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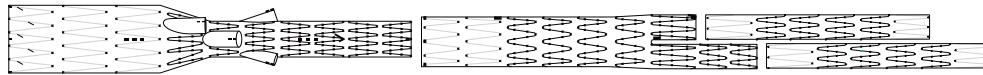


Figure 1

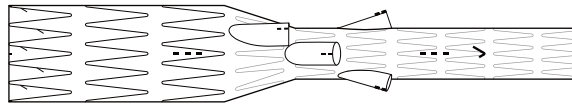


Figure 2

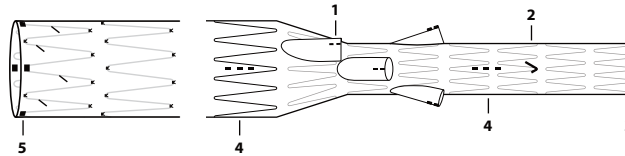


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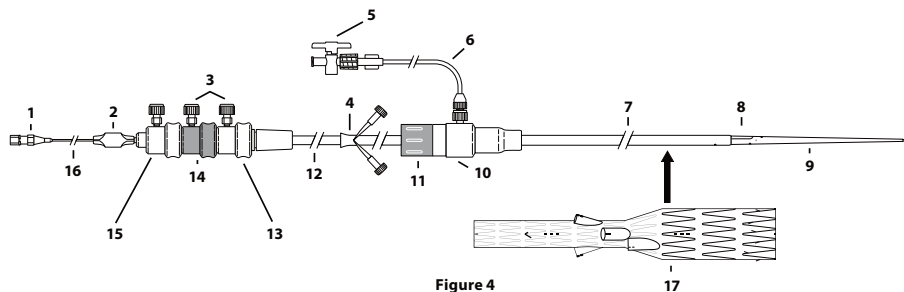


Figure 4

- | | | |
|--|---|---|
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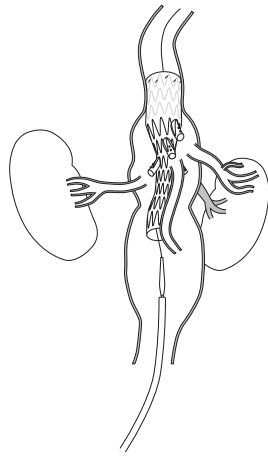


Figure 11

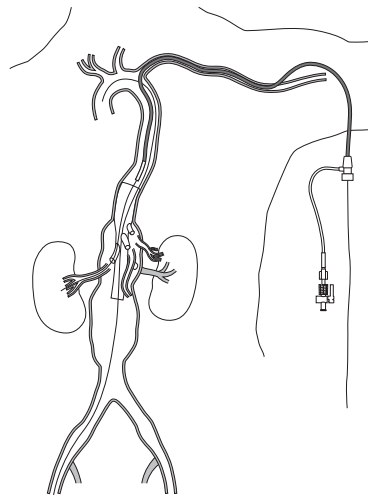


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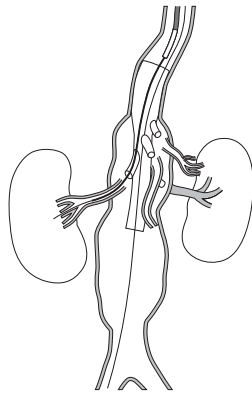


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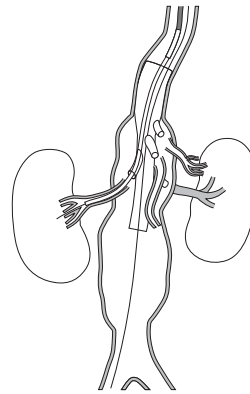


Figure 14

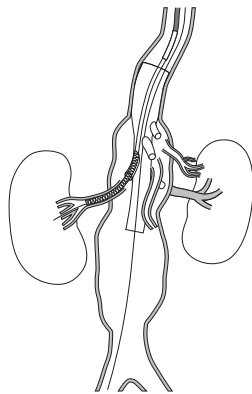


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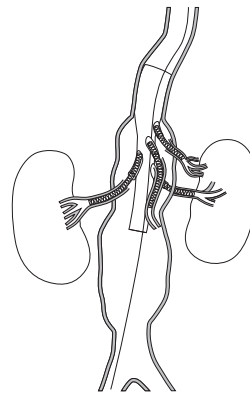


Figure 16

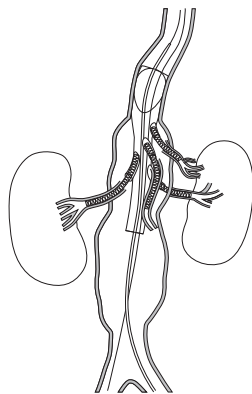


Figure 17

ZENITH® T-BRANCH™ THORACOABDOMINAL ENDOVASCULAR GRAFT

CAUTION: This device is to be used by appropriately trained physicians familiar with branched endovascular stent grafting. It should be recognised that endovascular repair for TAAA is currently only utilised for those high risk patients not amenable to open surgery.

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

For the Zenith product line, there are several applicable Instructions for Use (IFU). This IFU describes the Zenith t-Branch Thoracoabdominal Endovascular Graft. For information on other Zenith devices, please refer to the appropriate Instructions for Use.

