Anaconda™ AAA Stent-Graft System (Custom made)

Anaconda™ Iliac Stent-Graft System (Custom made)

Instructions for Use

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1. GENERAL INFORMATION

1.1 INSTRUCTIONS FOR USE

This booklet provides instructions for the routine use of the Anaconda ™ AAA Stent-Graft System (Custom made) and Anaconda™ Iliac Stent-Graft System (Custom made), referred to as Anaconda throughout this booklet, manufactured specifically in accordance with a written prescription for the treatment of a particular patient.

Sizing of the aorta and of the iliac and access vessels must be determined before the implant takes place using appropriate imaging. This information must be available during the implantation of the Anaconda devices supplied by Vascutek Ltd. All CT Data will be analysed by Vascutek Ltd to advise on case suitability and device design.

The main body of the Anaconda Stent-Graft System (Custom made) should be oversized by 10-25% for standard valley and fenestrated valley designs and 15-30% for augmented valley designs.

Clinicians must have received training and have established clinical experience in vascular interventional procedures prior to using the devices in this pack, provided by Vascutek Ltd.

The Anaconda devices supplied by Vascutek Ltd are sterilised by ethylene oxide and are supplied sterile.

Information on material:

Material	Polyester	Polyethylene	Tantalum	Nitinol
Weight (g)	1.01	0.04	0.2445	2.29
Proportion	28%	1%	7%	64%

The delivery system, Flexible Contralateral Magnet Wire (FCLMW), and Contralateral Guiding Catheter (CLGC) contain cobalt (CAS No. 7440-48-4) defined as a CMR1B (carcinogen, toxic to reproduction) in a concentration above 0.1% weight by weight. There is no evidence of human reproductive effects following exposure to cobalt containing medical devices. Although available data do not allow drawing a conclusion on the carcinogenicity of cobalt in humans, scientific data suggests cobalt containing alloys in medical devices are unlikely carcinogenic hazard to patients. Therefore, based on the negligible potential exposure to cobalt during use of the delivery system and accessories, the low bioavailability of cobalt from the stainless steel and nitinol alloys used, and the short term exposure in clinical use (<24hours); the risk of cobalt exposure during use are low. The potential benefits of the device outweigh potential residual risks associated with the intended clinical use of the devices containing these components with residual cobalt.

The delivery system contains Tris (4-nonylphenol, branched and linear) phosphite (TNPP, CAS No.26523-78-4) defined as having endocrine disrupting (ED) properties in a concentration above 0.1% weight by weight. A tolerable exposure (TE) of 16.7 mg/day protective for reproductive and developmental toxicity (relevant sequalae for ED's) has been derived based on animal testing in rats with a NOAEL for reproduction of 167 mg/kg determined. The maximum mass of TNPP present in components in contact with circulating blood is 5.6mg, less than the derived TE. Based on the negligible potential exposure of TNPP leaching from the delivery system, and the short term exposure to the system in clinical use (<24 hours), the risk of exposure to TNPP is low. The potential benefits of the device outweigh potential residual risks associated with the intended clinical use of the delivery system, which contains TNPP.

The FCLMW contains synthetic isoparaffin hydrocarbon (CAS No. 64742-48-9) defined as a CMR1B (carcinogen, mutagen) in a concentration above 0.1% weight by weight. This substance is contained in the pigment of the PTFE sleeve and is classified as CMR1B because benzene (hazardous component) may be present. Benzene is eliminated from the material during the pigment manufacturing process (calcination), and therefore the risk of patient exposure to this substance is low. The potential benefits of the device outweigh potential residual risks associated with the intended clinical use of the FCLMW accessory which contains synthetic isoparaffin hydrocarbon.

The product is terminally sterilised with Ethylene Oxide (EO, CAS No. 75-21-8), therefore residual EO is present on the product. EO is determined to be CMR 1B (carcinogen, mutagen, and toxic to reproduction) in a concentration above 0.1% weight to weight. Following sterilisation, the product is aerated under controlled conditions for 5 days, and thereafter meets the limits for EO residuals prescribed in ISO 10933-7:2008+A1:2022. The benefits of providing a sterile product outweigh the residual risk posed by residual EO present on the product. The level of EO present on the product does not pose a risk to patient safety.

