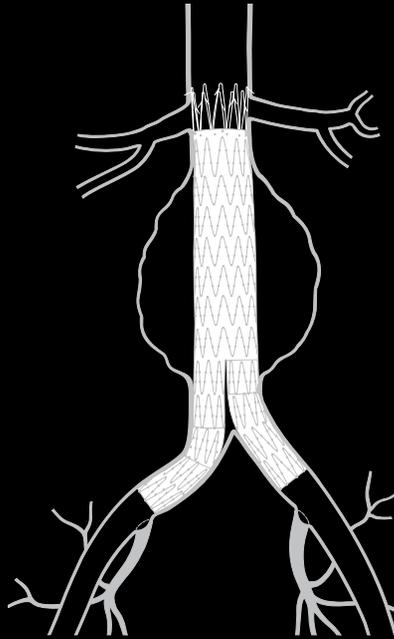


Zenith[®] 

AAA Endovascular Graft

Suggested Instructions for Use



COMPANY CONFIDENTIAL
Not For Distribution

COOK[®]

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CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

ZENITH® AAA ENDOVASCULAR GRAFT

1 DEVICE DESCRIPTION

The Zenith® AAA Endovascular Graft is an endovascular prosthesis intended for use in the abdominal aorta for aneurysm (AAA) repair. The deployment system is fabricated with a single lumen vinyl radiopaque tubing (14, 16, 18 or 20 FR depending upon the size of the preloaded component), an 8.5 FR TFE radiopaque tubing, 18 gage stainless steel cannula, .013 and .015 inch stainless steel trigger-wires, nylon radiopaque tubing and thick-wall radiopaque TFE sheath material (14, 16, 18 or 20 FR depending upon the size of preloaded component).

The main body graft consists of uncrimped bifurcated (tubular) Twillweave™ fabric with stainless steel stents strategically sewn into place with braided polyester monofilament polypropylene suture. The bare suprarenal stent at the proximal end of the graft contains barbs that are placed at 3 mm increments for additional fixation of the device. The main body graft is fully stented with self-expanding stainless steel Cook-Z® stents. These stents provide stability and the expansile force necessary to open the lumen of the graft during deployment. Additionally, they provide the necessary attachment and seal of the graft to the vessel wall.

The graft is compressed and loaded inside the delivery system. To facilitate fluoroscopic visualization of the stent graft, gold marker bands are positioned as follows: one on the lateral aspect of the most distal stent on the contralateral limb of the bifurcated section of the main body, and four in a circumferential orientation within 2 mm of the most superior aspect of the graft material.

The Zenith® AAA Endovascular Graft is a modular system consisting of an aortic main body and two iliac legs. Additional ancillary endovascular components (main body extenders, iliac leg extenders, converters and occluders) are available.

Zenith ancillary components are made of Twillweave™ fabric and are fully stented with self-expanding stainless steel Cook-Z® stents. These stents provide stability and the expansile force necessary to open the lumen of the component during deployment. They also provide the necessary attachment and seal of the graft to the vessel wall and at the overlap with the main endovascular graft where applicable.

DRAFT

3/03/2003

The Zenith® AAA Endovascular Graft is shipped preloaded onto the H & L-B One-Shot™ Introduction System. The delivery system is designed for ease of use with minimal preparation. It has a sequential deployment method with built-in features to provide continuous control of the endovascular graft throughout the deployment procedure. The H & L-B One-Shot™ Introduction System enables precise positioning and has the ability to readjust the final graft position before deploying the barbed suprarenal z-stent.

The design of the delivery system was developed in accordance with performance requirements from physicians, radiographers, engineers and technicians. These requirements are dictated by proper functioning of the system, the need to reduce/or eliminate complications, patient anatomical requirements and physician needs.

The main body graft delivery system uses an 18 Fr or 20 Fr H & L-B One-Shot™ Introduction System. Dual trigger-wire release mechanisms lock the endovascular graft onto the delivery system until released by the physician. All systems are compatible with a .035 inch wire guide.

Main body extenders and converters utilize 18 Fr and 20 Fr H & L-B One-Shot™ Introduction Systems. The main body extender introduction system contains a single trigger-wire release mechanism. No top cap is included with the dilator tip because the main body extender component does not contain a barbed, uncovered suprarenal z-stent. The converter has no trigger-wire release mechanism or top cap assembly. Deployment of the converter is achieved by sheath retraction.

A 14 Fr and 16 Fr H & L-B One-Shot™ Introduction System is used to deploy various sizes of the iliac legs and iliac leg extenders in the Zenith family of modular components. These delivery systems have no trigger-wire release mechanism or top cap assembly. Deployment is achieved by sheath retraction.

The occluder is preloaded into a cartridge for deployment. The device is packaged with a blunt pusher and an 18 Fr delivery sheath.

2 INDICATIONS

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

- Adequate iliac/femoral access (≥ 7.5 mm)
- Non-aneurysmal infrarenal proximal neck length of at least 15 mm.
- Neck diameter measured outer wall to outer wall of no greater than 28 mm and no less than 18 mm.
- Iliac artery distal fixation site length greater than 10 mm in length and no greater than 20 mm in diameter (measured outer wall to outer wall).
- One of the following:
 - An abdominal aortic aneurysm with a diameter ≥ 4 cm
 - An iliac aneurysm with diameter ≥ 3.5 cm
 - Aortic, aortoiliac, or iliac aneurysm with a history of growth ≥ 0.5 cm per year.

3 CONTRAINDICATIONS

MRI use is contraindicated. MRI procedures should not be performed at any time after implantation of the Zenith® AAA Endovascular Graft.

4 WARNINGS & PRECAUTIONS

(SEE ALSO INDIVIDUALIZATION OF TREATMENT [SECTION 7.2])

4.1 General Information

- Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.
- This device should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device. Specific training expectations are described in Section 10.1, **Physicians Training Program**.
- Do not use the Zenith® AAA Endovascular Graft in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies as described in Section 4.2, **Patient Selection, Treatment and Follow-up**.
- After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth, or changes in the structure or position of the stent graft.
- The device incorporates a suprarenal stent with fixation barbs. As reported in the clinical study, barb separation was noted to occur in 1.7% of the patients treated with this device as noted on a 12-month KUB. Exercise extreme caution when manipulating interventional devices in the region of the suprarenal stent and/or if stent repositioning is required.
- The safety and effectiveness of the Zenith® AAA Endovascular Graft for the treatment of abdominal aortic aneurysms has not been evaluated in patients:
 - with leaking, ruptured or symptomatic aneurysms
 - with uncorrectable coagulopathy
 - with indispensable mesenteric artery
 - with ilio femoral or thoracic aneurysms
 - with juxtarenal AAA
 - with pararenal AAA
 - with suprarenal or thoracoabdominal aneurysms
 - who are pregnant or nursing
 - < 18 years of age.
- Always have a vascular surgery team available at institutions performing endovascular grafting in the event that conversion to open surgical repair is required.

4.2 Patient Selection, Treatment And Follow-Up

- Do not use this device in patients with sensitivities or allergies to device materials. The materials of the graft include: stainless steel, polyester, solder, polypropylene and gold.
- The use of this device requires the use of intravascular contrast. Do not use this device in patients with risk of anaphylactic reactions to the contrast agent.

- Patients with uncorrectable coagulopathy may have an increased risk of bleeding complications or type II endoleak.
- The placement of the Zenith® AAA Endovascular Graft should be performed using sterile technique in an operating room or an interventional angiographic suite with the ability to rapidly convert to an open procedure if required.
- Patients with a systemic infection may be at increased risk of endovascular graft infection.
- Patients experiencing an increase in the size of their AAA need to be assessed for further therapy.
- Patients experiencing reduced blood flow through the graft limb and/or leaks may be required to undergo secondary interventions or minor surgical procedures.
- All patients should be monitored closely and checked periodically for aneurysmal size increase or occlusion of vessels in the treatment area. Patients who experience perigraft flow should undergo imaging studies more frequently.
- Aneurysm diameter less than 4.0 cm should not be treated unless there is evidence to support rapid growth or increased risk of rupture.
- Inability to maintain patency of at least one internal iliac artery may increase the risk of pelvic/bowel ischemia.
- Occlusion of an indispensable inferior mesenteric artery may lead to pelvic/bowel ischemia.
- Multiple large, patent lumbar arteries, mural thrombus and a patent inferior mesenteric artery may all predispose to type II endoleaks.
- Proximal aortic necks with a length less than 15 mm may be more conducive to graft migration and endoleaks.
- Proximal aortic necks greater than 28 mm in diameter may be more conducive to graft migration and endoleaks.
- Conical aortic necks with greater than 10% increase in diameter over 15 mm of proximal aortic neck length may be more conducive to graft migration and endoleaks.
- Aortic neck angulation greater than 60° (infrarenal neck to axis of AAA) may be more susceptible to endoleak(s) and may complicate device delivery.
- Immediate suprarenal neck angulation greater than 45° relative to the immediate infrarenal neck may be more susceptible to endoleak(s).
- Common iliac diameters exceeding 20 mm at expected graft/vessel interface site(s) may be more susceptible to endoleak or continued expansion.
- Vessel diameter (measured inner wall to inner wall) at the main body introduction site less than 7.5 mm may prevent delivery system access.
- 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.

- The use of the Zenith® AAA Endovascular Graft requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure postoperatively. Care should be taken to limit the amount of contrast media used during the procedure. It should be closely monitored and recorded accurately.

4.3 How Supplied

- The Zenith® AAA Endovascular Graft is supplied sterile in peel-open packages.
- The device is intended for single use only. Do not re-sterilize the device. Note product “use by” date.
- 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 INCORPORATED.
- 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.

4.4 Magnetic Resonance Imaging (MRI)

Magnetic resonance imaging (MRI) procedures should not be performed at any time following endovascular graft implantation with the Zenith® AAA Endovascular Graft.

4.5 Implantation Procedures

- Always use fluoroscopy for guidance and observation of any Zenith® AAA Endovascular Graft devices within the vasculature.
- Renal artery patency must be maintained to prevent/reduce the risk of renal failure and subsequent complications.
- Take care during manipulation of catheters, wires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus which can cause distal embolization.
- Do not bend or kink the delivery system. Doing so may cause damage to the delivery system and the Zenith® AAA Endovascular Graft.
- Unless medically indicated, do not deploy the Zenith® AAA Endovascular Graft in a location that will occlude arteries necessary to supply blood flow to organs or extremities.
- Always use fluoroscopic guidance to manipulate the delivery system. Do not use excessive force to advance or withdraw the delivery system if resistance is encountered. Exercise particular care in areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels.
- Inadequate fixation of the Zenith® AAA Endovascular Graft may result in increased risk of migration of the stent graft.
- Inaccurate placement and/or sealing of the Zenith® AAA Endovascular Graft within the vessel may result in increased risk of endoleak, migration, renal artery occlusion or internal iliac artery occlusion.

5 ADVERSE EVENTS

5.1. Observed Adverse Events

(from date of procedure to 1 year)

Table 5.1.1 Adverse Events (U.S. Clinical Trial)

| Item | Standard Risk | Surgical | | |
|---|---------------------------|---------------|--------------|--------------|
| | | Standard Risk | High Risk | Roll-in |
| All death (0-30 days) ² | 0.5% (1/199) ¹ | 2.5% (2/80) | 2.0% (2/100) | 1.9% (1/52) |
| All death (0-365 days) ^{2, 3} | 3.5% (7/199) | 3.8% (3/80) | 9.0% (9/100) | 11.5% (6/52) |
| AAA related | 0.5% (1/199) | 3.8% (3/80) | 5.0% (5/100) | 1.9% (1/52) |
| Non-AAA related | 3.0% (6/199) | 0.0% (0/80) | 4.0% (4/100) | 9.6% (5/52) |
| Rupture (0-30 days) | 0.0% (0/199) | 0.0% (0/80) | 0.0% (0/100) | 0.0% (0/52) |
| Rupture (0-365 days) | 0.0% (0/199) | 0.0% (0/80) | 1.0% (1/100) | 0.0% (0/52) |
| Other adverse events⁴ | | | | |
| Cardiovascular ⁵ | 3.0% (6/200) | 11% (9/80) | 14% (14/100) | 1.9% (1/52) |
| Pulmonary ⁶ | 1.0% (2/200) | 15% (12/80) | 2.0% (2/100) | 0.0% (0/52) |
| Renal ⁷ | 2.5% (5/200) | 10% (8/80) | 6.0% (6/100) | 5.8% (3/52) |
| Bowel ⁸ | 1.0% (2/200) | 3.8% (3/80) | 1.0% (1/100) | 1.9% (1/52) |
| Wound ⁹ | 4.5% (9/200) | 7.5% (6/80) | 2.0% (2/100) | 3.8% (2/52) |
| Neurological ¹⁰ | 0.0% (0/200) | 2.5% (2/80) | 0.0% (0/100) | 0.0% (0/52) |
| Vascular ¹¹ | 11% (21/200) | 31% (25/80) | 20% (20/100) | 19% (10/52) |
| Other | 15% (30/200) | 38% (30/80) | 16% (16/100) | 31% (16/52) |

¹ Denominator of 199 because one standard risk patient did not receive a device.

² All deaths (0-30 days) were considered AAA procedure related.

³ Of the deaths (0-365 days), ten were considered AAA related: 1 standard risk (cardiac failure), 3 surgical (massive hemorrhage, mesenteric ischemia, and septic shock from ischemic colitis), 5 high risk (respiratory failure, cardiac failure with pulmonary embolism, pancreatitis with renal failure and sepsis, hemorrhage from upper abdominal aneurysm [not treated AAA], and multiple system failure) and 1 roll-in (suspected cardiac failure).

⁴ Surgical patients had significantly more cardiovascular ($P=.02$), pulmonary ($P<.001$), renal ($P=.01$), vascular ($P<.001$), and other ($P=.001$) adverse events than standard risk patients. High risk patients had significantly more cardiovascular ($P=.001$) and vascular ($P=.03$) adverse events than standard risk patients.

⁵ Cardiovascular includes: Q-wave and non-Q-wave myocardial infarctions, congestive heart failure, arrhythmias requiring new medication or treatment, cardiac ischemia requiring intervention, inotropic support, medically intractable hypertension.

⁶ Pulmonary includes: reintubation or ventilation >24 hours, pneumonia requiring antibiotics, supplemental oxygen at discharge.

⁷ Renal includes: dialysis in patients with normal preoperative renal function, creatinine rise >30% from baseline on two or more follow-up tests.

⁸ Bowel includes: bowel obstruction, bowel ischemia, aorto-enteric fistula, paralytic ileus >4 days.

⁹ Wound includes: infection requiring antibiotic treatment, hernia, lymph fistula, dehiscence, necrosis requiring debridement.

¹⁰ Neurological includes: stroke, TIA, spinal cord ischemia/paralysis.

¹¹ Vascular includes: limb thrombosis, distal embolization resulting in tissue loss or requiring intervention, transfusion post procedure (resulting from pseudoaneurysm, vascular injury, aneurysm leak or other procedure-related causes), pseudoaneurysm, vascular injury (such as inadvertent occlusion, dissection or other procedure related causes), aneurysm leak or rupture, increase in aneurysm size by more than 0.5 cm relative to the smallest of any prior measurement.

5.2 Potential Adverse Events

- Death
- Emboli and subsequent tissue damage and/or loss
- Perforation of aorta
- Hypotension/hypertension
- Pseudoaneurysm
- Infection and pain at the vascular access site, hematoma
- Contrast reactions, which may include renal failure or require permanent or transient hemodialysis
- Vessel damage
- Graft or native vessel occlusion
- Wound dehiscence
- Anesthetic complications
- Myocardial infarction
- Gastrointestinal complications and subsequent attending problems
- Renal complications and subsequent attending problems
- Lymphatic complications
- Claudication
- Impotence
- Paralysis
- Transient fever and pain
- Arrhythmia
- Bleeding or coagulopathy
- Deep vein thrombosis (DVT)
- Pulmonary/respiratory complications
- Device failures due to:
 - Migration
 - Dilatation
 - Endoleak
 - Rupture
 - Erosion with fistula or pseudoaneurysm

5.3 Adverse Event Reporting

Any adverse event (clinical incident) involving the Zenith® AAA Endovascular Graft should be reported to COOK INCORPORATED immediately. To report an incident, **call the Customer Relations Department at 800-457-4500 or 812-339-2235.**

6 CLINICAL STUDIES

There have been two large-scale, prospective, multicenter studies of the Zenith® AAA Endovascular Graft. The first study, performed in Australia and New Zealand, enrolled 291 standard risk and high-risk patients from August 1994 to December 1998. The second, a U.S. pivotal study with enrollment from January 2000 to July 2001, was conducted under FDA approved IDE G990135. The U.S. clinical study was a multicenter, non-randomized study comparing standard medical risk patients who received an endovascular graft to an open surgical control. There were two additional study arms for high medical risk and roll-in treatment groups. Fifteen centers enrolled 200 standard risk, 80 surgical control, 100 high risk, and 52 roll-in patients. Patients were assigned to groups of the study, in part, based upon the characteristics of their aneurysm. The study was designed to evaluate the safety and effectiveness of the Zenith® AAA Endovascular Graft in the treatment of infrarenal abdominal aortic or aorto-iliac aneurysms.

