medical test such as a **CT Scan** or **ultrasound**.

If you know you have an **AAA** and you develop back pain, abdominal pain or dizziness, call your doctor immediately.



What causes an aneurysm?

Over time, **vascular** disease, injury or a hereditary defect of tissue within the arterial wall can cause a weakening of the **aorta** or **iliac arteries**. Blood pressure against the weakened area can cause ballooning (enlarging and thinning) of the vessel.

Risk factors for developing an **aneurysm** include family history, male gender, smoking, heart disease and high blood pressure. If you are at risk for developing an **aneurysm**, your doctor may recommend periodic checks. The checks could include a physical exam and possibly a **CT scan** or **ultrasound**.

Treatment of Abdominal Aortic Aneurysm

How do doctors treat an AAA?

When an **aneurysm** is small, your doctor may recommend periodic checkups to monitor it. If an **aneurysm** is larger, or is rapidly growing, it has a greater risk of **rupturing**. If your doctor thinks there is a risk the **aneurysm** may burst, he or she may recommend treatment. There are two types of treatment for **AAA**:

Open Surgical Repair

Endovascular Repair

The goal of all **AAA** repair is to prevent the **aorta** from bursting.

Important Note: Not every patient is a candidate for **endovascular repair**. **Open surgical repair** and **endovascular repair** both have advantages and disadvantages based upon each patient's condition and needs. Discuss the advantages and disadvantages with your doctor.

What is an open surgical repair?

In this approach, surgery is performed to repair the section of the **aorta** that has an **aneurysm**. To reach the **abdominal aortic aneurysm**, a doctor makes a cut through the abdomen or the side of the patient. The doctor repairs the vessel by replacing the **aneurysm** section with a fabric tube called a graft.

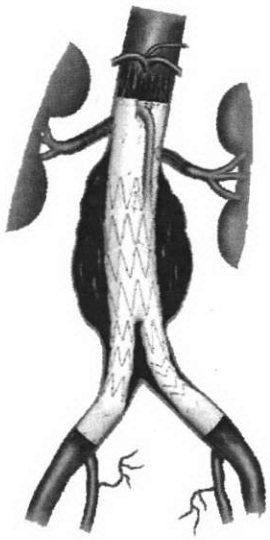
The graft is sewn into place and acts as a replacement blood vessel. The blood flow through the **aorta** is stopped while the graft is put in place. The surgery takes about two to four hours to complete.

Open surgical repair is a proven medical procedure that works. However, it also has a long recovery period. Patients usually stay overnight in the intensive care unit and stay another five to nine days in the hospital. Many patients are unable to eat normally for five to seven days after the surgery. The overall recovery period can last up to three months.

As with any medical procedure, **open surgical repair** has a risk of complications. Discuss these with your doctor.

What is an endovascular repair?

Endovascular repair is relatively new. **Endovascular** means "inside or within a blood vessel." Instead of making a large incision in the abdomen, the doctor makes a small cut near each hip (near the crease between the abdomen and thigh) to get to the **femoral arteries** (blood vessels).



Through these small cuts, a **sheath** containing a graft (fabric tube) is inserted into the arteries and positioned inside the appropriate blood vessel (**aorta** and **iliac arteries**). The **endovascular graft** is deployed and seals off the **aneurysm**. The graft makes a new path through which the blood flows. The graft remains inside the vessel permanently. **Endovascular repair** typically takes one to three hours to complete.

Because there are smaller cuts than those in **open surgical repair**, **endovascular repair** may result in less discomfort, a shorter hospital stay and faster recovery. Patients may have a hospital stay of only a few days. They can usually return to normal activity within four to six weeks after the procedure.

As with any medical procedure, **endovascular repair** has a risk of complications. **Endovascular repair** also requires routine follow-up visits with your doctor. Tests are done to evaluate the procedure and monitor success of the treatment. Refer to the follow-up section on *page 17* for more information. There is also a possibility that additional treatment or surgery may be required after the initial **endovascular repair**.