For unexpected events during the deployment procedure, please consult the Bailout Procedures.

1.2 INTENDED USERS

The intended users of the Anaconda devices supplied by Vascutek Ltd are clinicians and teams with experience and training in vascular interventional procedures. This includes clinicians with formal education/training in vascular surgery and interventional radiology.

1.3 INTENDED/EXPECTED CLINICAL BENEFITS

- To reduce the risk of aneurysm rupture and aneurysm related mortality in patients treated for aortic or iliac artery aneurysm.

1.4 TARGET PATIENT GROUP

The target patient group for the Anaconda devices are patients with aortic or iliac aneurysmal disease, for whom there is no commercially available treatment option and have appropriate anatomy as per the indications for use.

1.5 INTENDED PURPOSE

- The intended purpose of the Anaconda AAA Stent-Graft System (Custom made) is exclusion of abdominal aortic aneurysm from blood circulation, in order to reduce the risk of further enlargement and rupture.
- The intended purpose of the Anaconda Iliac Stent-Graft System (Custom made) is exclusion of an isolated iliac artery aneurysm from blood circulation, in order to reduce the risk of further enlargement and rupture.

1.6 PERFORMANCE CHARACTERISTICS

- The Anaconda Stent-Graft System (Custom made) (including bifurcate body, aorto uni-iliac (AUI), cuff and leg devices) provide a modular system allowing treatment of various anatomy and aneurysm morphologies with regards to length and diameter
- The graft material is a woven polyester. This lined fabric graft, with nitinol support, re-routes blood away from the expanding aneurysm sac, stabilising the weakened abdominal aortic wall, decreasing the risk of aneurysm rupture and aneurysm-related mortality.
- Self-expanding “ring-stents”, comprised of multiple turns of nitinol wire and attached with polyester sutures, provide a conformable seal with the vessel wall, and assist in anchoring of the device.

- The nitinol ring stent structure of the bifurcate body device provides adaptability of the device to angulated anatomy treating proximal aortic necks with 90-degree angulation.
- The main body device has three or four pairs of infra-renal hooks, depending on the proximal ring configuration, which provide secure fixation of the device within the aorta.
- The radiopaque ring stents and radiopaque markers allow accurate positioning of devices in relation to the anatomy and to other devices forming part of a modular implant.
- The main body device is attached to the delivery system at the peaks and valleys of the proximal ring stents allowing it to be closed and repositioned using the control collar on the handle of the delivery system.
- To aid cannulation of the contralateral limb of the bifurcate body device, an additional intrinsic guide wire, with a magnet attached, is pre-loaded within the contralateral limb. The contralateral guiding catheter and flexible contralateral magnet guide wire should be used to attach the magnets and cannulate the limb.
- The contralateral limb (optional) of the bifurcate body device provides a flared opening to aid cannulation in the event that free-style cannulation is required.
- Fenestrations reinforced by nitinol rings positioned accordingly in the device facilitate blood flow through the target vessels when bridged using appropriate peripheral stent grafts.

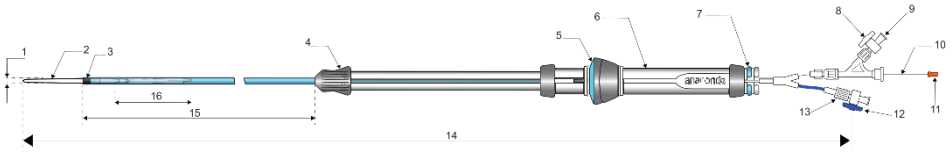
2 DEVICE COMPONENTS

The Anaconda™ Stent-Graft System (Custom made) includes:

- AAA Stent-Graft System (Custom made)
    - Anaconda™ (Custom made) Stent-Graft Delivery System (Figure 1)
    - Anaconda™ (Custom made) Bifurcate Device (Figure 2a)
    - Anaconda™ (Custom made) Cuff Device (Figure 2b)
    - Anaconda™ (Custom made) Aorto Uni Iliac (AUI) Device (Figure 2c)
    - Anaconda™ (Custom made) Hooked Iliac Leg (Figure 2d)
    - Contralateral Guiding Catheter (CLGC/01)
    - Flexible Contralateral Magnet Guidewire (FCLMW)

- Isolated Iliac Aneurysm Stent-Graft System (Custom made)
    - Anaconda™ (Custom made) Iliac Leg Delivery System (Figure 3)
    - Anaconda™ (Custom made) Flared/Tapered Iliac Leg Delivery System (Figure 4)
    - Anaconda™ (Custom made) Iliac Leg (Figure 5a)
    - Anaconda™ (Custom made) Flared Iliac Leg (Figure 5b)
    - Anaconda™ (Custom made) Tapered Iliac Leg (Figure 5c)
    - Anaconda™ (Custom made) Fenestrated Iliac Leg (Figure 5d)

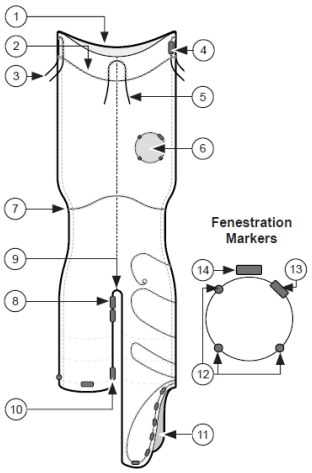
Figure 1. Anaconda™ (Custom made) Stent-Graft Delivery System



1. Sheath Diameter
2. Nose Cone
3. Radiopaque Marker
4. Sheath Slider
5. Control Collar
6. Handle
7. White & Blue Release Clips (Wires)
8. White Stopcock
9. White Flushing Port
10. Intrinsic Magnet Guidewire
11. Torque Device
12. Blue Stopcock
13. Blue Guidewire Port
14. Overall Length
15. Sheath Length
16. Compacted Body Device

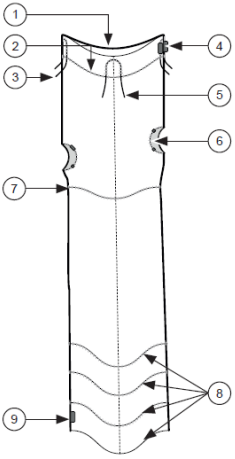
Note: There may be aesthetic differences in the delivery system supplied. There is no difference to the functionality of the delivery system.

Figure 2a. Anaconda™ (Custom made) Bifurcate Device



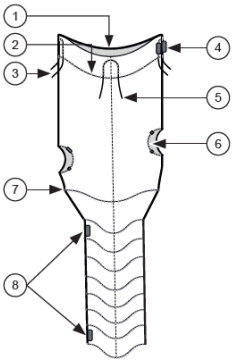
1	Proximal Ring
2	Secondary Ring
3	Peaks Hooks
4	Hook Markers
5	Valley Hooks
6	Fenestration(s)
7	Midring
8	Leg Docking Radiopaque Markers
9	Flow Splitter
10	Distal Radiopaque Marker
11	Contralateral Cannulation Flare with Radiopaque Markers
12	Fenestration Markers
13	Tantalum Crimp
14	Additional Marker (Available on Request/ Requirement)
Note: Each Custom Bifurcate Device will differ from that shown due to the customisable nature of this graft	
Note: The fenestration markers shown for the Anaconda™ Custom Bifurcate Device are applicable to all devices with fenestrations.	