The study tested whether standard risk patients experienced less 30-day morbidity, equivalent 30-day survival rates, equivalent 12-month survival rates, equivalent 12-month treatment success, and improved clinical utility measures compared to surgical control patients. Data from the clinical study positively supported all of these hypotheses.

6.1 Primary Endpoints

The primary endpoints used in the study include:

- Deployment success
- Procedure success at 30 days
- Treatment success at 12 months
- Morbidity at 30 days
- Survival at 30 days
- Survival at 12 months
- Aneurysm expansion >5 mm
- Aneurysm rupture
- Conversion
- Graft patency
- Endoleak
- Graft migration
- Device integrity including barb separation, limb separation, stent fracture, graft material rupture
- Secondary interventions

6.2 Secondary Endpoints

The secondary endpoints used in the study include:

- Days in the ICU
- Days to discharge
- Days to oral fluids
- Days to normal diet

- Days to normal bowel function
- Days to ambulation
- Hours of postoperative intubation
- Maximum daily temperature up to time of discharge or day 14
- SF-36™ Quality of Life questionnaire

6.3 Patients Studied

Patients were candidates for the study if they had at least one of the following:

General Inclusion Criteria for all groups:

- 1) Aortic or aortoiliac aneurysm with diameter \geq 4 cm.
- 2) Iliac aneurysm with diameter \geq 3.5 cm.
- 3) Aortic, aortoiliac, or iliac aneurysm with a history of growth \geq 0.5 cm per year.

Patients were excluded from the study if any of the following were true:

General Exclusion Criteria for all groups:

- 1) Less than 18 years of age
- 2) Life expectancy less than 2 years
- 3) Pregnant
- 4) Unwilling to comply with the follow-up schedule
- 5) Inability or refusal to give informed consent
- 6) Allergy to stainless steel or polyester
- 7) Anaphylactic reaction to contrast material
- 8) Leaking, ruptured or symptomatic aneurysm
- 9) Uncorrectable coagulopathy

Patients were excluded from endovascular treatment, but still eligible for surgical repair, if any of the following were true:

Anatomical Exclusion Criteria for Endovascular Treatment

- 1) Proximal neck <15 mm in length
- 2) Proximal neck, measured outer wall to outer wall on a sectional image (CT) >28 mm in diameter or <18 mm in diameter
- 3) Proximal neck angulated more than 60° relative to the long axis of the aneurysm
- 4) Immediate suprarenal neck angulated more than 45° relative to the immediate infrarenal neck
- 5) Proximal neck inverted funnel shape (change in neck diameter greater than 10% over the defined neck length)
- 6) Proximal neck with circumferential thrombus/atheroma
- 7) Iliac artery diameter, measured inner wall to inner wall on a sectional image (CT) <7.5 mm (prior to deployment)
- 8) Iliac artery diameter, measured outer wall to outer wall on a sectional image (CT) >20 mm at distal fixation site

- 9) Iliac artery distal fixation site <10 mm in length
- 10) Indispensable inferior mesenteric artery (IMA)
- 11) Inability to maintain at least one patent hypogastric artery
- 12) Unsuitable arterial anatomy

Patients were included in the high risk group and excluded from the standard risk and surgical control groups if at least one of the following criterion was met.

High Risk Inclusion Criteria:

- 1) Age >80
- 2) Baseline creatinine >2.0 mg/dl
- 3) Receiving home oxygen therapy
- 4) FEV₁ <1 liter
- 5) Ejection fraction <25%
- 6) Disabling chronic obstructive pulmonary disease (COPD)
- 7) New York Heart Classification 3 or 4
- 8) Hostile abdomen
- 9) Dialysis
- 10) MI within last 6 months
- 11) Medically intractable hypertension
- 12) Previous stroke with residual deficit
- 13) Cultural objection to receipt of blood or blood products
- 14) Previous renal bypass surgery
- 15) Inflammatory aneurysm
- 16) Significant occlusive disease, tortuosity or calcification
- 17) Renal artery stenosis >80%.

6.4 Methods

After informed consent was obtained, patients were assigned to groups according to entry criteria. Patients with aneurysm anatomy conducive to endograft placement were selected for either the standard risk group (standard medical risk) or the high-risk group (high medical risk). Patients with anatomy unsuitable for endograft placement were assigned to the surgical group. Zenith® AAA Endovascular Grafts or surgical grafts were implanted and followed with clinical, CT and KUB exams at pre-discharge (except surgical imaging), 30 days, 6 months (except surgical), 12 months and 24 months (except surgical). The intent-to-treat analysis involved centralized imaging analysis, clinical events adjudication, and a data safety committee.

Table 6.4.1 Patient demographics

| Item | Standard Risk | Surgical Standard Risk | High Risk | Roll-in |
|------------------------------------|---------------|------------------------|--------------|-------------|
| Age (years) | 71 ± 7 | 69 ± 7 | 77 ± 7 | 74 ± 8 |
| Gender male | 94% (187/200) | 89% (71/80) | 92% (92/100) | 90% (47/52) |
| Current medical conditions | | | | |
| Peripheral vascular disease | 16% (31/195) | 25% (19/76) | 24% (23/96) | 9.6% (5/52) |
| Hypertension | 64% (127/200) | 83% (65/78) | 68% (67/99) | 67% (35/52) |
| Renal failure | 0.0% (0/197) | 0.0% (0/79) | 5.2% (5/97) | 1.9% (1/52) |
| COPD | 20% (39/199) | 18% (14/78) | 34% (33/98) | 22% (11/51) |
| Thromboembolic event | 4.5% (9/199) | 7.7% (6/78) | 7.1% (7/99) | 1.9% (1/52) |
| Liver disease | 2.1% (4/192) | 5.1% (4/79) | 1.0% (1/99) | 1.9% (1/52) |
| Diabetes Mellitus | 12% (24/199) | 15% (12/79) | 17% (17/99) | 14% (7/51) |
| Insulin-dependent | 17% (4/24) | 8.3% (1/12) | 24% (4/17) | 43% (3/7) |
| Previous medical conditions | | | | |
| MI | 39% (74/192) | 29% (23/80) | 35% (34/98) | 35% (18/52) |
| Congestive heart failure | 5.0% (10/199) | 12% (9/78) | 16% (16/100) | 10% (5/50) |
| Angina | 49% (98/198) | 39% (31/79) | 45% (44/98) | 44% (23/52) |
| Arrhythmia | 20% (40/197) | 22% (17/78) | 28% (27/98) | 24% (12/51) |
| Cerebrovascular disease | 9.5% (19/199) | 16% (13/79) | 20% (20/99) | 9.8% (5/51) |
| Systemic infection | 1.0% (2/196) | 0.0% (0/78) | 3.1% (3/97) | 0.0% (0/49) |
| Cancer | 22% (43/200) | 19% (15/80) | 31% (31/99) | 29% (15/51) |
| Family history of | | | | |
| aneurysmal disease | 16% (24/150) | 27% (17/63) | 14% (11/77) | 26% (10/38) |
| Previous surgery at site | 10% (20/200) | 15% (12/79) | 10% (10/99) | 14% (7/51) |
| Previous radiation at site | 0.5% (1/197) | 0.0% (0/79) | 2.0% (2/100) | 2.0% (1/51) |

The standard risk and surgical standard risk groups were comparable with respect to demographics and patient characteristics, although, standard risk patients were older ($P=.03$) and had a lower incidence of hypertension ($P=.001$). Due to inclusion criteria, high risk patients were older ($P<.001$), had more renal failure ($P=.004$), COPD ($P=.01$), congestive heart failure ($P=.004$) and cerebrovascular disease ($P=.02$) than standard risk patients.

6.5 Results

Safety and effectiveness results are presented in table format below. Denominators less than 200, 80, 100 or 52 for standard risk, surgical, high risk and roll-in respectively, reflect the number of images available for analysis.

Table 6.5.1 Principle safety results

| Item | Standard Risk | Surgical Standard Risk | High Risk | Roll-in |
|--------------------------------------|---------------|------------------------|----------------|--------------|
| All death (0-30 days) | 0.5% (1/199) | 2.5% (2/80) | 2.0% (2/100) | 1.9% (1/52) |
| All death (0-365 days) | 3.5% (7/199) | 3.8% (3/80) | 9.0% (9/100) | 11.5% (6/52) |
| AAA related | 0.5% (1/199) | 3.8% (3/80) | 5.0% (5/100) | 1.9% (1/52) |
| Non-AAA related | 3.0% (6/199) | 0.0% (0/80) | 4.0% (4/100) | 9.6% (5/52) |
| All death (0-2 years) | 8.5% (17/199) | N/A | 21.0% (21/100) | 15.4% (8/52) |
| AAA related | 1.0% (2/199) | N/A | 5.0% (5/100) | 1.9% (1/52) |
| non-AAA related | 7.5% (15/199) | N/A | 16.0% (16/100) | 13.5% (7/52) |
| Rupture (0-30 days) | 0.0% (0/199) | 0.0% (0/80) | 0.0% (0/100) | 0.0% (0/52) |
| Rupture (0-365 days) | 0.0% (0/199) | 0.0% (0/80) | 1.0% (1/100) | 0.0% (0/52) |
| Rupture (0-2 years) | 0.0% (0/199) | 0.0% (0/80) | 1.0% (1/100) | 0.0% (0/52) |
| Conversion (0-30 days) | 0.0% (0/199) | 0.0% (0/80) | 0.0% (0/100) | 0.0% (0/52) |
| Conversion (0-365 days) | 1.0% (2/199) | 0.0% (0/80) | 1.0% (1/100) | 0.0% (0/52) |
| Conversion (0-2 years) | 1.5% (3/199) | 0.0% (0/80) | 2.0% (2/100) | 0.0% (0/52) |
| Secondary Interventions (0-30 days) | 3.0% (6/199) | 2.5% (2/80) | 3.0% (3/100) | 3.8% (2/52) |
| Secondary Interventions (0-365 days) | 11% (21/199) | 2.5% (2/80) | 12% (12/100) | 5.8% (3/52) |

All early deaths were considered AAA procedure related (none were classified as device related): 1 standard risk (cardiac failure), 2 surgical (massive hemorrhage and mesenteric ischemia), 2 high risk (respiratory failure and cardiac failure with pulmonary embolism), and 1 roll-in (suspected cardiac failure).

Of all late deaths, 5 were classified as AAA related: 1 standard risk (cardiac failure after open repair to treat graft infection), 1 surgical (septic shock from ischemic colitis), 3 high risk (pancreatitis with renal failure and sepsis, hemorrhage from upper abdominal aneurysm [not treated AAA], and multiple system failure). None were related to device failure, although in one device involvement could not be ruled out.

Standard risk patients underwent conversions due to a persistent, proximal type I endoleak, a graft infection, and a new proximal aneurysm. High risk patients underwent conversion due to an untreated distal type I endoleak resulting in rupture, and a graft infection. Three surgical patients had massive hemorrhages, of which 2 required re-operation and one died. The protocol required immediate repair of type I endoleaks resulting in more secondary interventions ($P=.03$).

Table 6.5.2 Principle effectiveness results

| Item | Standard Risk | High Risk | Roll-in |
|--|-----------------|----------------|--------------|
| Deployment success | 99.5% (199/200) | 100% (100/100) | 100% (52/52) |
| Early endoleaks identified within 30 days | | | |
| Proximal Type I | 2.8% (5/179) | 2.3% (2/88) | 0.0% (0/36) |
| Distal Type I | 1.7% (3/179) | 1.1% (1/88) | 0.0% (0/36) |
| Type II | 9.5% (17/179) | 9.1% (8/88) | 5.6% (2/36) |
| Type III | 1.1% (2/179) | 0.0% (0/88) | 2.8% (1/36) |
| Type IV | 0.0% (0/179) | 0.0% (0/88) | 0.0% (0/36) |
| Multiple | 1.1% (2/179) | 4.5% (4/88) | 0.0% (0/36) |
| Unknown | 1.1% (2/179) | 1.1% (1/88) | 2.8% (1/36) |
| Late endoleaks identified at 6 or 12 months | | | |
| Proximal Type I | 0.0% (0/184) | 0.0% (0/80) | 0.0% (0/38) |
| Distal Type I | 0.5% (1/184) | 0.0% (0/80) | 0.0% (0/38) |
| Type II | 3.3% (6/184) | 2.5% (2/80) | 2.6% (1/38) |
| Type III | 0.5% (1/184) | 2.5% (2/80) | 0.0% (0/38) |
| Type IV | 0.0% (0/184) | 0.0% (0/80) | 0.0% (0/38) |
| Unknown | 0.5% (1/184) | 0.0% (0/80) | 0.0% (0/38) |
| Graft migration¹ | | | |
| Migration with clinical sequelae | 0.0% (0/162) | 0.0% (0/71) | 0.0% (0/34) |
| Migration without clinical sequelae | 2.5% (4/162) | 2.8% (2/71) | 0.0% (0/34) |
| Graft patency | | | |
| Pre-discharge | 99% (180/181) | 100% (85/85) | 100% (43/43) |
| 30 day | 100% (185/185) | 99% (85/86) | 100% (47/47) |
| 6 month | 99% (183/184) | 100% (74/74) | 100% (39/39) |
| 12 month | 99% (153/155) | 100% (62/62) | 100% (30/30) |
| Barb separation - without clinical sequelae | | | |
| Pre-discharge | 0.0% (0/176) | 0.0% (0/86) | 0.0% (0/39) |
| 30 day | 0.0% (0/178) | 0.0% (0/86) | 0.0% (0/43) |
| 6 month | 1.2% (2/167) | 2.5% (2/80) | 0.0% (0/35) |
| 12 month | 2.0% (3/149) | 1.7% (1/60) | 0.0% (0/28) |
| Stent fractures² | | | |
| Pre-discharge | 0.0% (0/172) | 0.0% (0/81) | 0.0% (0/39) |
| 30 day | 0.0% (0/172) | 0.0% (0/83) | 0.0% (0/43) |
| 6 month | 0.0% (0/166) | 0.0% (0/78) | 0.0% (0/35) |
| 12 month | 0.0% (0/148) | 0.0% (0/60) | 0.0% (0/28) |
| Limb separation | | | |
| Pre-discharge | 0.0% (0/176) | 0.0% (0/86) | 0.0% (0/39) |
| 30 day | 0.0% (0/178) | 0.0% (0/86) | 0.0% (0/43) |
| 6 month | 0.0% (0/167) | 0.0% (0/80) | 0.0% (0/35) |
| 12 month | 0.0% (0/149) | 0.0% (0/60) | 0.0% (0/28) |
| Graft material rupture | | | |
| Pre-discharge | 0.0% (0/176) | 0.0% (0/86) | 0.0% (0/39) |
| 30 day | 0.0% (0/178) | 0.0% (0/86) | 0.0% (0/43) |
| 6 month | 0.0% (0/167) | 0.0% (0/80) | 0.0% (0/35) |
| 12 month | 0.0% (0/149) | 0.0% (0/60) | 0.0% (0/28) |

¹Migration with clinical sequelae include endoleak, conversion, rupture or AAA related death.

²Stent fracture percentages are for main body. There were also no right iliac, left iliac, occluder, converter, right iliac extension, left iliac extension or main body extension fractures out of the images assessed by the core lab.

Table 6.5.3 Aneurysm change

Change from pre-discharge to follow-up

| Follow-up | Item | Standard Risk | High Risk | Roll-in |
|-----------|----------------|---------------|-------------|---------------|
| 30 day | Decrease >5 mm | 1.7% (3/180) | 4.8% (4/84) | 0.0% (0/40) |
| | Unchanged | 97% (174/180) | 94% (79/84) | 97.5% (39/40) |
| | Increase >5 mm | 1.7% (3/180) | 1.2% (1/84) | 2.5% (1/40) |
| 6 month | Decrease >5 mm | 36% (63/173) | 41% (30/73) | 49% (18/37) |
| | Unchanged | 62% (108/173) | 59% (43/73) | 51% (19/37) |
| | Increase >5 mm | 1.2% (2/173) | 0.0% (0/73) | 0.0% (0/37) |
| 12 month | Decrease >5 mm | 68% (102/151) | 63% (39/62) | 67% (20/30) |
| | Unchanged | 31% (47/151) | 35% (22/62) | 33% (10/30) |
| | Increase >5 mm | 1.3% (2/151) | 1.6% (1/62) | 0.0% (0/30) |

In three patients, aneurysm diameter increased >5 mm from pre-discharge to 12 months. Two patients had a graft infection, and one increased due to a late endoleak.