1 DEVICE DESCRIPTION

1.1 Overall Device Description

The Zenith t-Branch Thoracoabdominal Endovascular Graft (Zenith t-Branch) is designed to be used in combination with other Zenith thoracic endovascular grafts (e.g. Zenith® TX2 Thoracic TAA Endovascular Graft), Zenith distal endovascular grafts (e.g., Zenith® Universal Distal Body Endovascular Graft) and iliac leg grafts (e.g., Zenith® Flex AAA Endovascular Graft Iliac Leg or Zenith Spiral-Z AAA Iliac Leg). Refer to **Figure 1**.

1.2 Graft

The Zenith t-Branch Thoracoabdominal Endovascular Graft (Zenith t-Branch) is a tubular endovascular graft with four branches and with a covered stent at the proximal end that contains barbs for additional fixation of the device. The purpose of the branches is to allow uninterrupted blood flow to visceral vessels of the aorta. The graft is designed to be connected with the celiac, superior mesenteric and two renal arteries via self-expanding covered vascular bridging stents.

The graft is constructed of woven polyester fabric sewn to self-expanding stainless steel Cook Z-stents with braided polyester and monofilament polypropylene suture. The graft is fully stented to provide stability and the expansile force necessary to open the lumen of the graft during deployment. Additionally, the stents provide the necessary attachment and seal of the graft to the vessel wall. Refer to **Figure 2**.

To facilitate fluoroscopic visualisation, gold radiopaque markers are positioned on the graft. Four gold markers are positioned in a circumferential orientation within 2 mm of the most superior aspect of the graft material and one gold marker is positioned on the lateral aspect of the most distal stent. To facilitate orientation of the graft during deployment, anterior gold markers are located above and below the branches. Each branch has three gold markers at the proximal internal edge and two gold markers at the distal outer edge. Additional gold markers are positioned anteriorly in the shape of a tick or check marker. Refer to **Figure 3**.

1.3 Delivery System

The Zenith t-Branch is shipped loaded onto the H&L-B One-Shot Introduction System. It has a sequential deployment method with built-in features to provide continuous control of the graft throughout the deployment procedure.

The proximal end of the graft is attached to the delivery system by three nitinol trigger wires. The distal end of the graft is also attached to the delivery system and held by an independent stainless steel trigger-wire. The trigger wire enables precise positioning and allows readjustment of the final graft position before full deployment. Refer to **Figure 4**.

The graft is reduced in diameter by an independent wire tied to diameter reducing ties. This allows the graft to be manipulated within the aorta to allow accurate positioning of the graft, and enables the branches to line up with the desired arteries.

The delivery system uses an 8.5 mm O.D. (22 Fr) H&L-B One-Shot Introduction System. All systems are compatible with a 0.89 mm (0.035") wire guide.

For added haemostasis, the Captor® Haemostatic Valve can be opened or closed for the introduction and/or removal of ancillary devices into and out of the sheath. The delivery system features a Flexor® introducer sheath which resists kinking and is hydrophilically coated. Both features are intended to enhance trackability in the iliac arteries and abdominal aorta. Refer to **Figure 4**.

1.4 Devices used in combination with the Zenith t-Branch Thoracoabdominal Endovascular Graft

The Zenith t-Branch requires the use of registered, self-expanding covered vascular bridging stents.

The Zenith t-Branch can be used in conjunction with other approved Zenith devices. Examples include the following:

- Zenith TX2 Thoracic TAA Endovascular Graft
- Zenith Universal Distal Body Endovascular Graft
- Zenith Flex AAA Endovascular Graft Iliac Leg
- Zenith Spiral-Z AAA Iliac Leg.

Refer to the respective Instructions for Use for any of these devices.

2 INDICATIONS FOR USE

The Zenith t-Branch Thoracoabdominal Endovascular Graft is indicated for the endovascular treatment of high-risk patients with thoracoabdominal aneurysms who are not amenable to open surgical repair. The patient must have morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with an 8.5 mm O.D. (22 Fr) delivery system,
- Non-aneurysmal thoracic aorta fixation segment proximal to the aneurysm:
 - With an angle less than 90 degrees relative to the long axis of the aneurysm
 - With a length of at least 25 mm, (50 mm of wall contact is preferred)
 - With a diameter measured outer wall to outer wall of no greater than 30 mm and no less than 24 mm
- Alternatively, the Zenith t-Branch graft may be attached to a pre-existing endovascular graft such as the Zenith TX2 Thoracic TAA Endovascular Graft.

- Visceral vessel anatomy compatible with Zenith t-Branch, specifically:
 - Four indispensable arteries from the abdominal viscera
 - All target arteries to be accessible from an antegrade approach
 - Celiac and superior mesenteric artery (SMA) to be 6 mm to 10 mm in diameter
 - Renal arteries to be 4 mm to 8 mm in diameter
 - The distance between each cuff and the corresponding arterial orifice is less than 50 mm
 - The line between the cuff and the arterial orifice as projected onto the vessel wall deviates by no more than 45 deg from the long axis of the aorta.