Figure 2b. Anaconda™ (Custom made) Cuff Device



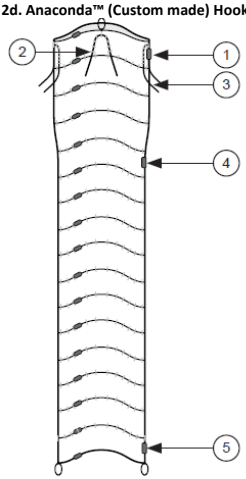
1	Proximal Ring
2	Secondary Ring
3	Peaks Hooks
4	Hook Markers
5	Valley Hooks
6	Fenestration(s)
7	Midring
8	Distal Sealing Rings
9	Distal Radiopaque Marker
Note: Each Custom Cuff Device will differ from that shown due to the customisable nature of this graft	

Figure 2c. Anaconda™ (Custom made) Aorto Uni Iliac (AUI) Device



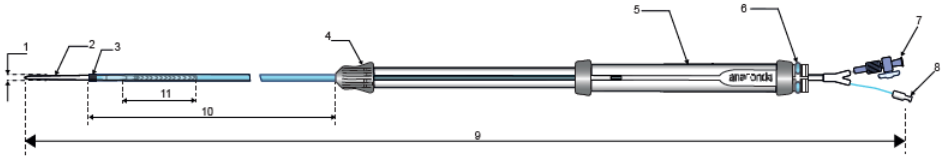
1	Proximal Ring
2	Secondary Ring
3	Peaks Hooks
4	Hook Markers
5	Valley Hooks
6	Fenestration(s)
7	Midring
8	Distal Radiopaque Marker
Note: Each Custom AUI Device will differ from that shown due to the customisable nature of this graft	

Figure 2d. Anaconda™ (Custom made) Hooked Iliac Leg



1. Proximal Radiopaque Hook Marker
2. Peak Hook
3. Valley Hook
4. Transition Marker
5. Distal Radiopaque Marker

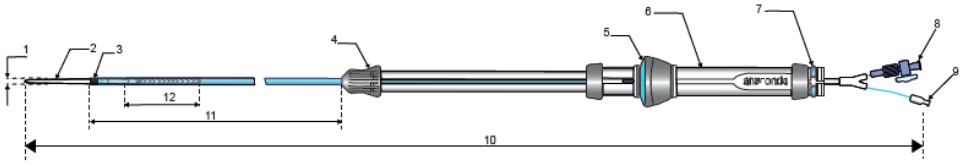
Figure 3 Anaconda™ (Custom made) Iliac Leg Delivery System



1. Sheath Diameter
2. Nose Cone
3. Radiopaque Marker
4. Sheath Slider
5. Handle
6. Blue Release Clip (Wire)
7. Flushing Port
8. Guidewire Port
9. Overall Length
10. Sheath Length
11. Compacted Iliac Leg Device

Note: There may be aesthetic differences in the delivery system supplied. There is no difference to the functionality of the delivery system.

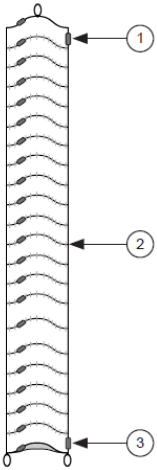
Figure 4 Anaconda™ (Custom made) Flared/Tapered Iliac Leg Delivery System



1. Sheath Diameter
2. Nose Cone
3. Radiopaque Marker
4. Sheath Slider
5. Fixed Collar
6. Handle
7. Blue Release Clip (Wire)
8. Flushing Port
9. Guidewire Port
10. Overall Length
11. Sheath Length
12. Compacted Flared/Tapered Iliac Leg Device

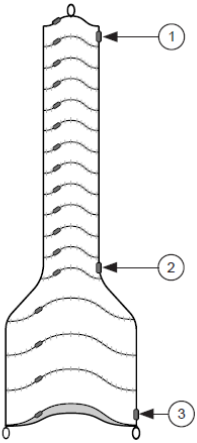
Note: There may be aesthetic differences in the delivery system supplied. There is no difference to the functionality of the delivery system.