Table 6.5.4 Secondary endpoints

| Item | Standard Risk | Surgical Standard Risk | High Risk | Roll-in |
|-------------------------------|---------------|------------------------|--------------|--------------|
| Anesthesia time (min) | 221.6 ± 67.3 | 304.5 ± 102.7 | 218.9 ± 69.6 | 213.9 ± 57.7 |
| Procedure time (min) | 153.2 ± 56.3 | 238.7 ± 92.2 | 153.5 ± 58.6 | 155.9 ± 43.2 |
| Blood bank products received | | | | |
| PRBC | 4.5% (9/200) | 61% (49/80) | 10% (10/100) | 3.8% (2/52) |
| FFP | 0.0% (0/200) | 8.8% (7/80) | 1.0% (1/100) | 0.0% (0/52) |
| Platelets | 0.5% (1/200) | 6.3% (5/80) | 1.0% (1/100) | 0.0% (0/52) |
| Cryoprecipitates | 0.0% (0/200) | 7.5% (6/80) | 0.0% (0/100) | 0.0% (0/52) |
| Blood loss (cc) | 299 ± 324 | 1676 ± 1676 | 356 ± 514 | 265 ± 226 |
| Days in ICU | 0.4 ± 0.9 | 3.4 ± 4.6 | 0.5 ± 1.2 | 0.5 ± 0.9 |
| Days to discharge | 2.6 ± 1.7 | 8.8 ± 5.6 | 3.0 ± 2.8 | 2.7 ± 1.5 |
| Days to oral fluids | 0.5 ± 0.8 | 3.9 ± 2.5 | 0.5 ± 0.6 | 0.7 ± 0.5 |
| Days to normal diet | 1.3 ± 1.2 | 6.6 ± 4.9 | 1.3 ± 0.8 | 1.1 ± 0.7 |
| Days to normal bowel function | 2.6 ± 1.4 | 4.2 ± 2.1 | 2.6 ± 1.5 | 2.0 ± 1.2 |
| Days to ambulation | 1.2 ± 0.7 | 3.5 ± 3.4 | 1.2 ± 0.7 | 1.2 ± 0.6 |
| Hours of intubation | 1.9 ± 2.2 | 11.7 ± 13.6 | 1.2 ± 1.7 | 2.6 ± 4.6 |
| Maximum temperature | 101.1 ± 1.3 | 100.7 ± 1.2 | 100.8 ± 1.1 | 101.0 ± 1.2 |

The average procedure time for standard risk patients was less than that of surgical patients ($P < .001$). The average anesthesia time for standard risk patients was less than that of surgical patients ($P < .001$).

A larger percentage of surgical patients received PRBC ($P < .001$), FFP ($P < .001$), platelets ($P = .01$) and cryoprecipitates ($P < .001$) than standard risk patients. Surgical patients lost more blood than standard risk patients ($P < .001$).

Standard risk patients spent fewer days in the ICU than surgical patients, spent less time in the hospital than surgical patients, resumed consumption of oral fluids sooner than surgical patients, resumed normal diets in less time than the surgical patients, returned to normal bowel function sooner than surgical patients, ambulated sooner than surgical patients and were intubated less frequently than surgical patients ($P < .001$).

6.6 Endoleak Management

During the clinical study type I endoleaks were treated during the initial procedure by use of additional balloon seating or if unsuccessful, additional prostheses. Type II endoleaks were observed for a period of one to six months to determine if they would spontaneously thrombose or in the absence of enlarging aneurysms, they were treated with endovascular techniques at the discretion of the practicing physician. If the aneurysm enlarged, treatment by embolization or ligation was considered and, in some cases performed. Type III endoleaks caused by graft defects, inadequate seal or disconnection of the modular components were treated with additional ballooning or prostheses. As reported by the angiographic core lab, there were no type IV endoleaks during the U.S. clinical study. The graft material used to manufacture the Zenith® AAA Endovascular Graft is of standard thickness and is the same material used in open surgical procedures.

7 PATIENT SELECTION AND TREATMENT

7.1 Use In Specific Populations

(See Section 7.2)

7.2 Individualization of Treatment

- Each patient must be evaluated on an individual basis.
- 10 to 15% device oversizing of graft diameter is typical in endovascular grafting. Therefore, the patient's proximal aortic neck diameter must be at least 2 to 4 mm smaller than labeled device diameter.
- The patient's distal iliac diameter, at fixation site, should be at least 1 to 2 mm smaller than the labeled diameter.

8 PATIENT COUNSELING INFORMATION

The physician should consider the following points when counseling the patient and/or family members about this device:

- Differences between endovascular repair and surgical repair
- Risks related to open surgical repair
- Risks related to endovascular repair (refer to adverse events)
- Endovascular repair is a new option with potential advantages related to minimally invasive approach and potential disadvantages relating to unknown rates of late failure.
- It is possible that subsequent endovascular or open surgical repair of the aneurysm may be required
- At a minimum, annual imaging and adherence to routine post-operative follow-up requirements is required
- Importance of keeping the patient implant card and showing it to future health care practitioners, especially when the patient needs to undergo diagnostic procedures
- **Magnetic Resonance Imaging (MRI) procedures should not be performed at any time following endovascular graft implantation with the Zenith® AAA Endovascular Graft**

9 HOW SUPPLIED

The Zenith® AAA Endovascular Graft components are available in the following lengths and diameters:

Table 9.1 Bifurcated Main Bodies

| Renal Artery to Bifurcation Distance/Range | Graft Proximal Diameter | Introduction Sheath French Size | Cook Reorder Number |
|--|-------------------------|---------------------------------|---------------------|
| 80-95 mm | 22 mm | 18 Fr | TFB-1-22 |
| | 24 mm | 18 Fr | TFB-1-24 |
| | 26 mm | 18 Fr | TFB-1-26 |
| | 28 mm | 20 Fr | TFB-1-28 |
| | 30 mm | 20 Fr | TFB-1-30 |
| | 32 mm | 20 Fr | TFB-1-32 |
| 95-110 mm | 22 mm | 18 Fr | TFB-2-22 |
| | 24 mm | 18 Fr | TFB-2-24 |
| | 26 mm | 18 Fr | TFB-2-26 |
| | 28 mm | 20 Fr | TFB-2-28 |
| | 30 mm | 20 Fr | TFB-2-30 |
| | 32 mm | 20 Fr | TFB-2-32 |
| 110-125 mm | 22 mm | 18 Fr | TFB-3-22 |
| | 24 mm | 18 Fr | TFB-3-24 |
| | 26 mm | 18 Fr | TFB-3-26 |
| | 28 mm | 20 Fr | TFB-3-28 |
| | 30 mm | 20 Fr | TFB-3-30 |
| | 32 mm | 20 Fr | TFB-3-32 |
| 125-140 mm | 22 mm | 18 Fr | TFB-4-22 |
| | 24 mm | 18 Fr | TFB-4-24 |
| | 26 mm | 18 Fr | TFB-4-26 |
| | 28 mm | 20 Fr | TFB-4-28 |
| | 30 mm | 20 Fr | TFB-4-30 |
| | 32 mm | 20 Fr | TFB-4-32 |
| 140-155 mm | 22 mm | 18 Fr | TFB-5-22 |
| | 24 mm | 18 Fr | TFB-5-24 |
| | 26 mm | 18 Fr | TFB-5-26 |
| | 28 mm | 20 Fr | TFB-5-28 |
| | 30 mm | 20 Fr | TFB-5-30 |
| | 32 mm | 20 Fr | TFB-5-32 |

Table 9.2 Ipsilateral/Contralateral Iliac Legs

| Distal Iliac Leg Diameter | Working Length of Iliac Leg | Introduction Sheath French Size | Cook Reorder Number |
|---------------------------|-----------------------------|---------------------------------|---------------------|
| 8 mm | 37 mm | 14 Fr | TFLE-8-37 |
| | 54 mm | 14 Fr | TFLE-8-54 |
| | 71 mm | 14 Fr | TFLE-8-71 |
| | 88 mm | 14 Fr | TFLE-8-88 |
| | 105 mm | 14 Fr | TFLE-8-105 |
| | 122 mm | 14 Fr | TLFE-8-122 |
| 10 mm | 37 mm | 14 Fr | TFLE-10-37 |
| | 54 mm | 14 Fr | TFLE-10-54 |
| | 71 mm | 14 Fr | TFLE-10-71 |
| | 88 mm | 14 Fr | TFLE-10-88 |
| | 105 mm | 14 Fr | TFLE-10-105 |
| | 122 mm | 14 Fr | TLFE-10-122 |
| 12 mm | 37 mm | 14 Fr | TFLE-12-37 |
| | 54 mm | 14 Fr | TFLE-12-54 |
| | 71 mm | 14 Fr | TFLE-12-71 |
| | 88 mm | 14 Fr | TFLE-12-88 |
| | 105 mm | 14 Fr | TFLE-12-105 |
| | 122 mm | 14 Fr | TFLE-12-122 |
| 14 mm | 37 mm | 14 Fr | TFLE-14-37 |
| | 54 mm | 14 Fr | TFLE-14-54 |
| | 71 mm | 14 Fr | TFLE-14-71 |
| | 88 mm | 14 Fr | TFLE-14-88 |
| | 105 mm | 14 Fr | TFLE-14-105 |
| | 122 mm | 14 Fr | TFLE-14-122 |
| 16 mm | 37 mm | 14 Fr | TFLE-16-37 |
| | 54 mm | 14 Fr | TFLE-16-54 |
| | 71 mm | 14 Fr | TFLE-16-71 |
| | 88 mm | 14 Fr | TFLE-16-88 |
| | 105 mm | 14 Fr | TFLE-16-105 |
| | 122 mm | 14 Fr | TFLE-16-122 |
| 18 mm | 37 mm | 16 Fr | TFLE-18-37 |
| | 54 mm | 16 Fr | TFLE-18-54 |
| | 71 mm | 16 Fr | TFLE-18-71 |
| | 88 mm | 16 Fr | TFLE-18-88 |
| | 105 mm | 16 Fr | TFLE-18-105 |
| | 122 mm | 16 Fr | TFLE-18-122 |
| 20 mm | 37 mm | 16 Fr | TFLE-20-37 |
| | 54 mm | 16 Fr | TFLE-20-54 |
| | 71 mm | 16 Fr | TFLE-20-71 |
| | 88 mm | 16 Fr | TFLE-20-88 |
| | 105 mm | 16 Fr | TFLE-20-105 |
| | 122 mm | 16 Fr | TFLE-20-122 |
| 22 mm | 37 mm | 16 Fr | TFLE-22-37 |
| | 54 mm | 16 Fr | TFLE-22-54 |
| | 71 mm | 16 Fr | TFLE-22-71 |
| | 88 mm | 16 Fr | TFLE-22-88 |
| | 105 mm | 16 Fr | TFLE-22-105 |
| | 122 mm | 16 Fr | TFLE-22-122 |
| 24 mm | 37 mm | 16 Fr | TFLE-24-37 |
| | 54 mm | 16 Fr | TFLE-24-54 |
| | 71 mm | 16 Fr | TFLE-24-71 |
| | 88 mm | 16 Fr | TFLE-24-88 |

Table 9.3 Converter

Used to convert an *in-situ* bifurcated graft to an aortouni-iliac repair.

| Cook Reorder Number | Proximal Diameter | Introduction Sheath French Size | Distal Diameter | Distal Length |
|---------------------|-------------------|---------------------------------|-----------------|---------------|
| ESC-24-12-80 | 24 mm | 18 Fr | 12 mm | 80 mm |
| ESC-28-12-80 | 28 mm | 20 Fr | 12 mm | 80 mm |
| ESC-32-12-80 | 32 mm | 20 Fr | 12 mm | 80 mm |

Table 9.4 Iliac Leg Extension

Used for extending the distal iliac leg of an *in-situ* endovascular graft.

| Cook Reorder Number | Diameter | Introduction Sheath French Size | Length |
|---------------------|----------|---------------------------------|--------|
| ESLE-8-55 | 8 mm | 14 Fr | 55 mm |
| ESLE-10-55 | 10 mm | 14 Fr | 55 mm |
| ESLE-12-55 | 12 mm | 14 Fr | 55 mm |
| ESLE-14-55 | 14 mm | 14 Fr | 55 mm |
| ESLE-16-55 | 16 mm | 14 Fr | 55 mm |
| ESLE-18-55 | 18 mm | 16 Fr | 55 mm |
| ESLE-20-55 | 20 mm | 16 Fr | 55 mm |
| ESLE-22-55 | 22 mm | 18 Fr | 55 mm |
| ESLE-24-55 | 24 mm | 18 Fr | 55 mm |

Table 9.5 Occluder

Used to occlude an iliac artery when an aortouni-iliac device or a converter has been implanted; and a femoral-to-femoral crossover procedure is required.

| Cook Reorder Number | Diameter | Introduction Sheath French Size | Length |
|---------------------|----------|---------------------------------|--------|
| ESP-14-20 | 14 mm | 18 Fr | 20 mm |
| ESP-16-20 | 16 mm | 18 Fr | 20 mm |
| ESP-20-20 | 20 mm | 18 Fr | 20 mm |
| ESP-24-20 | 24 mm | 18 Fr | 20 mm |

Table 9.6 Main Body Extension

Used for extending the proximal body of an *in-situ* endovascular graft.

| Cook Reorder Number | Diameter | Introduction Sheath French Size | Length |
|---------------------|----------|---------------------------------|--------|
| ESBE-22-36 | 22 mm | 18 Fr | 36 mm |
| ESBE-24-36 | 24 mm | 18 Fr | 36 mm |
| ESBE-26-36 | 26 mm | 18 Fr | 36 mm |
| ESBE-28-36 | 28 mm | 20 Fr | 36 mm |
| ESBE-30-36 | 30 mm | 20 Fr | 36 mm |
| ESBE-32-36 | 32 mm | 20 Fr | 36 mm |

10 CLINICAL USE INFORMATION**10.1 Physician Training Program**

CAUTION: Physicians performing the Zenith® AAA Endovascular Graft procedure must be trained in vascular interventional procedures and are required to have successfully completed additional training and certification in the use of the Zenith® AAA Endovascular Graft System.

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 COOK INCORPORATED.

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).
- Heparinized saline solution

10.4 Materials Recommended

(Not included in 3-Piece modular system)

The following products are recommended:

- Cook Amplatz Extra Stiff Wire Guides (AES)
- Cook Lunderquist Extra Stiff Wire Guides (LES)
- Cook .035 inch Wire Guides
- Cook Nimble™ Wire Guides
- Molding Balloons
- Cook Check-Flo® Introducer Sets
- Cook Extra Large Check-Flo® Introducer Sets
- Cook Flexor® Balkin Up & Over® Contralateral Introducers
- Cook Aurous® Centimeter Sizing Catheters
- Cook Beacon® Tip Angiographic Catheters
- Cook Beacon® Tip Royal Flush Catheters
- Cook Single Wall Entry Needles

10.5 MRI Information

Magnetic Resonance Imaging (MRI) procedures should not be performed at any time following endovascular graft implantation with the Zenith® AAA Endovascular Graft.

11 SUGGESTED INSTRUCTIONS FOR USE OF THE ZENITH® AAA ENDOVASCULAR GRAFT

Prior to use of the Zenith® AAA Endovascular Graft, review this Suggested Instructions for Use booklet. The following instructions embody a basic guideline for device placement. Variations in the following instructional procedures may be necessary. These instructions are intended to help guide the physician and do not take the place of physician judgment.