3 CONTRAINDICATIONS

The Zenith t-Branch Thoracoabdominal Endovascular Graft is contraindicated in:

- Patients with known sensitivities or allergies to stainless steel, nitinol, polyester, solder (tin, silver), polypropylene, urethane or gold.
- Patients with a systemic infection, as this may increase the risk of an 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 Zenith t-Branch 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 9.1, Physician Training**.
- 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.
- Pre-procedure imaging reconstruction thicknesses >3 mm may result in sub-optimal device sizing, or in failure to appreciate focal stenosis from CT.
- The long-term performance of thoracoabdominal endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in **Section 11, Imaging Guidelines and Post-Operative 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 endovascular graft. At a minimum, annual imaging is required, 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 t-Branch 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 11, 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 and/or leaks may be required to undergo secondary interventions or surgical procedures.
- A vascular surgery team should always be made available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

4.2 Patient Selection, Treatment and Follow-Up

The Zenith t-Branch has not been evaluated in the following patient populations:

- Traumatic aortic injury
- Leaking, pending rupture or ruptured aneurysms
- Mycotic aneurysms
- Pseudoaneurysms resulting from previous graft placement
- Revision of previously placed endovascular grafts
- Uncorrectable coagulopathy
- Indispensable inferior mesenteric artery
- Genetic connective tissue disease (e.g., Marfan's or Ehlers-Danlos Syndromes)
- Concomitant thoracic aortic aneurysms
- Patients with active systemic infections
- Pregnant or nursing females
- Morbidly obese patients
- Patients less than 18 years of age.

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 an 8.5 mm O.D. (22 Fr) vascular introducer sheath. Vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude placement of the endovascular graft and/or may increase the risk of embolisation.

Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (>90 degrees for aorta fixation segment relative to the long axis of the aneurysm); and circumferential thrombus and/or calcification at the arterial implantation sites, specifically the proximal aortic neck. 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 t-Branch is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging.

The Zenith t-Branch is not recommended in patients exceeding weight and/or size limits which compromise or prevent the necessary imaging requirements.

The Zenith t-Branch is not recommended in patients with known sensitivities or allergies to stainless steel, nitinol, polyester, solder (tin, silver), polypropylene, urethane or gold.

Patients with a systemic infection may be at increased risk of endovascular graft infection.

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.

Loss of visceral vessel patency may increase the risk of renal failure, mesenteric ischemia, and subsequent complications.

Patients with uncorrectable coagulopathy may have an increased risk of endoleak or bleeding complications.

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.
- Minimise 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 t-Branch graft.
- Fluoroscopy should be used during introduction and deployment to confirm proper operation of the delivery system components, proper placement of the graft, and desired procedural outcome.
- The use of the Zenith t-Branch 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, incomplete sealing, or inadequate fixation of the Zenith t-Branch within the vessel may result in increased risk of endoleak, migration or inadvertent occlusion of the visceral vessels. Visceral vessel patency must be maintained to prevent/reduce the risk of renal failure, mesenteric ischemia, and subsequent complications.
- Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
- The Zenith t-Branch proximal stent incorporates fixation barbs. Exercise extreme caution when manipulating interventional devices in the region of the proximal 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.
- Take care during manipulation of catheters, wires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus which can cause distal embolisation.
- Before deployment of the proximal stent, verify that the position of the access wire guide extends sufficiently into the aortic arch.
- Care should be taken not to damage the graft or disturb graft positioning after graft placement in the event recannulation of the graft is necessary.

4.4 Moulding Balloon Use (Optional)

Confirm complete deflation of balloon prior to repositioning.

Do not inflate balloon in any vessel outside of graft as doing so may cause damage to the vessel. Use the balloon in accordance with its labelling and Instructions for Use.

Use care when inflating the balloon within the graft in the presence of calcification, as excessive inflation may cause damage to the vessel.

The Captor™ Haemostatic Valve should be loosened prior to insertion and withdrawal of a moulding balloon.

4.5 MRI Safety and Compatibility

Non-clinical testing conducted on the standard Zenith t-Branch Thoracoabdominal Endovascular Graft has demonstrated that the graft is MR Conditional according to ASTM F2503. A patient with this device may be scanned safely 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
- Normal operating mode: 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)

4.5.1 Static Magnetic Field

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

4.5.2 MRI-Related Heating

1.5 Tesla Systems:

In non-clinical testing, the Zenith t-Branch Thoracoabdominal Endovascular Graft produced a maximum temperature rise of 1.7°C during 15 minutes of MR imaging (i.e., for one scanning sequence) performed in a MR 1.5 Tesla System (Siemens Magnetom, Software Numaris/4) at an MR system reported whole-body-averaged SAR of 2.9 W/kg (associated with a calorimetry measured whole body averaged value of 2.1 W/kg).

3.0 Tesla Systems:

In non-clinical testing, the Zenith t-Branch Thoracoabdominal Endovascular Graft produced a maximum temperature rise of 2.0°C during 15 minutes of MR imaging (i.e., for one scanning sequence) performed in a MR 3.0 Tesla System (General Electric Excite, HDx, Software 14X.M5) at an MR system reported whole-body-averaged SAR of 2.9 W/kg (associated with a calorimetry measured whole body averaged value of 2.7 W/kg).

4.5.3 Image Artifact

MR image quality of the standard Zenith t-Branch Thoracoabdominal Endovascular Graft may be compromised if the area of interest is within the lumen or within approximately 50 mm of the position of the graft as found during non-clinical testing using T1-weighted, spin echo and gradient echo pulse sequence in a 3.0 Tesla MR system (Excite, General Electric Healthcare, Milwaukee, WI). Therefore it may be necessary to optimize MR imaging parameters for this metallic implant.

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.