Figure 5a Anaconda™ (Custom made) Iliac Leg



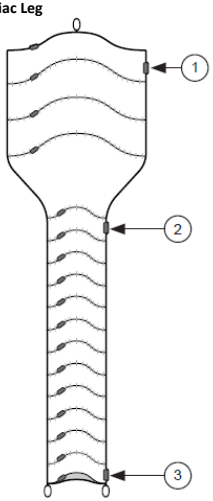
1. Proximal Radiopaque Marker
2. Individual Ring Stents with Radiopaque Alignment Markers
3. Distal Radiopaque Marker

Figure 5b o Anaconda™ (Custom made) Flared Iliac Leg



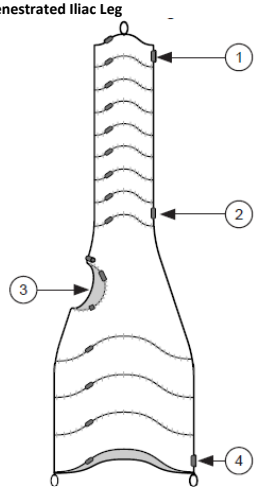
1. Proximal Radiopaque Marker
2. Transition Marker
3. Distal Radiopaque Marker

Figure 5c Anaconda™ (Custom made) Tapered Iliac Leg



1. Proximal Radiopaque Marker
2. Transition Marker
3. Distal Radiopaque Marker

Figure 5c Anaconda™ (Custom made) Fenestrated Iliac Leg



1. Proximal Radiopaque Marker
2. Transition Marker
3. Fenestration
4. Distal Radiopaque Marker

3 INDICATIONS

The Anaconda™ (Custom made) Stent-Graft System is indicated for use in endovascular procedures as the requesting clinician prescribes, providing the morphology is suitable for Fenestrated Endovascular Aneurysm Repair (FEVAR), including:

- Suitable landing zone with non-significant calcification and/or non-significant thrombus
- Native proximal aortic neck diameters of 16-32.5mm
- Aortic angulation in the region of the proximal landing zone ≤90º
- Adequate iliac or femoral vessel access
- Minimum native iliac artery diameters of 8.5mm
- Distal fixation length of ≥20mm

Additional Indications for Isolated Iliac repair:

- Adequate iliac or femoral vessel access.
- Minimum native iliac artery diameters of 8.0mm
- Proximal fixation length of ≥25mm
- Distal fixation length of ≥20mm

4 CONTRAINDICATIONS

The Anaconda devices are contraindicated for:

1 Known allergy to nitinol, polyester, tantalum or polyethylene
2 Known allergy to contrast medium, which cannot be adequately pre-medicated
3 Excessive tortuosity of access vessels (femoral or iliac arteries)

Additional Contraindications for Isolated Iliac repair:

- Patients with inadequate proximal (<25mm) and/or distal sealing zones (<20mm) within the iliac artery being treated

The safety and performance of the Anaconda devices have not been evaluated in the following patient populations:

1 Pregnant or nursing mothers
2 Patients <18 years of age
3 Ruptured aneurysm
4 Clinically serious concomitant medical disease or infection
5 Connective tissue diseases (e.g., Marfan's Syndrome)

5 WARNINGS

1 Do not use beyond the indicated expiration date.
2 Do not re-sterilise, for single use only.
3 Do not use if the packaging is damaged, return the device to the manufacturer.
4 Do not reuse, reprocess or resterilise. Reuse, reprocessing or resterilisation may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in deterioration of health or death of patients. Reuse, reprocessing or resterilisation 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 or end-user.
5 Do not kink or excessively bend the outer sheath of the system.
6 Never advance, manipulate, or withdraw equipment in the vasculature without the use of fluoroscopy.
7 Patients with pre-existing renal insufficiency may have an increased risk of renal failure postoperatively.