11.1 Bifurcated System (Figure 1)

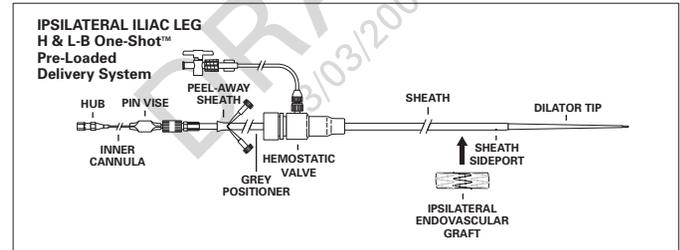
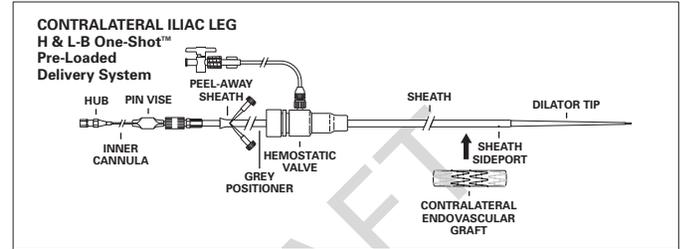
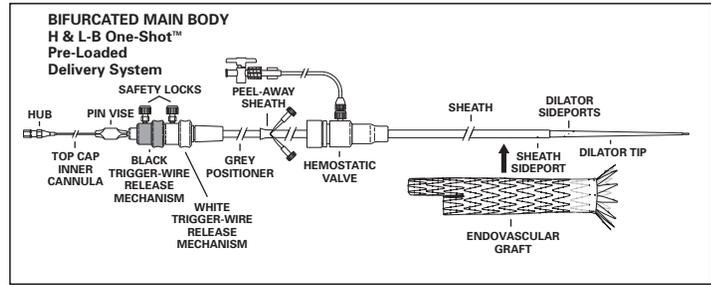


Figure 1

General Use Information

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

The Zenith® AAA Endovascular Graft with the H & L-B One-Shot™ delivery system is compatible with .035 inch diameter wire guides.

Pre-Implant Determinants

Verify from pre-implant planning 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. Length from the aortic bifurcation to the hypogastric (internal iliac) arteries/attachment site(s).
7. Aneurysm(s) extending into the iliac vessels may require special consideration in selecting a suitable graft/vessel interface site.

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. Prepare pressurized, heparinized saline drips, if used, for connection to each indwelling sheath to be used during the course of the procedure.
4. Expose both common femoral arteries using standard surgical technique.
5. Establish adequate proximal and distal vascular control of both femoral vessels.

11.1.1 Bifurcated Main Body Preparation/Flush

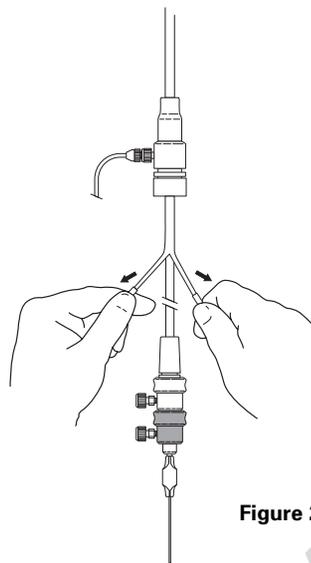


Figure 2

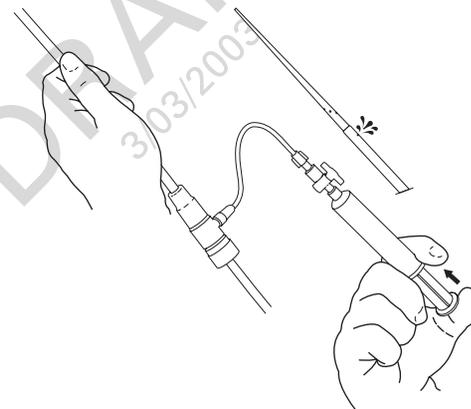


Figure 3

1. Remove black-hubbed inner stylet (from the inner cannula) and dilator tip protector (from the dilator tip). Remove Peel-Away[®] sheath from back of hemostatic valve. **(Figure 2)** Elevate distal tip of system and flush through the hemostatic valve until fluid emerges from the side hole near the tip of the introduction sheath. **(Figure 3)** 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.

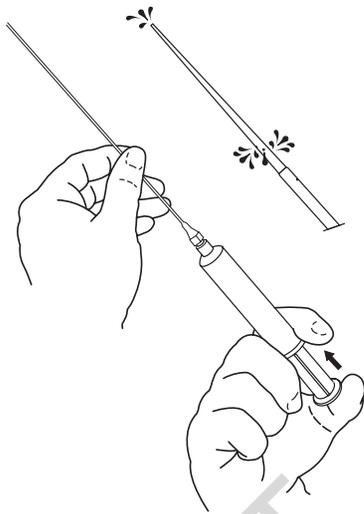


Figure 4

2. Attach syringe with heparinized saline to the hub on the inner cannula. Flush until fluid exits the distal side hole ports and dilator tip. (Figure 4)

11.1.2 Contralateral Iliac Leg Preparation/Flush

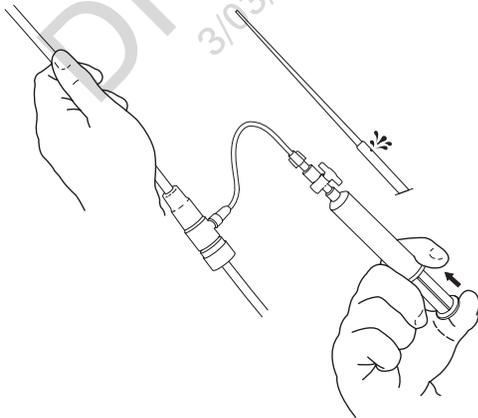


Figure 5

1. Remove black-hubbed inner stylet (from the inner cannula) and dilator tip protector (from the dilator tip). Remove Peel-Away® sheath from back of the hemostatic valve. Elevate distal tip of system and flush through the hemostatic valve until fluid emerges from the sideport near the tip of the introduction sheath. (Figure 5) Continue to inject a full 20 cc of flushing solution through the device. Discontinue injection and close stopcock on connecting tube.

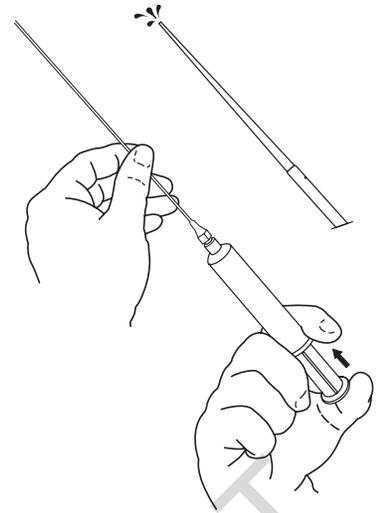


Figure 6

2. Attach syringe with heparinized saline to the hub on the distal inner cannula. Flush until fluid exits the distal dilator tip. (Figure 6)

11.1.3 Ipsilateral Iliac Leg Preparation/Flush

Follow the previous “**Contralateral Iliac Leg Preparation/Flush**” instructions to ensure proper flushing of the Ipsilateral Iliac Leg graft.

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.

11.1.5 Main Body Placement

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 (AES or LES) .035 inch, 260 cm and advance through catheter and up to the thoracic aorta. Remove flush catheter and sheath. Maintain wire guide position.
4. Before insertion, position main body delivery system on patient's abdomen under fluoroscopy to determine the orientation of the contralateral limb radiopaque marker. The sidearm of the hemostatic valve may serve as an external reference to the contralateral limb radiopaque marker.

5. Insert main 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 system, be careful to rotate all of the components of the system together (from outer sheath to inner wire guide).

6. Advance delivery system until the four gold radiopaque markers (which indicate the upper limit of the graft material) (Figure 7, Illustration A) are just inferior to the most inferior renal orifice.

7. Verify position of wire guide in the thoracic aorta. Ensure the graft system is oriented such that the contralateral limb is positioned above and anterior to the origin of the contralateral iliac. If the contralateral limb radiopaque marker is not properly aligned, rotate the entire system until it is correctly positioned half way between a lateral and an anterior position on the contralateral side.

- A marker formation of a \checkmark indicates an anterior position of the short (contralateral) limb. (Figure 7, Illustration B)
- A marker formation of a \vee indicates a posterior position of the short (contralateral) limb. (Figure 7, Illustration C)
- A marker formation of a $|$ indicates a lateral position of the short (contralateral) limb. (Figure 7, Illustration D)

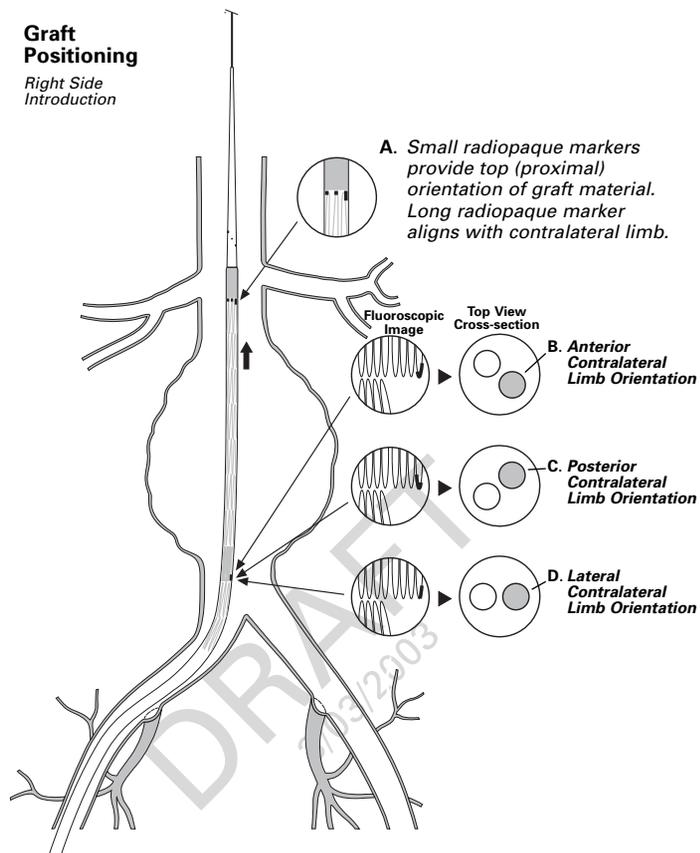


Figure 7

NOTE: Radiopaque markers on each stent between the renal arteries and the contralateral limb align with the contralateral limb radiopaque marker.

8. Repeat the angiogram to verify the four gold radiopaque markers are just inferior to the most inferior renal orifice.

11.1.6 Contralateral Iliac Wire Guide Placement

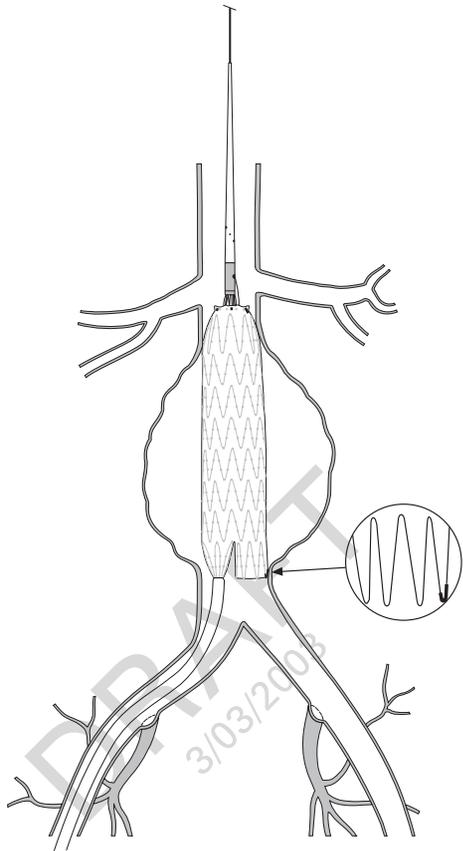


Figure 8

9. 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.
10. Without moving the table, decrease magnification to check position of the contralateral limb radiopaque marker and location of renal arteries. Proceed with deployment until the contralateral limb is fully deployed. (Figure 8) **Stop withdrawing sheath.**

NOTE: Verify contralateral limb is above the aortic bifurcation and in desired location for cannulation.

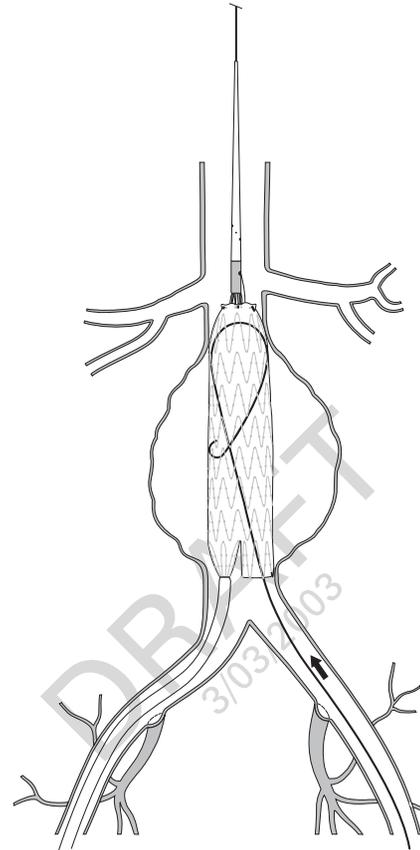


Figure 9

1. Manipulate catheter and wire guide through open end of contralateral limb into body of the graft. Advance the wire guide until it curves inside the body of the graft. AP and oblique fluoroscopic views can aid in verification of device cannulation.
2. After cannulation, advance the angiographic catheter over the wire into the body of the endovascular graft. Remove wire and perform angiography to confirm position. Advance wire guide until it curves inside the body of the graft. Remove angiographic catheter. (Figure 9)

11.1.7 Main Body Proximal (Top) Deployment

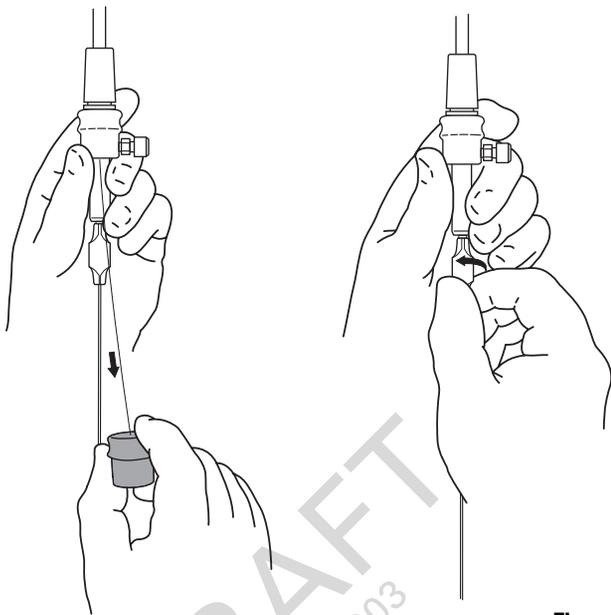


Figure 10

Figure 11

1. Perform angiography through either the main body delivery system cannula or an angiographic catheter to verify position of the endovascular graft with respect to the renal arteries. If necessary, carefully reposition the covered portion of the endovascular graft with respect to the renal arteries. (Repositioning can only take place over a small range of distance at this stage.)

NOTE: Cannula injection rate of 15 cc per second at 1200 psi is acceptable.

NOTE: Ensure patency of renal arteries by confirming that the proximal graft markers are 2 mm or more below the lowest patent renal artery.

2. Under fluoroscopic guidance, 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 inner cannula. (Figure 10)
3. Loosen the pin vise. (Figure 11) Control the position of the graft by stabilizing the grey positioner section of the introducer.

CAUTION: Before deployment of suprarenal attachment stent, verify that the position of the access wire extends just distal to the aortic arch.

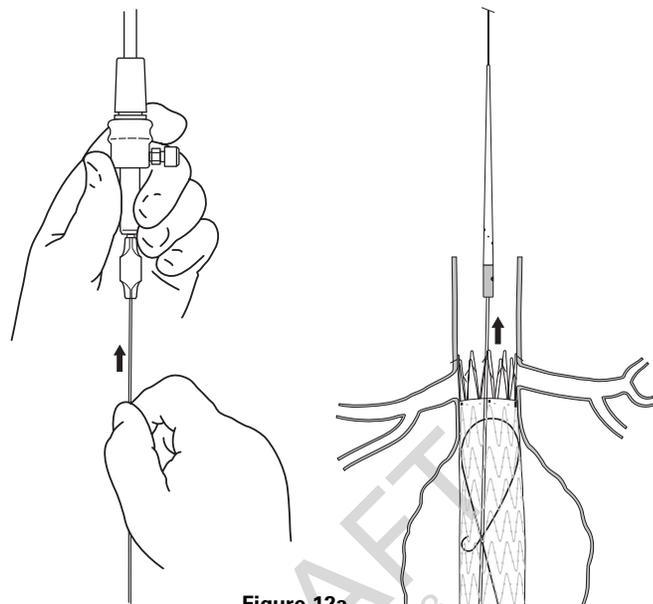


Figure 12a

Figure 12b

4. Deploy the suprarenal attachment stent by advancing the top cap inner cannula 1 to 2 mm at a time while controlling the position of the main body until the top stent is fully deployed. (Figures 12a & 12b) 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 device incorporates a suprarenal stent with fixation barbs. As reported in the clinical study, barb separation was noted to occur in 1.7% of standard risk patients treated with this device as noted on a 12-month KUB or CT. Exercise extreme caution when manipulating interventional devices in the region of the suprarenal stent.