NOTE: For the Zenith t-Branch, the clinical benefit of an MRI scan should be balanced with the potential risk of the procedure.

4.6 Haemostatic Valve Precaution

Endovascular stent grafting is a surgical procedure, and blood loss from various causes may occur, infrequently requiring intervention (including transfusion) to prevent adverse outcomes. It is important to monitor blood loss from the haemostatic valve throughout the procedure, but is specifically relevant during and after manipulation of the grey positioner. After the grey positioner has been removed, if blood loss is excessive, consider placing an uninflated molding balloon or an introduction system dilator within the valve, restricting flow.

4.7 Trigger Wire Release and Use of Fluoroscopy Precaution

Fluoroscopy should be used during introduction and deployment to confirm proper operation of the delivery system components, proper placement of the graft, and desired procedural outcome.

CAUTION: During trigger-wire removal and deployment, verify that the position of the wire guide extends just distal to the ascending aorta and that support of the system is maximized.

5 POTENTIAL ADVERSE EVENTS

Adverse events associated either with the Zenith t-Branch or the implantation procedure that may occur and/or require intervention include, but are not limited to:

- Amputation
- Anaesthetic 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
- Arteriovenous fistula
- Bleeding, haematoma 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
- Embolisation (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
- Extremity ischemia or neurologic complications (e.g., brachial plexus injury, claudication)
- Fever and localised inflammation
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, haematuria, 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., stroke, transient ischemic attack, paraplegia, paraparesis, paralysis)
- Occlusion of device or native vessel
- Open surgical conversion
- Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- Splenic injury (e.g., infarction, ischemia)
- Vascular access site complications, including infection, pain, haematoma, pseudoaneurysm, arteriovenous fistula
- Vessel damage
- Visceral vessel occlusion and attendant complications
- Wound complications and subsequent attendant problems (e.g., dehiscence, infection)
- Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death).

5.1 Device-Related Adverse Event Reporting

Any adverse event (clinical incident) involving the Zenith t-Branch should be reported to **William Cook Australia** immediately. To report an incident, call your local Cook Aortic Intervention representative or contact the Quality Assurance Department on 1800 777 222 (toll-free within Australia) or +61 7 3841 1188.

6 PATIENT SELECTION AND TREATMENT

(Refer to Section 4, Warnings and Precautions)

All lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (diameters/lengths) are not certain. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes. Additional considerations for patient selection include but are not limited to:

- Patient's age and life expectancy
- Co-morbidities (e.g., cardiac, pulmonary or renal insufficiency prior to surgery, morbid obesity)
- Patient's suitability for open surgical repair
- Patient's anatomical suitability for endovascular repair
- The risk of aneurysm rupture compared to the risk of treatment with the Zenith t-Branch Thoracoabdominal Endovascular Graft
- Ability to tolerate general, regional or local anaesthesia
- Ilio-femoral access vessel size and morphology (minimal thrombus, calcium and/or tortuosity) should be compatible with vascular access techniques and accessories of the delivery profile of an 8.5 mm OD (22 Fr) vascular introducer sheath
- Non-aneurysmal thoracic aorta fixation segment proximal to the aneurysm
 - With an angle less than 90 degrees relative to the long axis of the aneurysm
 - With a length of at least 25 mm (50 mm of wall contact is preferred)
 - With a diameter measured outer wall to outer wall of no greater than 30 mm and no less than 24 mm
- Alternatively, the Zenith t-Branch may be attached to a pre-existing endovascular graft (e.g. Zenith TX2 Thoracic TAA Endovascular Graft).
- Visceral vessel anatomy compatible with Zenith t-Branch, specifically:
 - Four indispensable arteries from the abdominal viscera
 - All target arteries to be accessible from an antegrade approach
 - Celiac and superior mesenteric artery (SMA) to be 6 mm to 10 mm in diameter
 - Renal arteries to be 4 mm to 8 mm in diameter
 - The distance between each cuff and the corresponding arterial orifice is less than 50 mm
 - The line between the cuff and the arterial orifice as projected onto the vessel wall deviates by no more than 45 deg from the long axis of the aorta.

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

7 PATIENT COUNSELING INFORMATION

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

- Risks and differences between endovascular repair and open surgical repair
- Potential advantages of traditional open surgical repair
- Potential advantages of endovascular repair
- The possibility that subsequent interventional or open surgical repair of the 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:

- The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in Section 11, Imaging Guidelines and Post-Operative Follow-Up.
- Patients should be counselled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of TAAAs. At a minimum, annual imaging and adherence to routine post-operative follow-up requirements is required and should be considered a life-long commitment to the patient's health and well-being.
- Physicians must advise all patients that it is important to seek prompt medical attention if he/she experiences signs of limb occlusion, aneurysm enlargement or rupture. Signs of graft limb occlusion include pain in the hip(s) or leg(s) during walking or at rest or discoloration or coolness of the leg. Aneurysm rupture may be asymptomatic, but often presents as: pain; numbness; weakness in the legs; any back, chest, abdominal or groin pain; dizziness; fainting; rapid heartbeat or sudden weakness.

8 HOW SUPPLIED

8.1 General

The Zenith t-Branch is supplied STERILE (100% Ethylene Oxide) in peel-open pouches (sterile inner pouch).

This device is intended for single patient use only. Do not reuse, reprocess or resterilise any part of this device. Reuse, reprocessing, or re-sterilisation may compromise the structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury, illness or death.