Warnings

The use of this endovascular graft has not been studied in patients who:

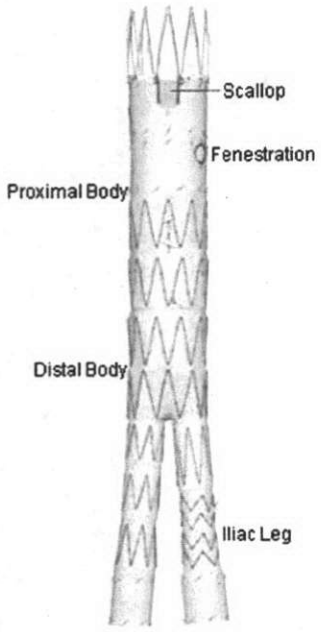
- Are pregnant.
- Are less than 18 years old.
- Have a **ruptured** aneurysm.
- Already have a device in the same location.

Your doctor will need to help you decide if it is appropriate to get the device if any of these situations apply.

The device may not be recommended by your physician if you:

- Do not have suitable anatomy.
- Cannot complete regular follow-up.
- Cannot tolerate imaging dyes.
- Have an allergy to the materials used in the device.
- Have an infection.

About the Zenith Fenestrated AAA Endovascular Graft



What is the Zenith Fenestrated AAA Endovascular Graft?

The **Zenith Fenestrated AAA Endovascular Graft** is a unique type of endovascular graft that was developed to provide an **endovascular repair** option for patients with a length of **aorta** above the **aneurysm** that is too short to form a seal using a standard (non-fenestrated) endovascular graft.

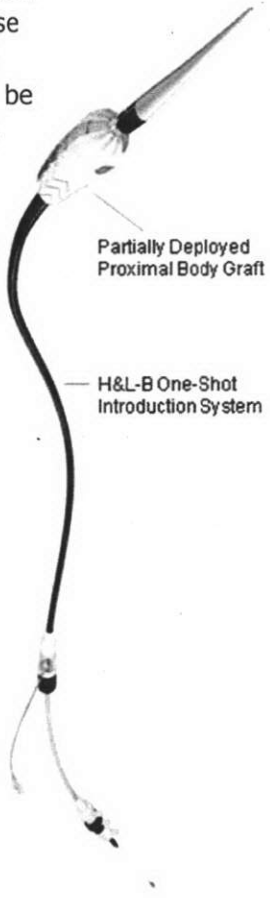
The **Zenith Fenestrated AAA Endovascular Graft** is made up of three parts: a proximal body, distal body and an iliac leg. The proximal body has carefully positioned **scallops** (u-shaped openings/cut-outs) or **fenestrations** (holes) in the graft material. The **scallops** and **fenestrations** allow the **endovascular graft** to achieve a seal of the **aneurysm** higher in the **aorta** while still permitting blood to continue flowing into the **branch vessels** (renal arteries and superior mesenteric artery). **Fenestration stents** are placed through the **scallops** or **fenestrations** into the **branch vessels**. These stents help to maintain blood flow to the **branch vessels** through the scallops/fenestrations. The distal body connects to the proximal body and provides a seal in one of the **iliac arteries**. The iliac leg graft connects to the distal body and provides a seal in the other iliac artery.

The graft itself is made of a polyester graft material like that used in **open surgical repair**. Standard surgical suture is used to sew the graft material to a frame of stainless steel **stents**. These self-expanding **stents** provide support. The **fenestrations** (holes) are also supported by a ring of wire made of another type of metal (nitinol). The graft has several gold markers to help your doctor see the device during placement. All of these materials have a long history of use in medical implants.

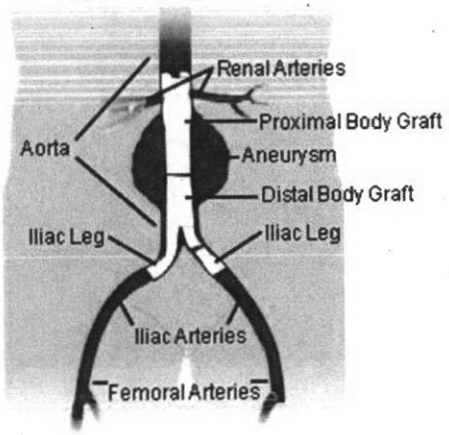
How are the grafts implanted?