6 CAUTIONS

1. Store in a clean, dry area at room temperature.
2. Avoid excessive rotation of the Anaconda (Custom made) or Anaconda (Custom made) Iliac Leg delivery system greater than 90° in either direction.
3. Patients should be monitored on a regular basis for adverse events for example, but not limited to, aneurysm growth, occlusion of vessels within the treatment area, pulsatility, migration, and endoleaks.
4. The use of a balloon expandable stent to treat a Type I endoleak may result in abrasion of the graft material leading to graft failure.
5. A vascular surgical team must be available immediately in the event of need for emergency open surgical conversion and must take care to avoid the risk of potential injury resulting from the sharp device fixation hooks.
6. Patients with hypercoagulopathy should be treated with caution.
7. Devices supplied in this packaging by Vascutek Ltd require accurate fluoroscopic imaging.
8. When devices supplied by Vascutek Ltd in this packaging are deployed, the overall length of the device may differ from the expected length due to angulated or tortuous anatomy.
9. During system preparation the system sheath slider must not be retracted. The sheath slider must only be retracted when the device has been positioned in the aorta. The sheath slider allows the compacted stent graft to be opened fully into the aorta.
10. If this custom made stent graft is being used in combination with other manufacturer's components or with an existing in situ medical device neither compatibility nor performance testing can be carried out between these components. Therefore, we cannot confirm the long-term performance or durability of this combination of devices.
11. Cuffs/AUI's only – The torque device and haemostatic valve at the distal end of the delivery system should not be opened or moved. If these are moved, this may change the tension on the back-tether loops and result in decreased control of the distal end of the graft.
12. If the Anaconda™ Stent-Graft System (custom made) is designed to cradle a vessel in the anterior valley, lateral imaging should be performed to ensure there is sufficient clearance between the first proximal ring of the anterior valley and the respective vessel before the device is released from the delivery system.

7 PATIENT COUNSELLING

The clinician should review all associated risks and benefits when counselling the patient about this endovascular device and all associated procedures. These include but are not limited to:

- patient age and life expectancy
- risks and benefits related to open repair
- risks and benefits related to endovascular repair
- risks related to non-interventional treatment or medical management
- risk of aneurysm rupture compared to endovascular repair
- possibility that subsequent endovascular or open repair of the aneurysm may be required
- long term monitoring requirements

Vascutek Ltd. recommends that the clinician inform the patient of all associated risks and benefits, in written form.
Details regarding risks occurring during or after implantation of the device are provided in the Potential Adverse Events section.

8 POTENTIAL ADVERSE EVENTS

Apart from risks associated with (general) endovascular surgeries and anesthesia, risks related to the use of Anaconda devices include, but are not limited to:

- Improper component placement
- Incomplete component deployment
- Component migration
- Suture break
- Occlusion of device or native vessel
- Graft infection
- Stent fracture
- Graft twisting and/or kinking
- Insertion and removal difficulties
- Graft material wear
- Dilatation of proximal landing zone
- Endoleaks (perigraft flow)
- Aneurysm enlargement
- Aneurysm rupture
- Conversion to open surgical repair
- Death

9 DEVICE RELATED ADVERSE EVENT REPORTING

Any adverse event involving the Anaconda Stent-Graft System (Custom made) should be immediately reported to Vascutek Ltd. using either the email address complaintsuk@terumoaortic.com or via your local distributor and also to the local competent authority.

10 TRAINING

Vascutek Ltd. can provide training (if required) in the use of the Anaconda Stent-Graft System (Custom made) which includes, but is not limited to, device training, case planning & bailout procedures.

11 PREPARATION FOR IMPLANTATION

11.1 ADDITIONAL COMPONENTS SUPPLIED SEPARATELY

- Flexible Contralateral Magnet Guidewire (FCLMW)
- Contralateral Guiding Catheter (8Fr) (CLGC/01)

11.2 EQUIPMENT REQUIRED BUT NOT PROVIDED WITH DEVICE

- Fluoroscopic imaging and the ability to record and recall all images
- Appropriately sized introducer sheaths for introduction into the femoral arteries; an assortment of guidewires and catheters
- Non-compliant and compliant balloon catheters
- Interventional endovascular snare devices
- Heparinised saline
- Power injector for angiographic contrast studies
- Radiopaque contrast media
- Radiopaque calibrated angiography catheter
- Selection of appropriate peripheral stents

12 PATIENT FOLLOW UP

The expected minimum implant lifetime is 10 years. Regular follow-up including imaging of the Anaconda Stent-Graft System (Custom made) should be performed in accordance with the standard of care of the treating hospital/clinician. Patients should be monitored on a regular basis, beyond 10 years, for aneurysm growth, occlusion of vessels within the treatment area, pulsatility, migration, endoleaks and device integrity.