Reuse, reprocessing, or re-sterilisation may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

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 sterilisation barrier has been damaged or broken. If this occurs, return the device to William A. Cook Australia Pty Ltd.

The label includes the device code, components supplied, expiry date and storage requirements to be followed for this device.

- The device is loaded into an 8.5 mm OD (22 Fr) introducer sheath
- The sheath's surface is treated with a hydrophilic coating that, when hydrated, enhances trackability
- The device is supplied with a tip protector (tip end), cannula protector (handle end) and shipping stylet (handle end) that are to be removed prior to use.

8.2 Device Options and Sizing Guidelines

8.2.1 Device Options*

The Zenith t-Branch device is supplied in one size only (TBRANCH-34-18-202), namely;

- Proximal graft diameter of 34 mm
- Distal graft diameter of 18 mm
- Graft length of 202 mm
- Introducer sheath ID 7.3 mm, OD 8.5 mm (22 Fr)

*All dimensions are nominal.

8.2.2 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 oversizing may result in incomplete sealing or compromised flow.

The Zenith t-Branch is supplied with a proximal graft diameter of 34 mm. This is intended to suit an aortic vessel diameter of between 24 mm and 30 mm. Refer to Table 8.1.

For information on the sizing guidelines for other Zenith devices, please refer to the appropriate Instructions for Use.

Table 8.1 – Sizing Guidelines for Zenith t-Branch Proximal Vessel Diameter

Intended Aortic Vessel Diameter	Zenith t-Branch Proximal Diameter
24 – 30 mm	34 mm

A 2 mm-4 mm interference fit, combined with a minimum 2 stent overlap, is typical in the use of a distal endovascular graft with a proximal component to reduce the risk of component separation.

8.2.3 Self-Expanding Covered Vascular Bridging Stent Diameter Sizing Guidelines

Consult the self-expanding covered stent manufacturer's instructions for selecting the appropriate covered stent.

A minimum 1-2mm interference fit and a minimum 15mm overlap between the self-expanding covered vascular bridging stents and the side branches of the Zenith t-Branch is suggested to reduce the risk of component separation. The length of the self-expanding covered vascular bridging stent to be used is dependent on the patient's anatomy.

9 CLINICAL USE INFORMATION

9.1 Physician Training

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

CAUTION: The Zenith t-Branch should only be used by physicians and teams trained in endovascular interventional techniques and in the use of this device. The recommended skill/knowledge requirements for physicians using the Zenith t-Branch are outlined below:

Patient selection:

- Knowledge of the natural history of thoracoabdominal aortic aneurysm (TAAA), abdominal aortic aneurysms (AAA) and co-morbidities associated with endovascular aneurysm repair.
- Knowledge of radiographic image interpretation, device selection and sizing.
- A multi-disciplinary team that has combined procedural experience with:
 - Femoral, subclavian, axillary, and brachial cutdown, arteriotomy and repair
 - Percutaneous access and closure techniques
 - Non-selective and selective wire guide and catheter techniques
 - Fluoroscopic and angiographic image interpretation
- Embolisation
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Appropriate use of radiographic contrast material
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities.

9.2 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 sterilisation barrier has been damaged or broken. If damage has occurred, do not use the product and return to **William Cook Australia**. 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. Also ensure the expiration date has not been surpassed and the device has been stored as per storage conditions printed on the device label.

The device is to be used in conjunction with materials and devices outlined in the following sections.

9.3 Materials Required

(Not included in system)

The following products are recommended to assist in the implantation of the Zenith t-Branch. For information on the use of these products, refer to the individual product's Instructions for Use:

- Fluoroscope with digital angiography capabilities (C-arm or fixed unit)
- Contrast media
- Syringe
- Heparinised saline solution
- Sterile gauze pads.

9.4 Recommended Devices

(Not included in system)

- 0.89 mm (0.035") extra stiff wire guide, 260cm; for example:
 - Cook Lunderquist Extra Stiff Wire Guides (LES)

- 0.89 mm (0.035") standard wire guide; for example:
 - Cook 0.035 inch wire guides
 - Cook Nimble™ Wire Guides
- Moulding Balloons; for example:
 - Cook Coda® Balloon Catheter
- Introducer sets; for example:
 - Cook Check-Flo® Introducer Sets
 - Cook Extra Large Check-Flo Introducer Sets
- Sizing catheter; for example:
 - Cook Aurous® Centimetre 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
- Wire Guides, for delivering covered stents to the visceral arteries, for example:
 - Cook Rosen Wire Guides.

10 DIRECTIONS FOR USE

Prior to use of the Zenith t-Branch, 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.

The suggested general order of implantation is:

1. Zenith thoracic endovascular graft, if required
2. Zenith t-Branch
3. Self-expanding covered vascular bridging stents
4. Zenith distal endovascular graft
5. Contralateral iliac leg graft
6. Ipsilateral iliac leg graft.

10.1 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 t-Branch. The Zenith t-Branch is compatible with 0.89 mm (0.035") diameter wire guides.

Endovascular stent grafting is a surgical procedure, and blood loss from various causes may occur, infrequently requiring intervention (including transfusion) to prevent adverse outcomes. It is important to monitor blood loss from the haemostatic valve throughout the procedure, but is specifically relevant during and after manipulation of the grey positioner. After the grey positioner has been removed, if blood loss is excessive, consider placing an uninflated moulding balloon or an introduction system dilator within the valve, restricting flow.