5. Advance the contralateral wire guide into the thoracic aorta.

11.1.8 Contralateral Iliac Leg Placement and Deployment

CAUTION: Before proceeding, verify that the predetermined contralateral iliac leg is selected for insertion on the contralateral side of the patient.

1. Orient the image intensifier to show both the contralateral internal iliac artery and contralateral common iliac artery.
2. Prior to the introduction of the contralateral limb delivery system, inject contrast through the contralateral femoral sheath to locate the contralateral internal iliac artery.
3. Remove the sheath and carefully introduce the contralateral iliac leg delivery system into the artery. Advance slowly until the iliac leg graft overlaps at least one full stent inside the contralateral limb of the main body. (Figure 13) If there is any tendency for the main body graft to move during this maneuver, hold it in position with traction on the grey positioner on the ipsilateral side.

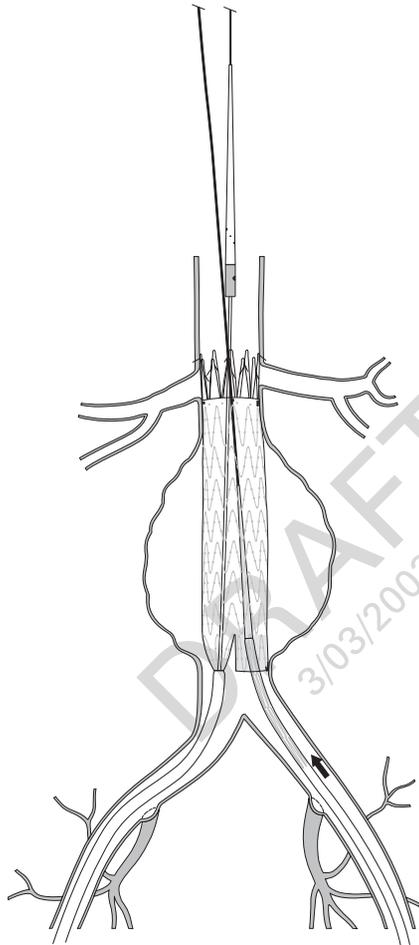


Figure 13

NOTE: If difficulty is encountered advancing the iliac leg delivery system, exchange to a more supportive wire guide. In tortuous vessels the anatomy may alter significantly with the introduction of the rigid wires and sheath systems.

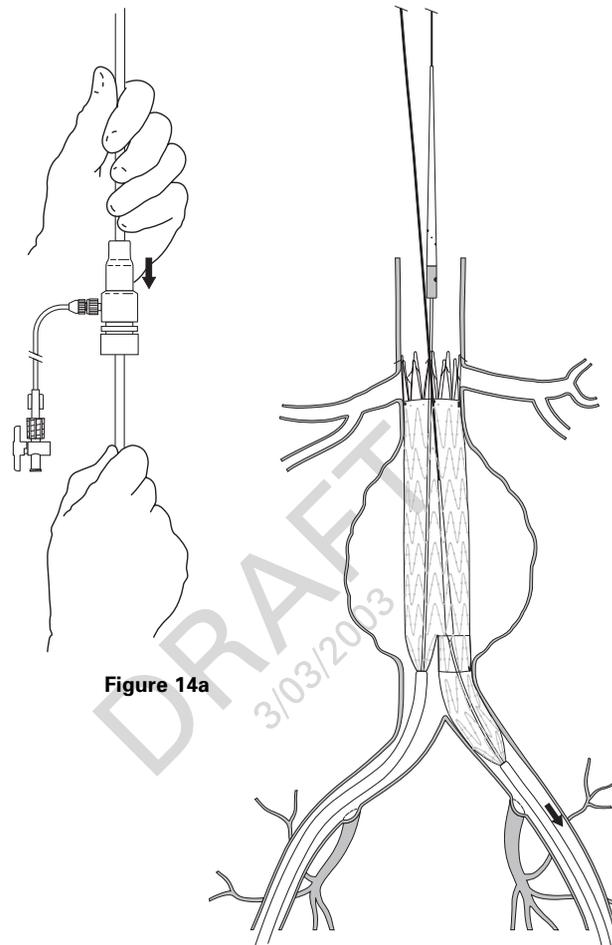


Figure 14a

Figure 14b

4. Confirm position of distal end of the iliac leg graft. Reposition the iliac leg graft if necessary to ensure both internal iliac patency and a minimum of one full stent overlap (maximum of 1 1/2 stents) within the main body endovascular graft.
5. To deploy, hold the iliac leg graft in position with the grey positioner while withdrawing the sheath. (Figures 14a & 14b) Ensure one stent overlap is maintained.
6. Stop withdrawing the sheath as soon as the distal end of the iliac leg graft is released.

11.1.9 Main Body Distal (Bottom) Deployment

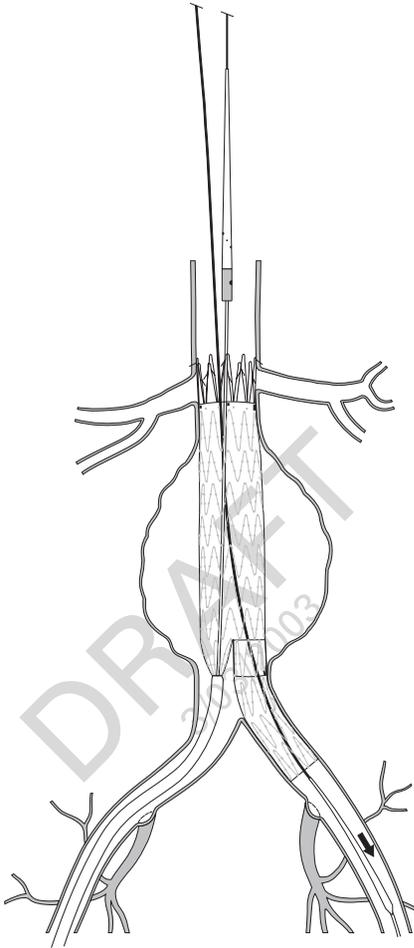


Figure 15

7. Under fluoroscopy and after verification of iliac leg graft position, loosen pin vise, retract inner cannula to dock tapered dilator to grey positioner. Tighten pin vise. Maintain sheath position while withdrawing grey positioner with secured inner cannula. (Figure 15)
8. Re-check the position of the wire guide.

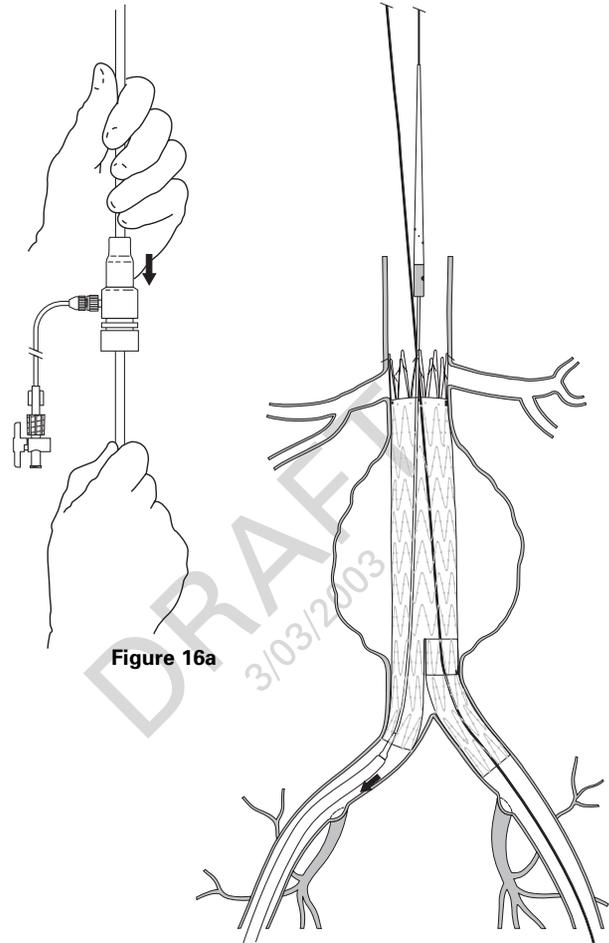


Figure 16a

Figure 16b

1. Return to the ipsilateral side.
2. Fully deploy the ipsilateral limb of the main body by withdrawing the sheath until the most distal stent has expanded. (Figures 16a & 16b) **Stop withdrawing sheath.**

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

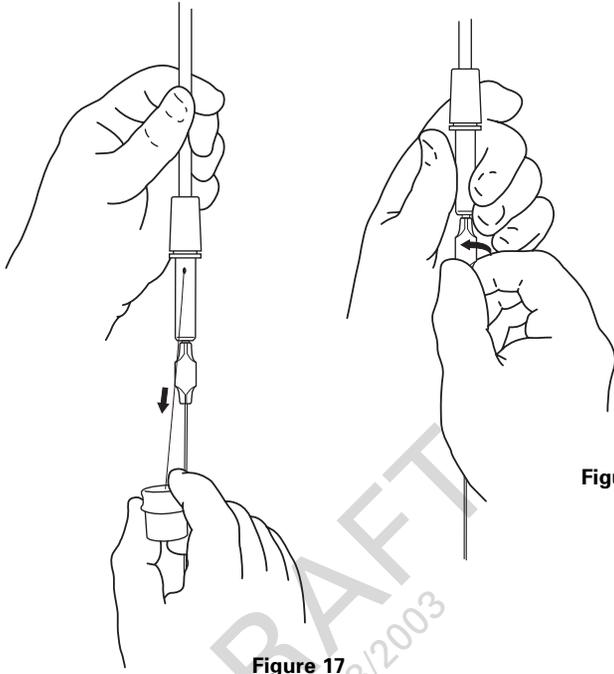


Figure 18

Figure 17

3. 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 17)

11.1.10 Docking of Top Cap

1. Loosen the pin vise. (Figure 18)

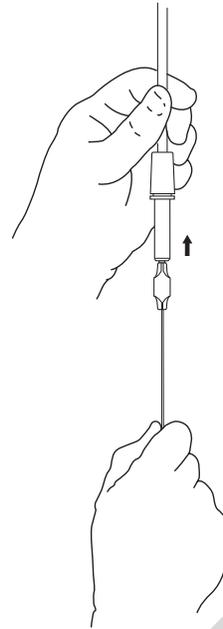


Figure 19a



Figure 19b

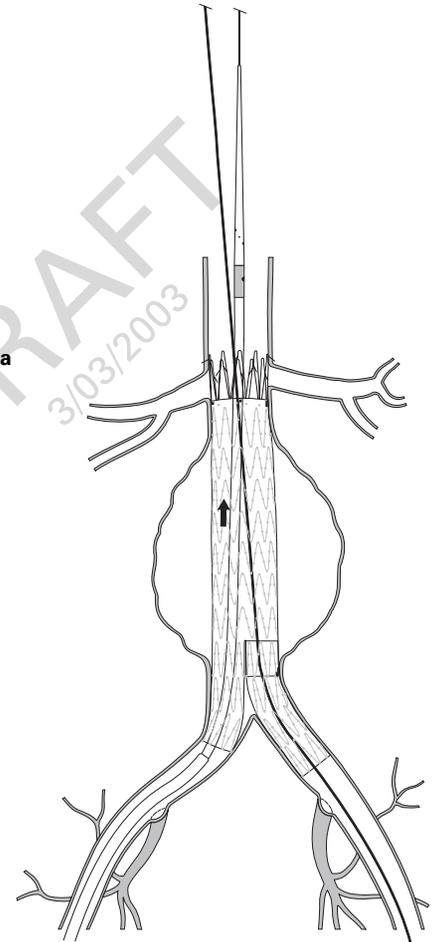


Figure 19c

2. Secure sheath and inner cannula and advance the grey positioner over the inner cannula until it docks with the top cap. (Figures 19a, 19b & 19c)

NOTE: If resistance occurs, gently advance with slight rotation.

11.1.11 Ipsilateral Iliac Leg Placement and Deployment

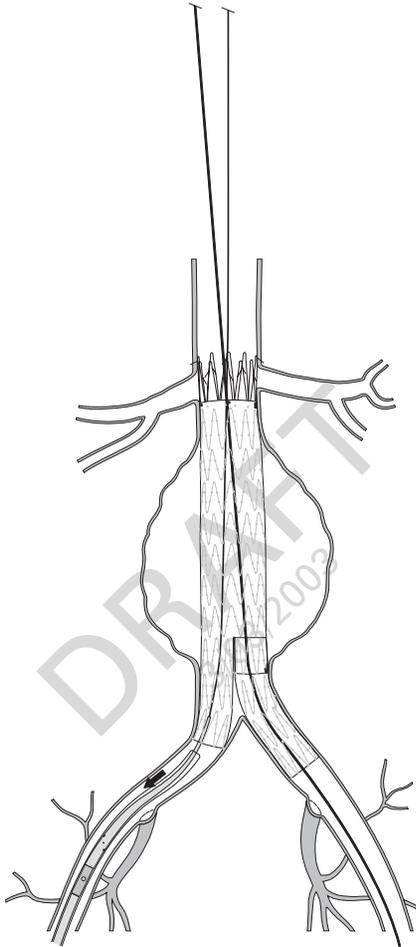


Figure 20

3. Retighten the pin vise and withdraw the entire top cap and grey positioner through the graft and through the sheath by pulling on the inner cannula. (Figure 20) Leave the sheath and wire guide in place.

NOTE: Maintain position of sheath and wire guide.

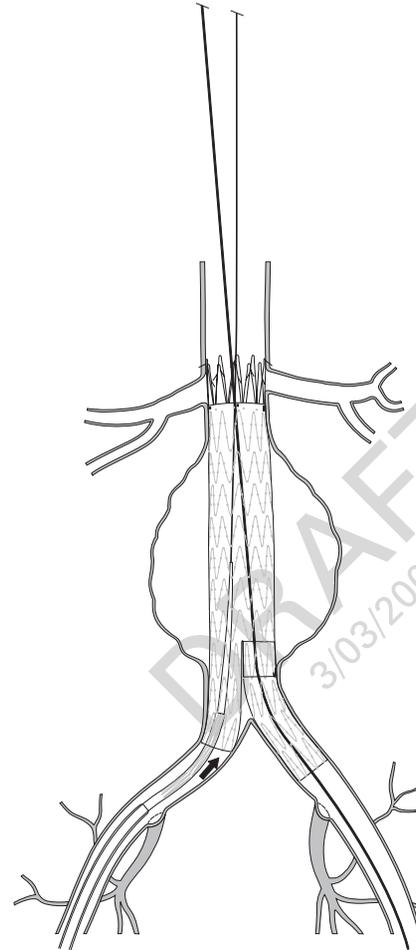


Figure 21

2. Advance slowly until the ipsilateral iliac leg graft overlaps a minimum of one full stent (i.e., proximal stent of iliac leg graft, maximum of three full stents) inside the ipsilateral limb of the main body. (Figure 21)

NOTE: If an overlap of > 3.5 iliac leg stents are required, it may be necessary to consider use of a leg extension in the bifurcation area of the opposite side.

3. Confirm position of distal end of the iliac leg graft. Reposition the iliac leg graft if necessary to ensure internal iliac patency.

1. Utilize the main body graft wire and sheath assembly to introduce the ipsilateral iliac leg graft. Advance dilator and sheath assembly into the main body sheath.

NOTE: In tortuous vessels, the position of the internal iliac arteries may alter significantly with the introduction of the rigid wires and sheath systems.