Before the procedure, your doctor looks at pictures (**CT scan** and **angiogram**) of your **aorta** and **iliac arteries**. From these pictures, the doctor can choose the proper size for each part of the **Zenith Fenestrated AAA Endovascular Graft** so that it will fit in your blood vessels. These pictures are also used to determine the number, size, and location of the **fenestrations** and **scallops** so that the proximal body graft can be individually made to fit your individual anatomy. During the procedure, the doctor uses x-rays to see the grafts and position them correctly.

Each component of the device is supplied to the physician in its own **sheath** (plastic tube). The **sheath** of the **Zenith Fenestrated AAA Endovascular Graft** is called the **H&L-B One-Shot Introduction System**. Each **sheath** is removed after the graft is put in place.



To place the graft, your doctor makes a small cut near each hip (near the crease between the abdomen and thigh) to get to the **femoral arteries** (blood vessels). Through these small cuts, each part of the graft is inserted separately into your bloodstream. The proximal body of the **Zenith Fenestrated AAA Endovascular Graft** is positioned in the **aorta** and contains **scallops** and **fenestrations** to maintain blood flow to **branch vessels**. To help maintain blood flow to branch vessels, **fenestration stents** may be placed through the **scallops** or **fenestrations** of the proximal body into the **branch vessels** (such as the **renal** and **superior mesenteric arteries)**. The distal body connects the proximal body to one of the **iliac arteries**. The iliac leg connects the distal body to the other iliac artery. When each part of the graft is released from its **sheath**, it opens up to fill and reinforce the **aorta**. When all pieces are in place, the graft seals off (excludes) the **aneurysm.**



Before the procedure is finished, your doctor uses x-rays to confirm that blood is flowing to the **branch vessels** and **iliac arteries**, and also makes sure that blood is not flowing into the **aneurysm**. Your doctor then closes up the cut in each leg with a few stitches.

What possible complications can occur?

In the clinical study of 42 patients treated with the **Zenith Fenestrated AAA Endovascular Graft,** patients had these complications within 30 days after their **endovascular repair.**

Possibility (%)	Complications within 30 days[1]
16-20%	Blood transfusion
11-15%	**Renal infarct**
5-10%	Abnormal or irregular heartbeat
<5%	Loose blood clot
	Decreased blood flow to the intestine
	Bowel obstruction
	Wound infection
	Need for supplemental oxygen

After your endovascular repair, an **endoleak** may occur. An endoleak may cause your aneurysm to continue to grow and **rupture.**

There is also a possibility that the graft may move or shift in position over time, resulting in an **endoleak.** Movement of the graft may also result in **occlusion** of a **branch vessel**, which may cause organ (e.g., kidney) damage.

Occlusion of a **branch vessel** may also result from inadvertent injury to the vessel during placement of a **fenestration stent.**

Occlusion of the **iliac legs** may also occur.

All of these complications may require an additional procedure to fix.

What are the possible benefits of endovascular treatment?

The biggest benefit of getting your **aneurysm** treated is a decreased chance of **rupture**.

The chance of **rupture** depends on the size (diameter) of your **aneurysm**, which you should discuss with your doctor.

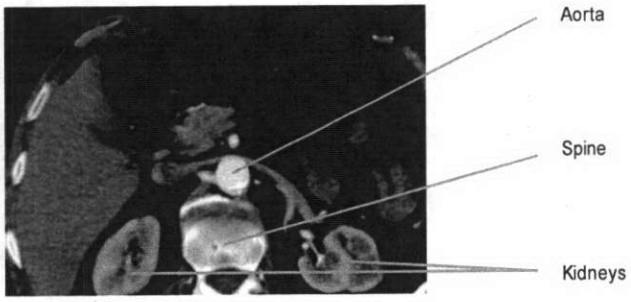
Options for treatment are **endovascular repair or open surgical repair.** Clinical study results in the table below suggest some benefits with endovascular repair for specific outcomes.