10.2 Pre-Implant Review

Verify from planning that the correct device has been selected.

10.3 Patient Preparation

1. Refer to institutional protocols relating to anaesthesia, anticoagulation and monitoring of vital signs.
2. Position patient on imaging table allowing fluoroscopic visualisation from the aortic arch to the femoral bifurcations.
3. Gain access to both femoral arteries using standard surgical techniques or percutaneous techniques.
4. Establish adequate proximal and distal vascular control of both femoral arteries.

10.4 Graft Preparation/Flush

1. Remove black-hubbed shipping stylet (from the inner cannula), cannula protector (from the inner cannula) and tip protector (from the dilator tip). Remove Peel-Away® sheath from the back of the haemostatic valve. Refer to **Figure 5**.
2. Elevate tip of system and flush through the stopcock on the haemostatic valve with heparinised saline until fluid emerges from the flushing groove in the tip. Refer to **Figure 6**. Continue to inject a full 20 ml of flushing solution through the device. Discontinue injection and close stopcock on connecting tube.
3. Attach syringe with heparinised saline to the hub on the inner cannula. Flush until fluid exits the dilator tip. Refer to **Figure 7**.

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

4. Soak 4x4 gauze pads in saline solution and use to wipe Flexor introducer sheath to activate the hydrophilic coating. Hydrate both sheath and dilator tip liberally.

10.5 Vascular Access and Angiography

1. Puncture the selected common femoral arteries using standard techniques with an 18 or 19 UT gage arterial needle. Upon vessel entry, insert:
 - Wire guides – standard 0.89 mm (0.035") diameter, 260 cm long, soft tip Wire Guide
 - Appropriate size sheaths (e.g., 2.0 mm I.D. (6 Fr) or 2.7 mm I.D.) (8 Fr)
 - Flush catheter (often radiopaque sizing catheters – e.g., Centimetre Sizing Catheter or straight flush catheter)
2. Perform angiography as needed to identify positions of the celiac, SMA, renal arteries, and the aortic bifurcation.

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

10.6 Placement of Additional Devices

1. Add any proximal devices, for example Zenith TX2 Thoracic TAA Endovascular Graft as required. Refer to the Instructions for Use of these devices for deployment instructions.

10.7 Zenith t-Branch Graft Placement

1. Ensure the delivery system has been flushed with heparinised saline and that all air is removed from the system.
2. Give systemic heparin if required. Flush each catheter and/or wipe the wire guide after any exchange.

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

3. On ipsilateral side, replace starter wire with an appropriate stiff wire guide 0.89 mm (0.035"), at least 260 cm long. Maintain wire guide position.
4. Before insertion, position delivery system on patient's abdomen under fluoroscopy to assist with orientation and positioning.

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 cannula).

5. Advance the delivery system to the required position so that the branches are positioned relative to their corresponding target vessels. Use gold markers to position distal edge of branches to within 50mm of target vessels proximally. Refer to **Figure 8**.
6. Verify position of wire guide in the thoracic aorta.
7. Perform an angiogram to verify the position and orientation.
8. Ensure the Captor™ Haemostatic Valve is turned to the open position.

NOTE: The Captor™ Haemostatic Valve must only be turned until it stops and the open/close marks must be correctly aligned. Do not overturn the Captor Haemostatic Valve as overturning will damage the valve which may result in significant blood loss.
9. Stabilise the grey positioner (the shaft of the delivery system) and begin withdrawal of the outer sheath. As the graft expands, the position of the branches and markers will become more obvious. Repeat the angiogram to verify the position and re-orientate as required. Refer to **Figure 9**.
- NOTE:** As the graft has proximal barbs, the ability to manipulate the graft once unsheathed will be significantly restricted.
10. Proceed with the deployment until the distal end is fully deployed. Stop withdrawing the sheath.
11. Repeat the angiogram and reposition if necessary.
12. Verify proper position of graft. To release the diameter reducing ties, remove the safety lock from the gold trigger-wire release mechanism. Under fluoroscopy, withdraw and remove the trigger-wire by sliding the gold trigger-wire release mechanism off the handle and then remove via its slot over the inner cannula.

NOTE: If resistance is felt or system bowing is noticed during the removal of any release mechanism, the trigger wire is under tension. Excessive force may cause the graft position to be altered. If excessive resistance or delivery system movement is noted, stop and assess the situation.

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

CAUTION: During trigger-wire removal and subsequent deployment, verify that the position of the wire guide extends just distal to the ascending aorta and that support of the system is maximised.

13. Remove the safety lock from the black trigger-wire release mechanism. Under fluoroscopy, withdraw and remove the trigger-wire to release the graft's proximal attachment by sliding the black trigger-wire release mechanism off the handle and then remove via its slot over the inner cannula. Refer to **Figure 10**.

NOTE: Once the barbed stent has been deployed, further attempts to reposition the graft are not recommended.

NOTE: The distal stent is still secured by the trigger-wire.
14. Remove the safety lock from the white trigger-wire release mechanism. Under fluoroscopy, 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.
15. Remove the grey positioner and dilator tip as one unit by pulling on the inner cannula. Keep the wire guide and sheath immobilised. Refer to **Figure 11**.
16. Close the Captor valve immediately after removal of the grey positioner and dilator tip.