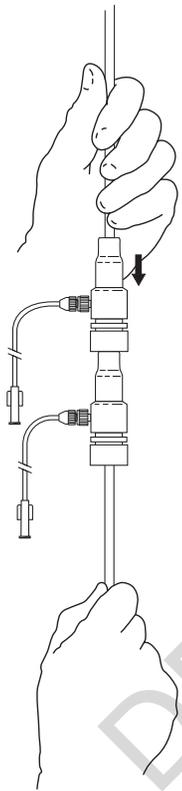


Figure 22a

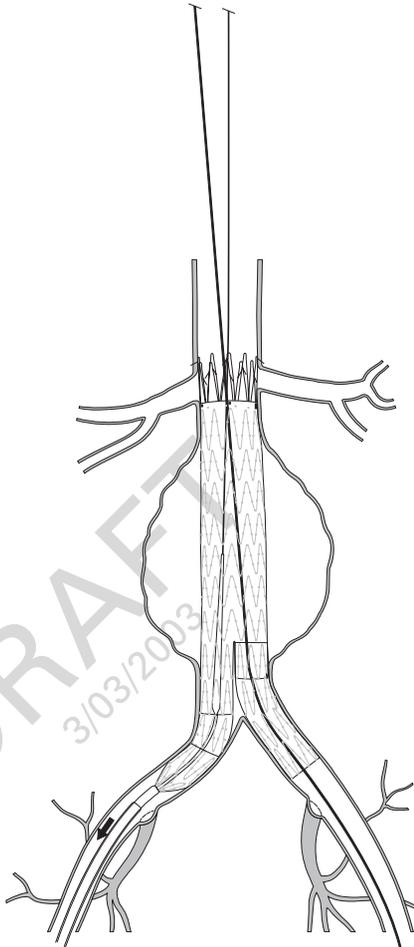


Figure 22b

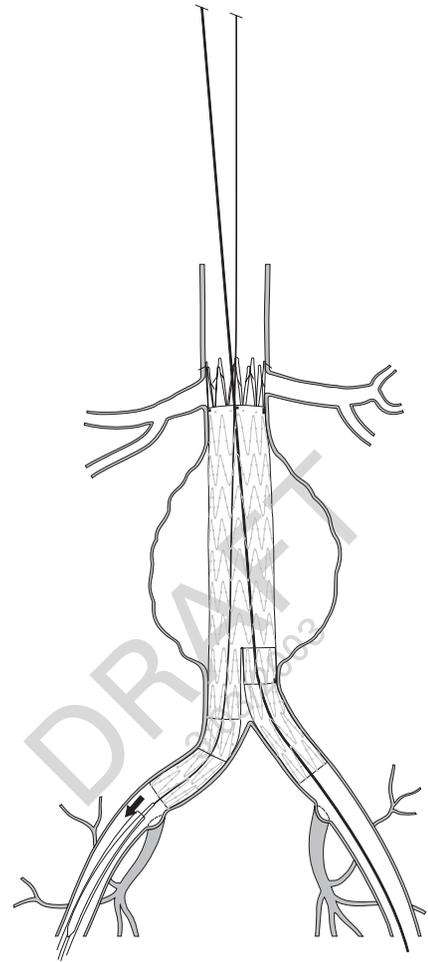
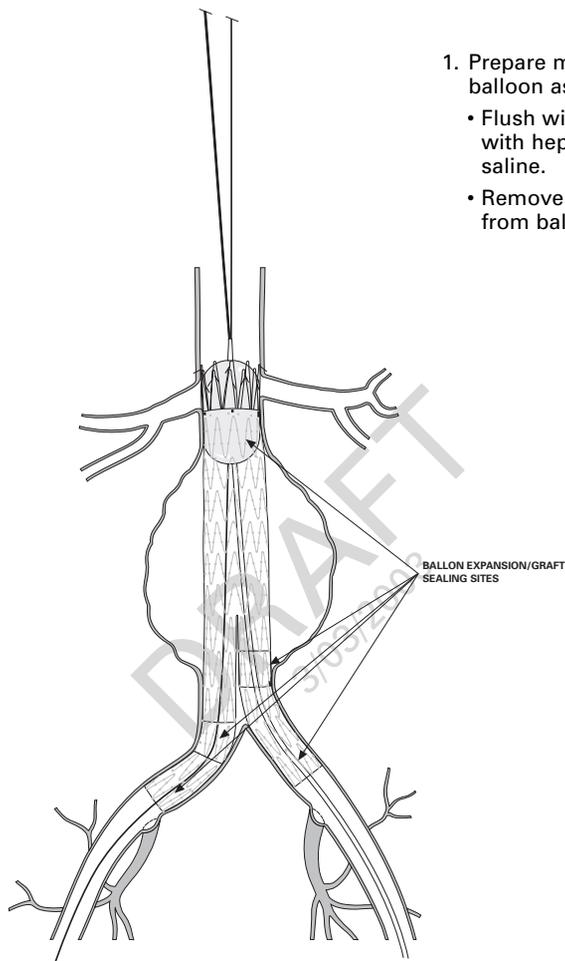


Figure 23

4. To deploy, stabilize the iliac leg graft with the grey positioner while withdrawing the iliac leg sheath. (Figure 22a & 22b) If necessary, withdraw the main body sheath.

5. Under fluoroscopy and after verification of iliac leg graft position, loosen pin vise, retract inner cannula to dock tapered dilator to grey positioner. Tighten pin vise. Maintain sheath position while withdrawing grey positioner with secured inner cannula. (Figure 23)
6. Re-check the position of the wire guides. Leave sheath and wire guides in place.

11.1.12 Molding Balloon Insertion



1. Prepare molding balloon as follows:
 - Flush wire lumen with heparinized saline.
 - Remove all air from balloon.

2. Advance the molding balloon over the wire guide and through the hemostatic valve of the main body introduction system to level of renal arteries. Maintain proper sheath positioning.
3. Expand the molding balloon, with diluted contrast media (as directed by the manufacturer) in the area of the attachment stent and the infrarenal neck, starting proximally and working in the distal direction. (Figure 24)

CAUTION: Confirm complete deflation of balloon prior to repositioning.

4. Withdraw the molding balloon to both the ipsilateral limb overlap and the ipsilateral distal fixation and expand.

CAUTION: Do not inflate balloon in iliac vessel outside of graft.

5. Transfer the molding balloon onto the contralateral wire guide and into the contralateral iliac leg introduction system. Advance molding balloon to the contralateral limb/contralateral iliac leg overlap site and expand. Withdraw the molding balloon to the contralateral iliac leg/vessel distal fixation and expand. (Figure 24)

CAUTION: Do not inflate balloon in iliac vessel outside of graft.

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

Final Angiogram

1. Position angiographic catheter just above the level of the renal arteries. Perform angiography to verify that the renal arteries are patent and that there are no endoleaks. Verify filling 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 the Ancillary Devices section, (page 48).

3. Repair vessels and close in standard surgical fashion.

Figure 24

11.2 Ancillary Devices (Figure 25)

Ancillary Devices

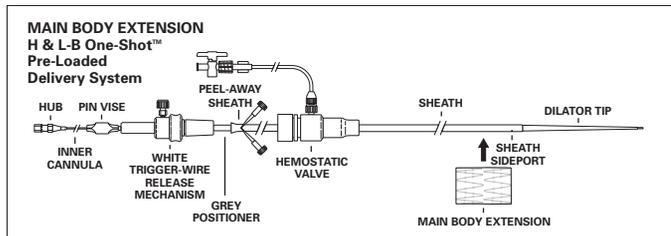
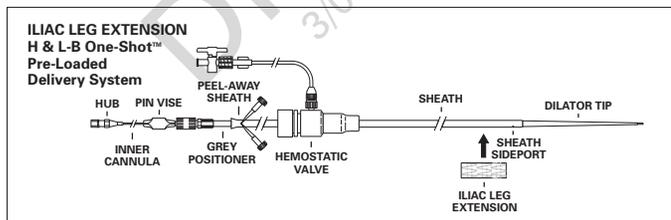
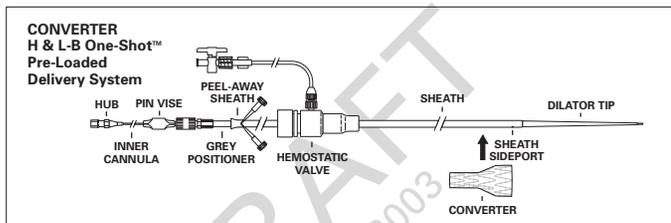
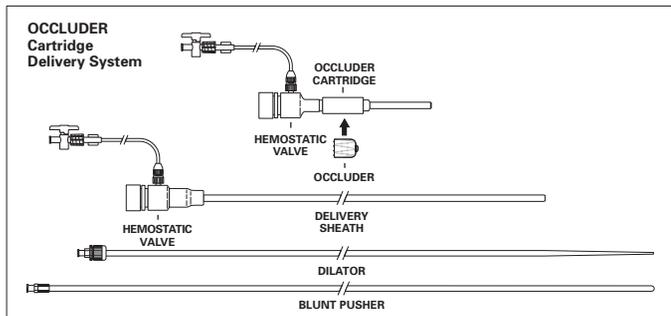


Figure 25

General Use Information

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

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

The Zenith® AAA ancillary devices with the H & L-B One-Shot™/Cartridge Delivery Systems are compatible with .035 inch diameter wire guides.

11.2.1 Occluder

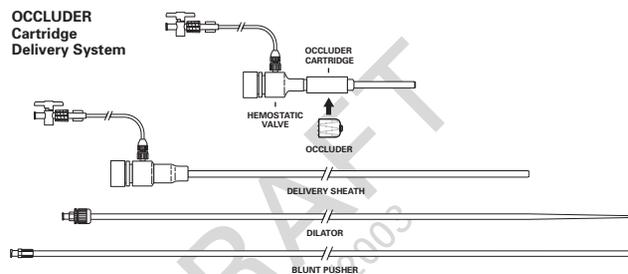


Figure 26

The occluder (Figure 26) is used for the occlusion of an iliac artery when the Converter system is placed and/or in conjunction with the femoral-to-femoral crossover procedure.

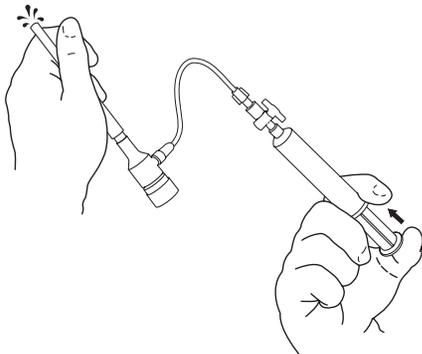


Figure 27

Occluder Preparation/Flush

1. Elevate the distal tip of the cartridge system containing the contralateral iliac occluder and flush system through the stopcock attached to the hemostatic valve. Continue flushing with heparinized saline until fluid exits the distal end of the cartridge. Discontinue injection and close stopcock. (Figure 27)

NOTE: Graft flushing solution of high heparin concentration is often used.

Occluder Placement & Deployment

1. Advance dilator and introducer sheath assembly (over the wire) to the site of the required intervention.
2. Remove the dilator and connect heparinized saline drip.
3. Insert a suitable catheter to perform angiography to determine proper occluder placement (below aortic bifurcation and above iliac bifurcation).
4. Verify placement of the delivery sheath and remove the catheter and wire guide (the tip of the sheath must be beyond the deployment site by at least 2 cm).

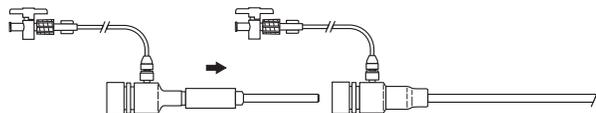


Figure 28

5. Insert the heparinized saline flushed occluder cartridge into the hemostatic valve of the delivery sheath. (Figure 28)

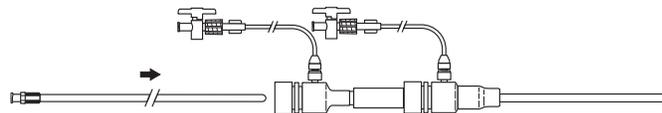


Figure 29

6. Advance the occluder through the cartridge and into the occluder delivery sheath using the blunt pusher. (Figure 29)



Figure 30

7. Advance the occluder to the deployment site (using the blunt pusher) ensuring that the device remains within the delivery sheath. (Figure 30)

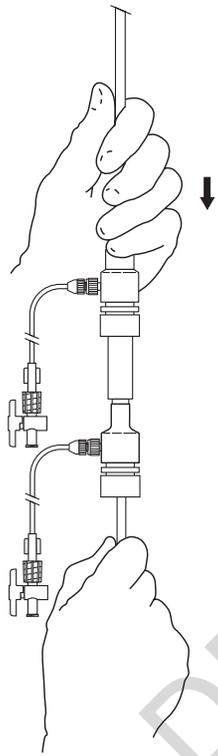


Figure 31a

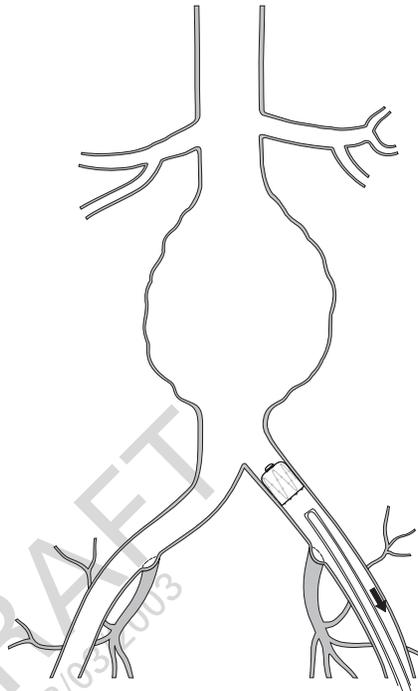


Figure 31b

8. After verification of appropriate device location, stabilize the blunt pusher and carefully withdraw the sheath to deploy the occluder. (Figures 31a & 31b)
9. After deployment, withdraw the blunt pusher and occluder cartridge leaving the delivery sheath in position.

Molding Balloon Insertion

1. Prepare molding balloon as follows:
 - Flush wire lumen with heparinized saline.
 - Remove all air from balloon.
2. Re-introduce wire guide and coil within occluder. Advance the molding balloon within the occluder.

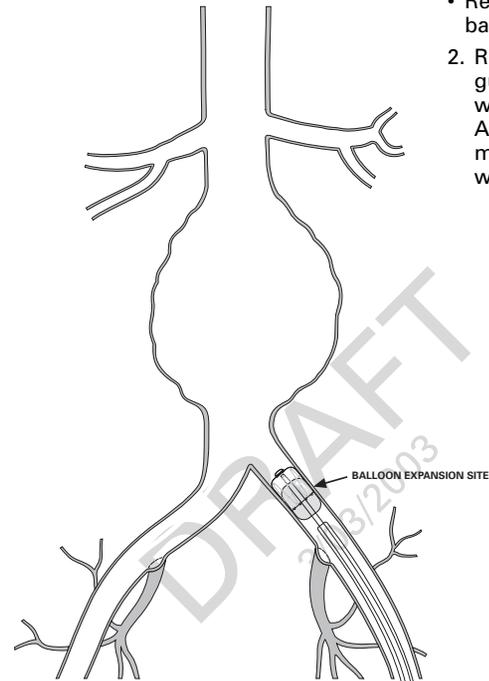


Figure 32

3. Expand the molding balloon within the occluder using diluted contrast media (as recommended by the manufacturer). (Figure 32)
4. Remove the molding balloon and perform completion angiograms. Verify proper occlusion of the appropriate common iliac artery.

Femoral-to-Femoral Cross-Over

Perform femoral-to-femoral crossover in standard surgical fashion to revascularize the contralateral limb. Repair vessels and close in standard fashion.

11.2.2 Converter

The converter (Figure 33) is used when the bifurcated main body has been positioned and access to the contralateral limb of the main body is unattainable. The converter converts the bifurcated endovascular graft into an aortouni-iliac endovascular graft.

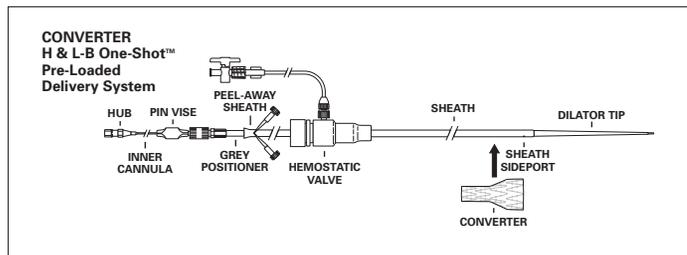


Figure 33

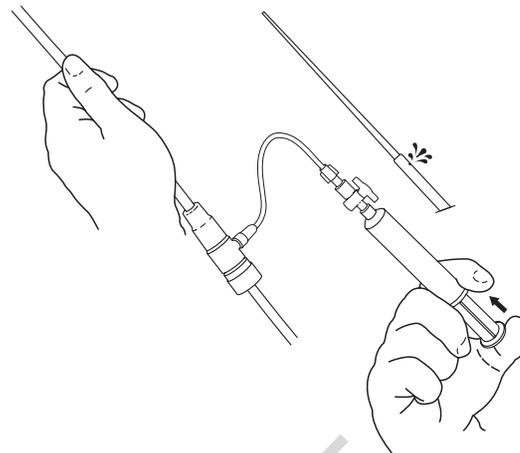


Figure 35

Converter

Preparation/Flush

1. Remove inner stylet (from the inner cannula) and dilator tip protector (from the dilator tip). Remove Peel-Away® sheath from back of the hemostatic valve. (Figure 34) 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 35) Continue to inject a full 20 cc of flushing solution through the device. Discontinue injection and close stopcock.