Complication	**Fenestrated Endovascular Repair[1]**	**Open Surgical Repair[2]**
Death within first 30 days	0%	2.5%
Any complication within first 30 days	33%	43%
Average blood loss during procedure (cc)	537	1,676
Average number of days spent in ICU	0.5	3
Average number of days spent in hospital	3.5	9
Average number of days to resume normal diet	1	7
Average number of days to resume oral fluids	0.5	4

After the Endovascular Procedure

Why is follow-up important?

If you receive a **Zenith Fenestrated AAA Endovascular Graft**, it is very important that you have regularly scheduled follow-up appointments with your doctor because less information is known about this endovascular graft compared to standard (non-fenestrated) endovascular grafts and the long-term results of this endovascular graft have not been established. It is possible for problems to occur that do not cause noticeable symptoms. Therefore, your doctor needs to look at pictures (x-ray, **CT scan**) of your **aneurysm** and graft on a regular basis. If a problem occurs, your doctor may recommend additional procedures.



If at any point following treatment you experience one of the following symptoms, you should call your doctor immediately:

- Pain in the legs, back, chest or abdomen
- Numbness in the legs, back, chest or abdomen
- Weakness in the legs, back, chest or abdomen
- Dizziness
- Fainting
- Rapid heartbeat
- Leg discoloration or coolness
- Decreased urination

What follow-up should I expect?

Recommended follow-up includes checkups at:

- 1 month
- 6 months
- 12 months
- Yearly thereafter

Follow-up exams usually include routine blood tests, x-rays, a **CT scan** and a physical exam.

These follow-up exams carry some minimal potential risk. However, the benefits of these tests clearly outweigh any potential risks. There is a rare risk of allergic reaction related to the **contrast** dye used in the **CT scan**. Talk with your doctor if you have any concerns regarding these exams. These exams should be considered a lifelong commitment to your health and well-being.

They are necessary to evaluate your treatment and any changes over time. Your doctor may request additional evaluations based on findings at the follow-up visits.

What if I need magnetic resonance imaging (MRI)?

If you receive a **Zenith Fenestrated AAA Endovascular Graft**, be sure to tell all of your healthcare providers that you have the graft. Show them your Patient ID Card. The card contains information related to **MRI** procedures for patients with these devices. More information is available at www.cookmedical.com or by phoning our help line at 800.457.4500. Discuss the potential risks and benefits of an **MRI** with your healthcare providers if you have any concerns about this diagnostic test.

What should I do with my patient ID card?

You will receive a **Zenith Fenestrated AAA Endovascular Graft** patient ID card. The card provides valuable information concerning:

- Type of device implanted
- Date of implant
- Your doctors
- **MRI** information

Be sure to tell all of your healthcare providers that you have the graft(s) and show them your patient ID card. You should keep your patient ID card available at all times.

Front

This patient has received a

COOK MEDICAL **Zenith®**

ENDOVASCULAR GRAFT

Cook Incorporated	William Cook Europe ApS	William Cook Australia Pty. Ltd.
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Bloomington, IN	Bjaeverskov, Denmark	Eight Mile Plains, QLD
47404 U.S.A.	+45 56 86 86 86	4113 Australia
812.339.2235		+61 7 38 41 11 88

MRI information on back side

Patient Name — Implant Date

Implanting Facility Name

Implanting Physician

Implanting Physician Phone #

Follow-up Physician

Follow-up Physician Phone Number

Product Catalog # ☐ Thoracic

Product Catalog # ☐ Abdominal

Before MRI, you must show this card to your doctor who should assess potential risks and consult the MR information in the device labeling on www.cookmedical.com (because of lesion variations in patient anatomy or wireless may increase risk the MRI facility should allow for prompt intervention if necessary)

Back

MR

Cook recommends that the patient register the MR conditions with the MedicAlert Foundation. The MedicAlert Foundation can be contacted in the following manner:

Mail: MedicAlert Foundation International
2323 Colorado Avenue
Turlock, CA 95382

Phone: 888.633.4298 (toll free) or
209.668.3333 (from outside the U.S.)