NOTE: The Captor Haemostatic Valve must only be turned until it stops and the open/close marks must be correctly aligned. Do not overturn the Captor Haemostatic Valve as overturning will damage the valve and may result in significant blood loss.

10.8 Cannulation of Visceral Vessels

1. Using standard endovascular techniques, pass a 2.33 or 2.67 mm O.D. (7 or 8 Fr) sheath (preferably Flexor) from a brachial/axillary/subclavian artery into the descending aorta. Advantages in control and stability have been described by passing this sheath through a previously placed 3.33 or 4 mm O.D. (10 or 12 Fr) Flexor sheath; therefore use of an outer sheath should be considered. Refer to **Figure 12**.
2. Advance the 2.33 or 2.67 mm O.D. (7 or 8 Fr) sheath to a suitable position so that a directional catheter and guide wire can be introduced through the sheath and then used to gain access into the proximal end of the graft. Continue by advancing the catheter through one of the branches and into a stable position in the target vessel. Refer to **Figure 13**.
3. Remove the access wire guide and replace with a support wire (e.g., Rosen).
4. Remove the access catheter.
5. Replace the tapered dilator into the arterial sheath and advance the sheath over the support wire into the target vessel.
6. Remove the dilator and advance a suitable self-expanding covered stent through the sheath until it is bridging the gap between the branch and the target vessel. Ensure that the proximal end of the self-expanding covered vascular bridging stent is within 1-2 mm of the proximal gold markers on the respective branch and there is adequate overlap of the self-expanding covered vascular bridging stent with the target vessel. Refer to **Figure 14**.
7. Repeat the above steps for all branches to ensure that the self-expanding covered vascular bridging stents are used to bridge the gap between all branches and their target vessel.

10.9 Self-Expanding Covered Vascular Bridging Stent Placement

1. Withdraw the sheath and deploy the self-expanding covered vascular bridging stent as per the manufacturer's supplied Instructions for Use. Refer to **Figure 15**.
2. Compatibility of co-axial sheath sizes should be checked prior to the procedure. Removal of the 2.33 or 2.67 mm O.D. (7 or 8 Fr) sheath may be required if an access sheath is included with the self-expanding covered vascular bridging stent.

3. Repeat the above steps to add additional bridging stents. Refer to **Figure 16**.

10.10 Placement of Additional Devices

1. Add any distal devices, including leg extensions as required. Refer to the Instructions for Use of these devices for deployment instructions.

10.11 Final Angiogram

1. Position an angiographic catheter just above the level of the visceral arteries. Perform angiography to verify that all the arteries are patent and that there are no endoleaks. If endoleaks or other problems are observed, address as appropriate.
2. Repair vessels and close access sites in standard surgical fashion.

10.12 Zenith t-Branch Moulding (Optional)

1. Prepare moulding balloon as follows:
 - Flush wire lumen with heparinized saline
 - Remove all air from balloon.
2. In preparation for the insertion of the moulding balloon, open the Captor Haemostatic Valve by turning it counter-clockwise.
3. Advance the moulding balloon over the wire guide and through the haemostatic valve of the introduction system to the level of the proximal seal zone. Maintain proper sheath positioning.

NOTE: Captor Haemostatic Valve may be utilised to assist with haemostasis by turning in a clockwise rotation to the "close" position.

NOTE: Captor Haemostatic Valve should always be in the "open" position when repositioning the moulding balloon.

4. Expand the moulding balloon with diluted contrast media (as directed by the manufacturer) in the area of the proximal seal zone. Refer to **Figure 17**.

NOTE: Do not inflate the moulding balloon outside the graft.

NOTE: Care should be taken when manipulating a moulding balloon in the vicinity of the graft branches.

NOTE: Confirm complete deflation of balloon prior to repositioning.

5. Remove moulding balloon.

11 IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

11.1 General

The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and 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) should receive additional follow-up. Patients should be counselled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of TAAA.

Physicians should evaluate patients on an individual basis and prescribe their follow-up relative to the needs and circumstances of each individual patient. The recommended imaging schedule is presented in **Table 11.1**. This schedule continues to be the minimum requirement for patient follow-up and should be maintained even in the absence of clinical symptoms (e.g., pain, numbness, weakness). Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the stent graft) should receive follow-up at more frequent intervals.

Annual imaging follow-up should include abdominal radiographs and both contrast and non-contrast CT examinations. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs, non-contrast CT and duplex ultrasound may be used.

- The combination of contrast and non-contrast CT imaging provides information on aneurysm diameter change, endoleak, patency, tortuosity, progressive disease, fixation length and other morphological changes.
- The abdominal radiographs provide information on device integrity (separation between components, stent fracture and barb separation).
- Duplex ultrasound imaging may provide information on aneurysm diameter change, endoleak, patency, tortuosity and progressive disease. In this circumstance, a non-contrast CT should be performed to use in conjunction with the ultrasound. Ultrasound may be a less reliable and sensitive diagnostic method compared to CT.

Table 11.1 lists the minimum imaging follow-up for patients with the Zenith t-Branch. Patients requiring enhanced follow-up should have interim evaluations.