13 MAGNETIC RESONANCE IMAGING SAFETY

The Anaconda Stent-Graft System (Custom made) devices were determined to be MR conditional (i.e. according to information provided in the following document: American Society for Testing and Materials (ASTM) International, Designation: F 2503-08). Clinicians implanting the Anaconda Stent-Graft System (Custom made) devices should follow Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

Non-clinical testing demonstrated that the Anaconda Stent-Graft System (Custom made) devices are MR Conditional. A patient with the Anaconda™ Stent-Graft System (Custom made) device can be scanned safely, immediately after placement under the following conditions:

Device Name	Anaconda Stent-Graft System (Custom made)
Static Magnetic Field Strength (Bo)	1.5T or 3.0T
Maximum Spatial Field Gradient	17.4 T/m (17,444 Gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	3 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration and Wait Time	15 continuous minutes of scan duration with 5 minutes wait time before additional scanning.
MR Image Artifact	In non-clinical testing, the image artifact caused by the device extends approximately 6mm from the devices when imaged with a gradient echo pulse sequence and a 3.0 T MR system.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Anaconda AAA Stent-Graft System (Custom made) or Anaconda Iliac Stent-Graft System (Custom made).

14 DISPOSAL

At the end of the procedure, care must be taken to ensure safe disposal of the Anaconda (Custom made) devices supplied by Vascutek Ltd in this packaging. Each operating team must ensure local and national regulatory requirements for the disposal of contaminated clinical waste products is adhered to.

15 RETURNING A USED DEVICE

All explanted devices and/or delivery systems should be returned to Vascutek Ltd. for analysis as soon as possible.

In the event of a used delivery system needing to be returned to Vascutek Ltd., the delivery system, and any other items used in the procedure must be returned in an explants box which can be obtained from Vascutek Ltd.'s Quality Assurance Department. If required, explant kits can be requested at complaintsuk@terumoaortic.com or through your local distributor and will be provided for the retrieval and preservation of explanted stent grafts and/or delivery systems or other components for transit to Vascutek Ltd.

16 DEPLOYMENT PROCEDURES

A variation of deployment methods is required for certain Custom Device designs. Locate the Custom Made Device Identifier Number on the Custom Made Device box to identify the relevant deployment steps in this IFU.
Anaconda™ Custom Stent Grafts which require alternate deployment methods out with the categories below will be supplied with a separate IFU supplement detailing any required deviations to the deployment steps.
These Instructions for Use must be used in conjunction with the Deployment Schematics located in Section 14.

NEVER ADVANCE, MANIPULATE OR WITHDRAW EQUIPMENT IN THE VASCULATURE WITHOUT THE USE OF FLUOROSCOPY

Custom Made Device Identifier Number	Custom Made Device Characteristics	Key
Custom made Bifurcate Devices		
BFV-01	Custom Fenestrated Body where 1 fenestration is between the proximal ring stents	**A**
BVLb-01	Custom Fenestrated Body where fenestrations are within the unsupported body	**B**
NBP-01	Non-fenestrated Body	**C**
Custom made Cuff Devices		
CV-01	Custom Fenestrated Cuff	**D**
CFV-01	Custom Fenestrated Cuff where one fenestration is between the proximal ring stents	**E**
NCP-01	Non-fenestrated Custom Cuff	**F**
Custom made AUI Devices		
AV-01	Custom Fenestrated AUI	**G**
AFV-01	Custom Fenestrated AUI where one fenestration is between the proximal ring stents	**H**
NAP-01	Non-fenestrated AUI	**I**
Custom made Leg Devices		
FL-01	Custom Fenestrated Leg	**J**
IL-01	Custom Leg for Isolated Iliac Repair	**K**