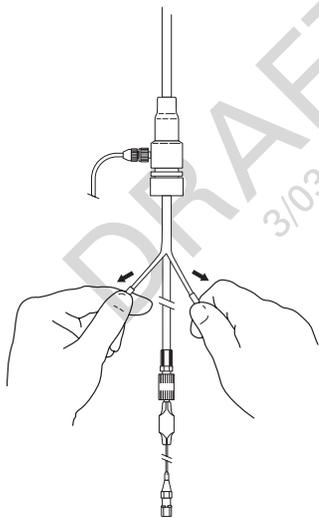


Figure 34

NOTE: Graft flushing solution of heparin concentration is often used.

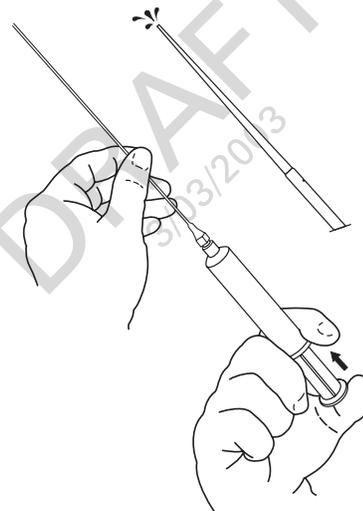


Figure 36

2. Attach syringe with heparinized saline to the hub on the inner cannula. Flush until fluid exits the dilator tip. (Figure 36)

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

Converter Placement & Deployment

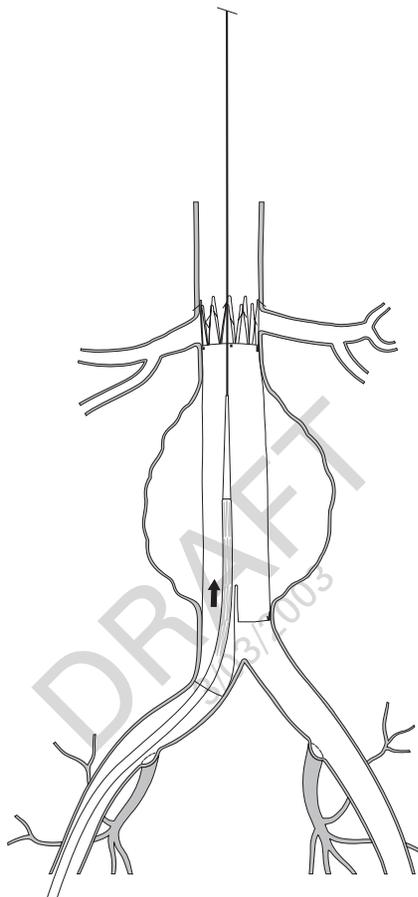


Figure 37

1. Remove main body delivery sheath. Utilize the main body graft wire to introduce the converter into the main body graft.
2. Advance slowly until the converter is at the site of the required intervention. (Figure 37) Verify appropriate stent graft overlap to ensure proper sealing and resistance to migration. The proximal two (2) stents should be positioned in the main body graft and distal two (2) stents should be positioned in the ipsilateral leg.
3. Connect the pressure drip to the stopcock on the hemostatic valve.

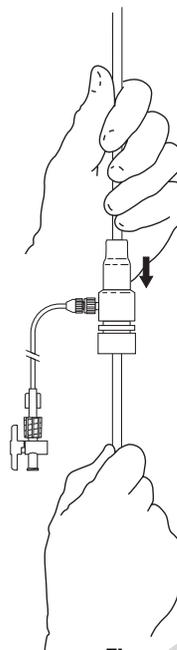


Figure 38

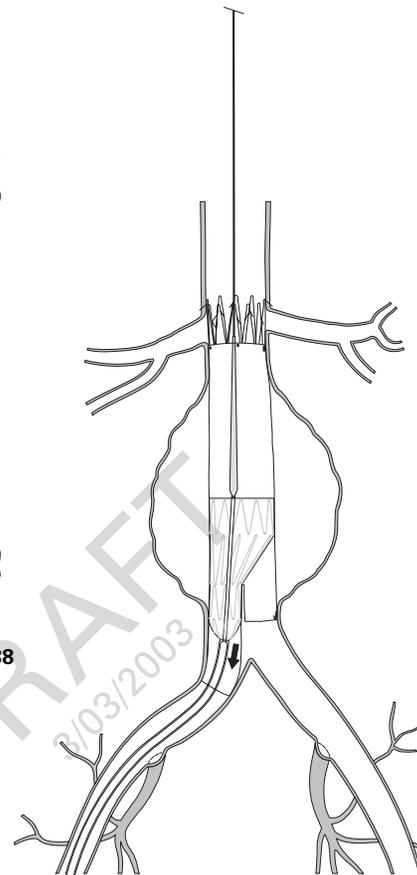


Figure 39

4. Deploy the device by withdrawing the sheath while stabilizing the grey positioner of the delivery system. (Figures 38 & 39)

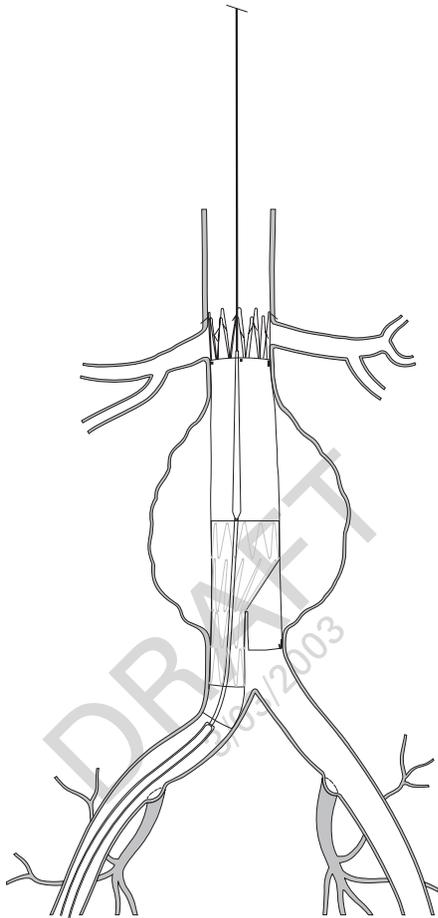


Figure 40

5. Continue to deploy the device until the distal stent is uncovered. (**Figure 40**)

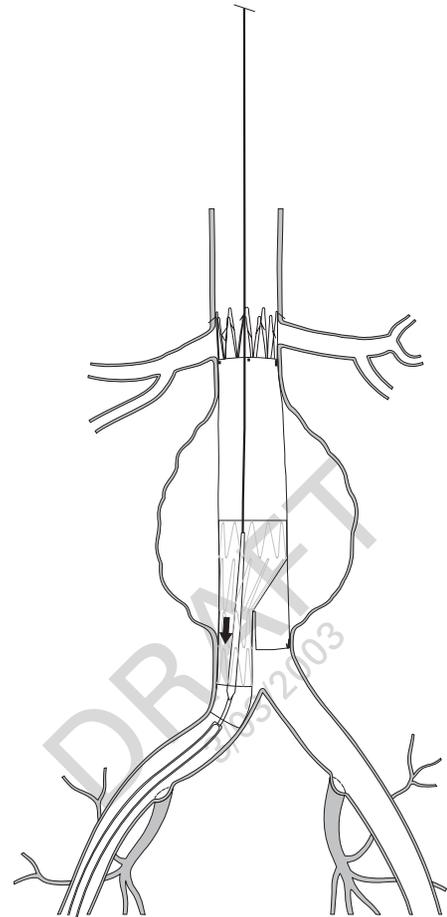


Figure 41

6. Withdraw the tapered tip of the introducer back through the converter graft and delivery system while maintaining wire guide position. (**Figure 41**) Ensure the endovascular graft is not displaced during withdrawal of delivery system.

Converter Molding Balloon Insertion

1. Prepare molding balloon as follows:
 - Flush wire lumen with heparinized saline.
 - Remove all air from balloon.
2. Advance the molding balloon over the wire guide and through the hemostatic valve to the proximal segment of the converter.
3. Expand the molding balloon in the proximal segment and then the distal segment of the converter. (Figure 42)
4. Deflate and remove the molding balloon, replace it with an angiographic catheter and perform completion angiograms.

Occluder (optional)

See Occluder Preparation/Flush, Occluder Placement & Deployment and Molding Balloon Insertion sections.

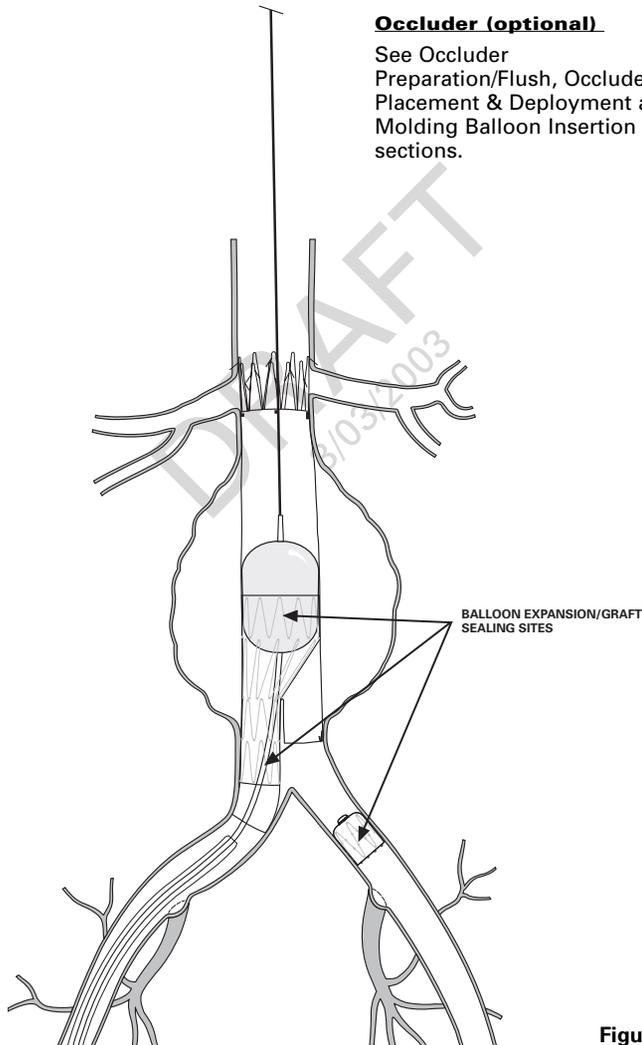


Figure 42

11.2.3 Main Body Extensions

Main body extensions (Figure 43) are used for extending the proximal body of an *in situ* endovascular graft.

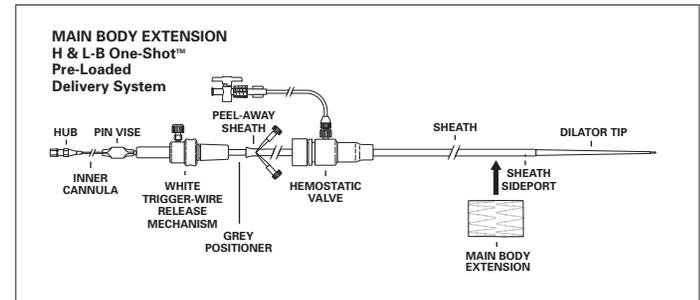


Figure 43

Main Body Extension Preparation/Flush

1. Remove inner stylet (from the inner cannula) and dilator tip protector (from the dilator tip). Remove Peel-Away® sheath from back of the hemostatic valve. (Figure 44) 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 45) Continue to inject a full 20 cc of flushing solution through the device. Discontinue injection and close stopcock.
2. Attach syringe with heparinized saline to the hub on the distal inner cannula. Flush until fluid exits the distal dilator tip. (Figure 46)

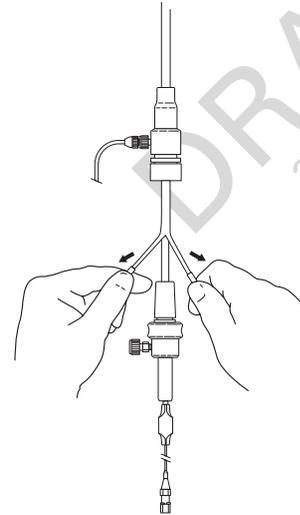


Figure 44

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

NOTE: Graft flushing solution of heparin concentration is often used.

Main Body Extension Placement & Deployment

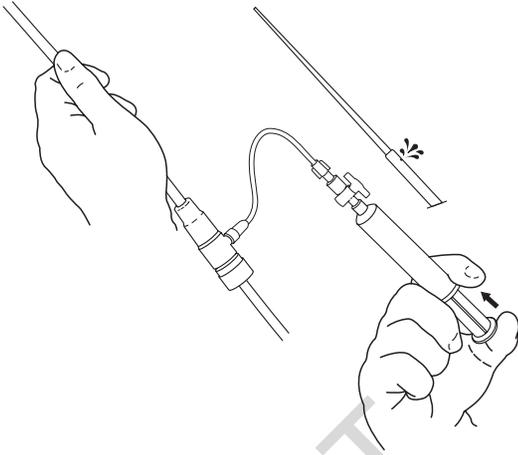


Figure 45

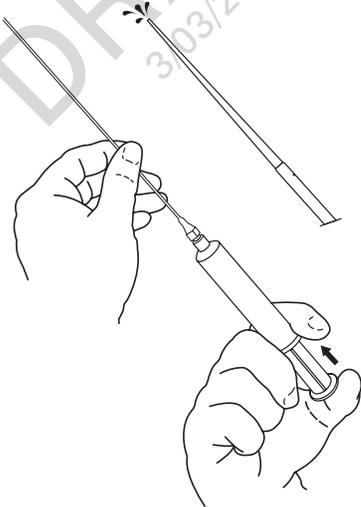


Figure 46

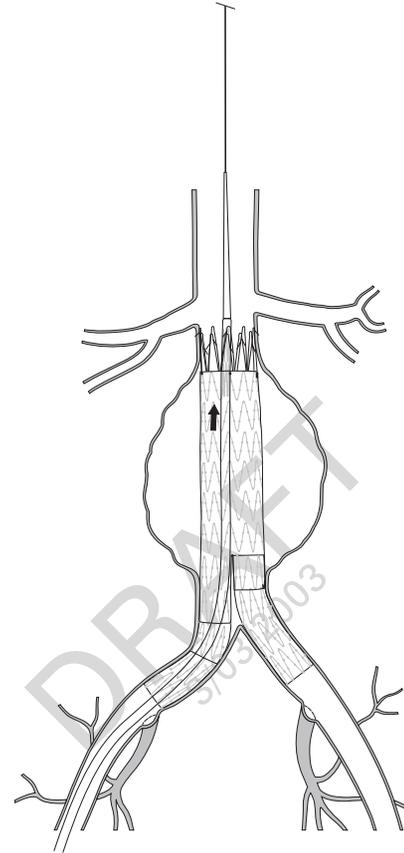


Figure 47

1. Advance slowly until the main body extension is at the site of the required intervention. (Figure 47) Ensure that a proper placement is achieved. Verify appropriate stent graft position to ensure proper sealing and resistance to migration.

CAUTION: Care should be taken not to displace the main body graft during the placement and deployment of the main body extension.

2. Connect the pressure drip to the stopcock on the hemostatic valve.
3. Verify placement with angiography to ensure that the renal arteries remain patent.