Table 11.1 Recommended Imaging Schedule for Endograft Patients

	Angiogram	CT	Abdominal Radiographs
Pre-procedure	X ¹	X ¹	
Procedural	X		
Pre-discharge (within 7 days)		X ^{2,3,4}	X
1 month		X ^{2,3,4}	X
6 month		X ^{2,4}	X
12 month (annually thereafter)		X ^{2,4}	X

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

²Duplex ultrasound may be used for those patients experiencing renal failure or who are otherwise unable to undergo contrast enhanced CT scan. With ultrasound, non-contrast CT is still recommended.

³Either pre-discharge or 1 month CT recommended.

⁴If Type I or III endoleak, prompt intervention and additional follow-up post-intervention recommended. See **Section 11.6, Additional Surveillance and Treatment**.

11.2 CT Recommendations

Image sets should include all sequential images at lowest possible slice thickness (≤ 3 mm). Do NOT perform large slice thickness (>3 mm) and/or omit consecutive CT images sets, as it prevents precise anatomical and device comparisons over time. When using a multiphase scan, the table positions must match.

Non-contrast and contrast enhanced baseline and follow-up imaging are important for optimal patient surveillance. It is important to follow acceptable imaging protocols during the CT exam. **Table 11.2** lists examples of acceptable imaging protocols.

Table 11.2 Acceptable Imaging Protocols

	Non-Contrast	Contrast
IV contrast	No	Yes
Acceptable machines	Spiral CT or high performance MDCT capable of > 40 seconds	Spiral CT or high performance MDCT capable of > 40 seconds
Injection volume	n/a	150 cc
Injection rate	n/a	>2.5 cc/sec
Injection mode	n/a	Power
Bolus timing	n/a	Test bolus: SmartPrep, C.A.R.E. or equivalent
Coverage - start	Humeral Head	Humeral Head
Coverage - finish	Proximal femur	Proximal femur
Collimation	<3 mm	<3 mm
Reconstruction	2.5 mm throughout – soft algorithm	2.5 mm throughout – soft algorithm
Axial DFOV	32 cm	32 cm
Post-injection runs	None	None

11.3 Abdominal Radiographs

The following views are required:

- Four images: supine-frontal (AP), cross-table lateral, 30 degree LPO and 30 degree RPO views centred on umbilicus
- Record the table-to-detector distance and use the same distance at each subsequent examination.

Ensure entire device is captured on each single image format lengthwise.

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

11.4 Ultrasound

Ultrasound imaging may be performed in place of contrast CT when patient factors preclude the use of image contrast media (**NOTE:** Imaging is limited to the abdominal aorta). Ultrasound may be paired with non-contrast CT. A complete aortic duplex is to be videotaped for maximum aneurysm diameter, endoleaks, stent patency and stenosis. Included on the videotape should be the following information as outlined below:

- Transverse and longitudinal imaging should be obtained of the abdominal aorta demonstrating the celiac, mesenteric and renal arteries to the iliac bifurcations to determine if endoleaks are present utilising colour flow and colour power Doppler (if accessible)
- Spectral analysis confirmation should be performed for any suspected endoleaks

- Transverse and longitudinal imaging of the maximum aneurysm should be obtained.

11.5 MRI Safety and Compatibility

For MRI safety and compatibility information refer to **Section 4.5**.

11.6 Additional Surveillance and Treatment

Additional surveillance and possible treatment is recommended for:

- Aneurysms with Type I endoleak
- Aneurysms with Type III endoleak
- Aneurysm enlargement, ≥ 5 mm of maximum diameter (regardless of endoleak status)
- Migration
- Inadequate seal length.

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



MR Conditional
Podmíněně bezpečný při vyšetření MRI (MR conditional)
MR conditional
Bedingt MRT-kompatibel
Ασφαλές για χρήση σε μαγνητική τομογραφία υπο προϋποθέσεις
MR conditional
Turvallinen MR-kuvauksessa tietyissä olosuhteissa
("MR Conditional")
« MR conditional » (compatible avec l'IRM sous certaines conditions)
Può essere sottoposto a MRI
MRI-veilig onder bepaalde voorwaarden
Warunkowe stosowanie RM
MR conditional (é possível realizar exames de rmn, desde que sejam respeitadas determinadas condições)
Podmienečne bezpečný v prostredí MR
MR conditional (MR-villkorad)



Quantity per box
Množství v krabici
Antal pr. æske
Anzahl pro Verpackung
Ποσότητα ανά κουτί
Cantidad por caja
Määrä/latikko
Quantité par boîte
Quantità per scatola
Aantal per doos
Ilość w pudełku
Quantidade por caixa
Počet kusov v škatelci
Kvantitet per ask



Keep dry
Chraňte před vlhkem
Opbevares tørt
Vor Feuchtigkeit schützen
Διατηρείτε στεγνό
Mantener seco
Pidettävä kuivana
Conserver au sec
Tenere al riparo dall'umidità
Droog houden
Chronić przed wilgocią
Manter seco
Prechovávať v suchu
Förvaras torrt



Keep away from sunlight
Chraňte před slunečním světlem
Beskyttes mod sollys
Vor Sonnenlicht schützen
Διατηρείτε μακριά από το ηλιακό φως
No exponer a la luz solar
Suojattava auringonvalolta
Conserver à l'abri de la lumière du soleil
Tenere al riparo dalla luce solare
Verwijderd houden van zonlicht
Chronić przed światłem słonecznym
Manter afastado da luz solar
Chraňte pred slnečným žiarením
Skyddas för solljus



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