Fax: 209.668.2450

Web: www.medicalert.org

- MR image artifact will extend throughout the anatomical region containing the device. Please refer to www.medicalert.org.
- A patient with this endovascular graft in place for at least 6 months can be scanned safely under the following conditions:

Static Magnetic Field
- Static magnetic field of 3.0 Tesla or less
- Highest spatial magnetic gradient field of 720 Gauss/cm

MRI-Related Heating

1.5 Tesla Systems:
- Static magnetic field of 1.5 Tesla
- Maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per scanning sequence)

3.0 Tesla Systems:
- Static magnetic field of 3.0 Tesla
- Maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per scanning sequence)

Questions to Discuss with your Doctor

- How long can the graft remain implanted in my body?
- How many endovascular repair procedures has this facility performed?
- How many Fenestrated endovascular repair procedures has this facility performed?
- How long will I need to limit my activities following treatment?

Where can I find more information?

Abdominal Aortic Aneurysms

Vascular Web Patient Information www.vascularweb.org
VascularWeb is an internet-based global resource of information and services for individuals interested in improving vascular health worldwide. VascularWeb is sponsored and owned by the Society for Vascular Surgery (SVS), and is governed by a board of directors and managed by an editorial board.

Interventional Therapy

Society of Interventional Radiology www.sirweb.org
The Society of Interventional Radiology (SIR) is a professional society for physicians who specialize in interventional or minimally invasive procedures. SIR is a nonprofit, national scientific organization deeply committed to its mission to improve health and quality of life through the practice of cardiovascular and interventional radiology.

U.S. National Library of Medicine www.medlineplus.gov
The National Library of Medicine (NLM), on the campus of the National Institutes of Health in Bethesda, Maryland, is the world's largest medical library. The library collects materials in all areas of biomedicine and healthcare, as well as works on biomedical aspects of technology, the humanities, and the physical, life and social sciences.

Product Information

Cook Medical Incorporated www.cookmedical.com
With international headquarters in Bloomington, Indiana, Cook is a leading designer, manufacturer and global distributor of minimally invasive medical device technologies for diagnostic and therapeutic procedures. Since its founding in 1963, Cook has been a privately held company that creates innovative technologies for stents and stent grafts, catheters, wire guides, introducer needles and sheaths, embolization coils, medical biomaterials, vena cava filters, implanted cardiac lead extraction equipment and other minimally invasive medical devices.

U.S. Department of Health and Human Services

Food and Drug Administration www.fda.gov
A U.S. government agency intended to promote and protect public health by helping safe and effective products reach the market in a timely way and monitoring products for continued safety after they are in use.

Notes

If you have any questions about your abdominal aortic aneurysm or treatment, we encourage you to talk to your doctor. He or she should always be your primary source of information. Talk to your doctor about the details of this procedure and its impact on your health.

Use the space below to record your doctor's name and phone number. You may also want to write down your questions, take notes or keep a record of your discussions with your doctor.

Patient Name	
Implantation Date	
Device Implanted	☐ Zenith Fenestrated AAA Endovascular Graft.
Implanting Facility's Name (Hospital)	
Implanting Physician	
Implanting Physician Phone #	

Endnotes

1. Average rates/results following endovascular treatment with the Zenith Fenestrated AAA Endovascular Graft. The results were obtained from the US clinical study to evaluate the Zenith Fenestrated AAA Endovascular Graft, which enrolled 42 endovascular treatment patients.

2. Average rates/results following open surgical treatment for abdominal aortic aneurysms. The results were obtained from the US multi-center study of the standard (non-fenestrated) Zenith AAA Endovascular Graft, which enrolled 80 open surgical treatment patients.

Customer Service Centers

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