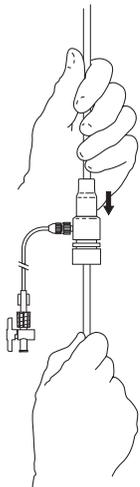


Figure 48a

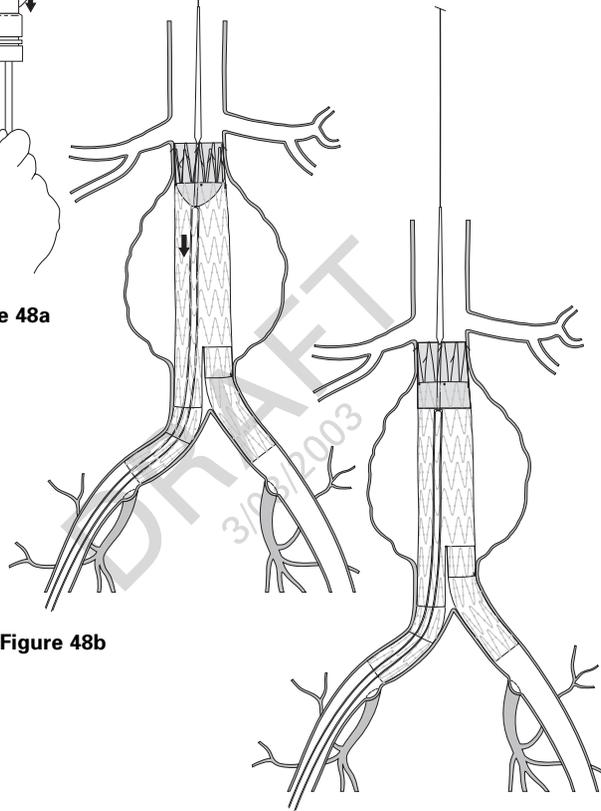


Figure 48b

Figure 49

4. Deploy the device by withdrawing the sheath while stabilizing the grey positioner of the delivery system. (Figure 48a & 48b) Continue to deploy the device until the most distal stent is uncovered. (Figure 49) Stop withdrawing the sheath.

5. 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 inner cannula. (Figure 50)

6. Withdraw the tapered tip of the introducer back through the main body extension graft and delivery system while maintaining wire guide position. (Figure 51) Ensure the main body extension and endovascular graft are not displaced during withdrawal of delivery system.

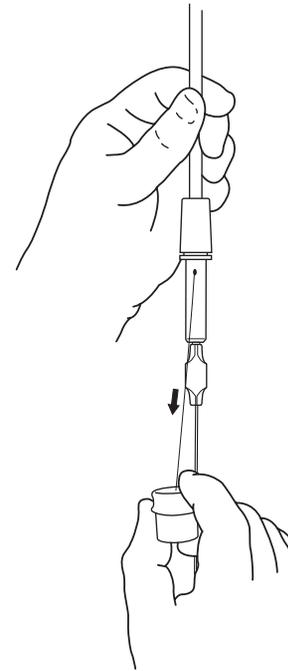


Figure 50

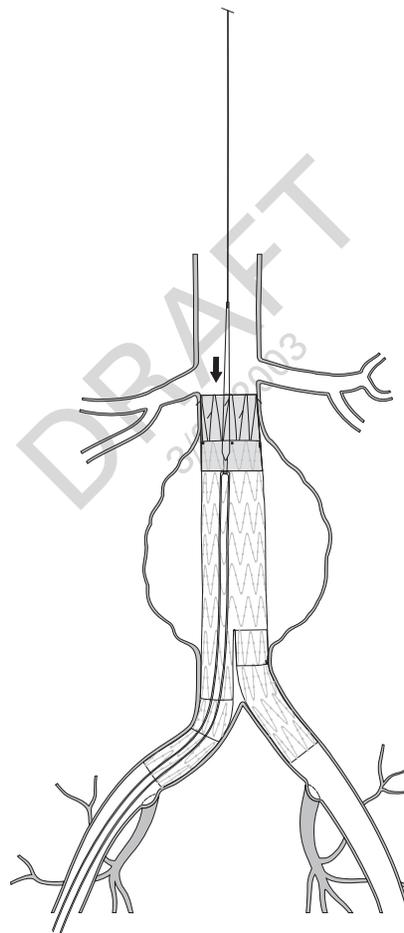


Figure 51

Main Body Extension Molding Balloon Insertion

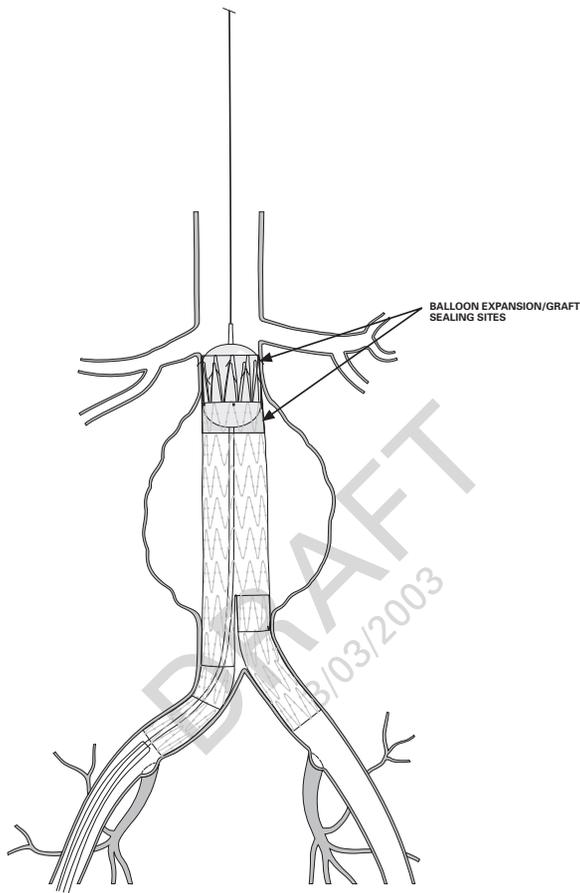


Figure 52

1. Prepare molding balloon as follows:
 - Flush wire lumen with heparinized saline.
 - Remove all air from balloon.
2. Advance the molding balloon over the wire guide and through the hemostatic valve of the main body introduction system to the level of the main body extension.
3. Expand the molding balloon in the most proximal segment of the main body extension and then the most distal segment of the main body extension. (Figure 52)
4. Deflate and remove the molding balloon, replace it with an angiographic catheter and perform completion angiograms.

11.2.4 Iliac Leg Extensions

The iliac leg extensions (Figure 53) are used for extending the distal iliac legs and/or bridge of an *in situ* endovascular graft. The iliac leg extension may be introduced through either an existing *in situ* sheath or in a "One-Shot" introducer.

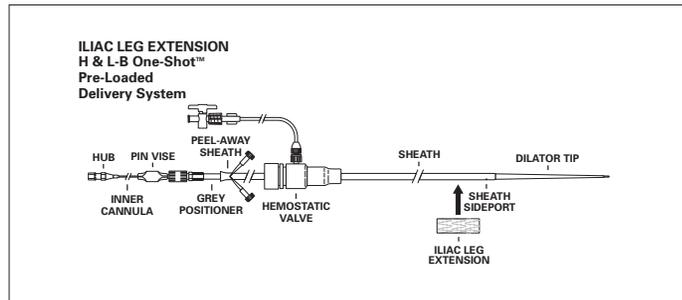


Figure 53

Iliac Leg Extension Preparation/Flush

1. Remove inner stylet (from the inner cannula) and dilator tip protector (from the dilator tip). Remove Peel-Away® sheath from back of the hemostatic valve. (Figure 54) 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 55) Continue to inject a full 20 cc of flushing solution through the device. Discontinue injection and close stopcock.

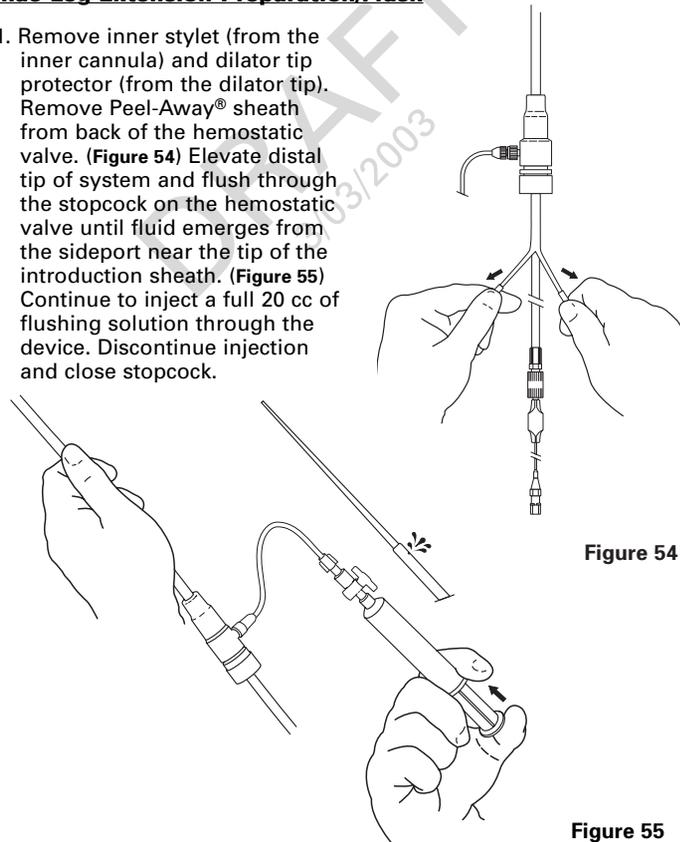


Figure 54

Figure 55

Iliac Leg Extension Placement & Deployment

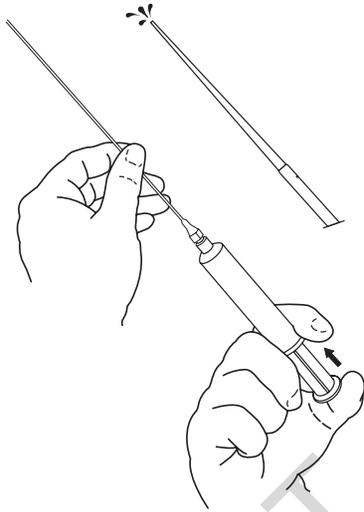


Figure 56

2. Attach syringe with heparinized saline to the hub on the distal inner cannula. Flush until fluid exits the distal dilator tip. (Figure 56)

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

NOTE: Graft flushing solution of heparin concentration is often used.

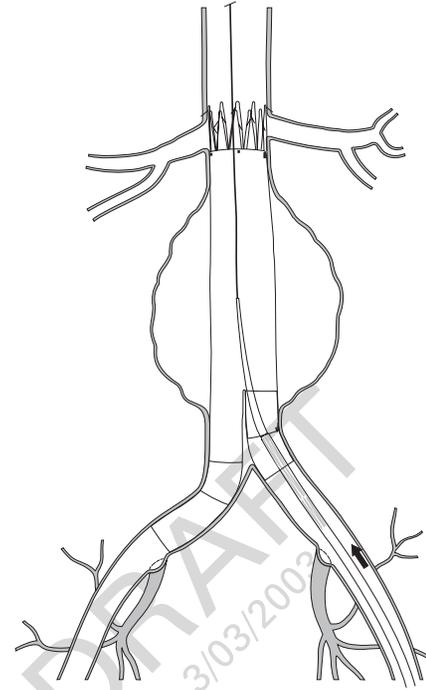


Figure 57

1. Utilize the appropriate wire and sheath assembly to introduce the iliac leg extension.
2. Advance slowly until the iliac leg extension is at the site of the required intervention. (Figure 57) Ensure that a proper placement is achieved. Verify appropriate stent graft overlap to ensure proper sealing and resistance to migration.
3. Connect the pressure drip to the stopcock on the hemostatic valve.
4. Verify placement with angiography to ensure the internal iliacs will remain patent.

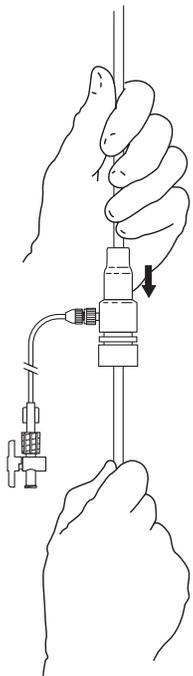


Figure 58a

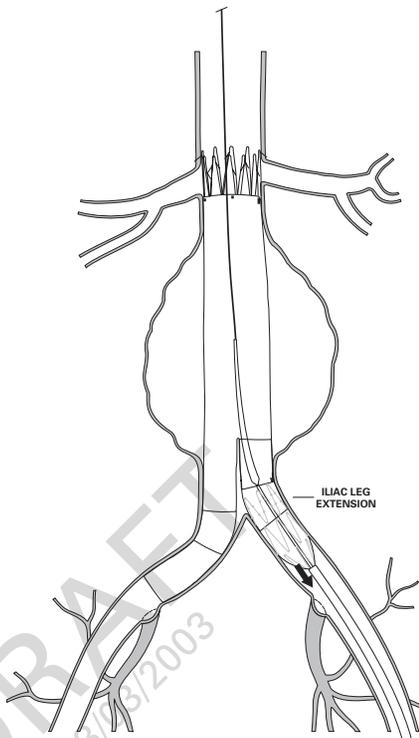


Figure 58b

5. Deploy the device by withdrawing the sheath while stabilizing the grey positioner of the delivery system. (Figure 58a & 58b)

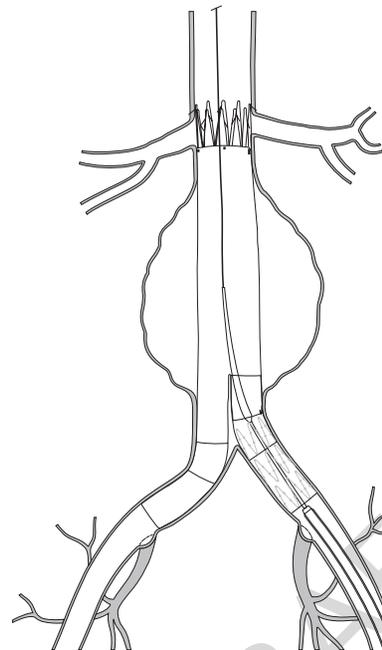


Figure 59

6. Continue to deploy the device until the distal stent is uncovered. (Figure 59) Stop withdrawing the sheath.

7. Withdraw the tapered tip of the introducer back through the iliac leg extension graft and delivery system while maintaining wire guide position. (Figure 60) Ensure the endovascular graft is not displaced during withdrawal of delivery system.

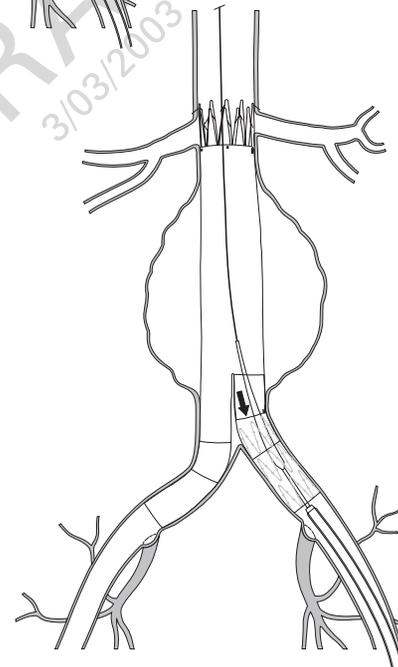


Figure 60

Iliac Leg Extension Molding Balloon Insertion

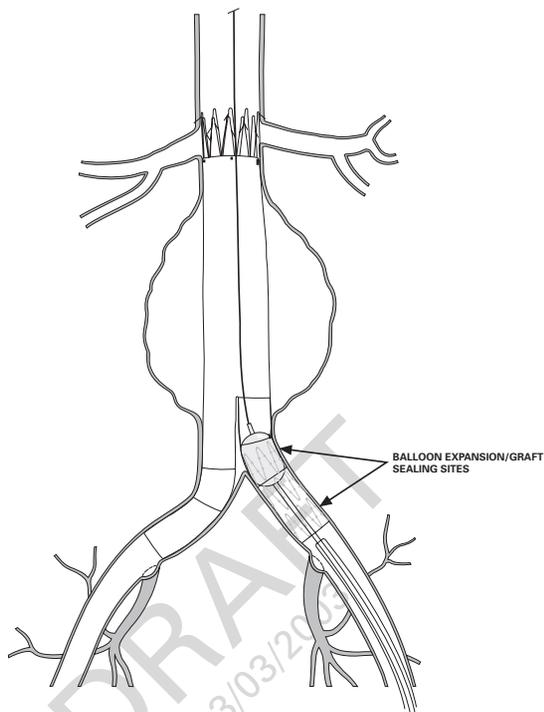


Figure 61

1. Prepare molding balloon as follows:

- Flush wire lumen with heparinized saline.
- Remove all air from balloon.

2. Advance the molding balloon to the most proximal segment of the iliac leg extension.

3. Expand the molding balloon in the most proximal segment and then the most distal segment of the iliac leg extension. (Figure 61)

NOTE: The molding balloon should be completely deflated.

CAUTION: Assure complete balloon deflation prior to repositioning.

4. Perform final angiogram.

12 PATIENT TRACKING INFORMATION

In addition to these Instructions for Use, the Zenith® AAA Endovascular Graft is packaged with a Device Tracking Form which the hospital staff is required to complete and forward to Cook Inc. for the purposes of tracking all patients who receive the Zenith® AAA Endovascular Graft (as required by Federal Regulation).

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