16.1 DEPLOYMENT PROCEDURE FOR ANACONDA™ STENT GRAFT-SYSTEM (CUSTOM MADE): BIFURCATE, CUFF, AUI AND FENESTRATED LEG

Step	Stage 1a Anaconda (Custom made) Main Body Device Delivery System Preparation	Key
1	Remove the Anaconda™ (Custom made) delivery system from the sterile packaging and place it on a sterile table while the device is still in its clear plastic tray. Take care not to excessively bend or kink the outer sheath whilst handling the delivery system.	
2	Flush the blue guidewire port with 30ml of sterile heparinised saline, then turn off the blue stopcock. Flush the white flushing port with 30ml of sterile heparinised saline, and then turn off the white stopcock of the flushing port. Open the blue stopcock of the guidewire port to allow passage of the guidewire.	**A B C D E F G H I**
3	Wet along the full length of the delivery system sheath with sterile heparinised saline. Ensure the sheath remains wet throughout the procedure. The delivery system is now ready for use.	
4	Ensure visualisation of the device markers and orientation of the device prior to insertion into the arterial system.	

Step	Stage 1b Anaconda™ (Custom made) Delivery System: Introduction & Positioning	Key
1	Having gained access using standard techniques insert an ultrastiff 0.035" guidewire into the ipsilateral side	
2	Before advancing the body delivery system over the ultrastiff 0.035" guidewire, position the delivery system on the patient's abdomen under fluoroscopy to assist with orientation and positioning. Rotate the delivery system until the hook markers are positioned as agreed at the design stage. Make note of the position of the white and blue release clips as an external reference to aid in orientation when inserting the delivery system within the patient's anatomy.	**A B C D E F G H I**
3	Advance the delivery system over the 0.035" ultrastiff guidewire.	
4a	Regardless of the access side (patient's right or left) the device should be orientated such that the hook markers are positioned as agreed at the design stage.	
	Step 4b is for fenestrated devices only	
4b	Each fenestration is marked with four equally spaced markers. The marker in the upper left quadrant is a Tantalum crimp and thus slightly larger. Check position relative to the target vessels and intended landing zone and adjust as required Figure 19. Note: Refer to the device scheme for design and orientation information specific to the Anaconda™ Custom Stent Graft supplied by Vascutek Ltd in this packaging.	**A B D E G H**
5	Perform angiography with delivery system in situ to ensure aortic anatomy has not been altered by introduction of the delivery system.	**A B C D E F G H I**
	Step 6a is for Custom made Bifurcate Devices only	
6a	Stabilise the delivery system handle. Gently retract the control collar fully to achieve a controlled deployment. The control collar should be held in this fully retracted position. At no point should you use excessive force. Slowly pull back the sheath slider completely to withdraw the outer sheath and expose the custom device graft. Figure 20.	**A B C**
	Step 6b is for Custom made Cuff or AUI Devices only	

Step	Stage 1b Anaconda™ (Custom made) Delivery System: Introduction & Positioning	Key
6b	Stabilise the delivery system handle. Gently retract the control collar fully to achieve a controlled deployment. The control collar should be held in this fully retracted position. At no point should you use excessive force. Slowly pull back the sheath slider to withdraw the outer sheath until the radiopaque marker of the sheath is approximately 5-10mm above the proximal ring of the distal sealing zone. If necessary, advance the sheath slider forward by approximately 5mm to de-tension the system and then relax the control collar fully forward. The device is now partially open in the aorta Figure 21.	**D E F G H I**
7	Once you are satisfied that the Anaconda™ (Custom made) device is positioned in the target landing zone gently advance the control collar fully forward. At this point, the Custom Stent Graft remains attached to the delivery system Figure 22. CAUTION: It is not recommended to use balloons, snares or any other adjunctives whilst the custom stent graft is still attached to the delivery system as they may interfere with the release of the control sutures.	
8	Consider performing angiography to verify the Anaconda (Custom made) device is in the target landing zone.	
9	If repositioning is required, the Anaconda™ (Custom made) delivery system handle gives full control of the top ring stents on the Custom made device to allow for precise repositioning of the ring stent in the targeted landing zone. To reposition the custom stent graft: 1. Close the ring stent by retracting the control collar fully 2. Advance the delivery system 3-4mm to ensure the stent graft hooks are clear of the aortic wall. 3. Hold the control collar in the fully retracted position and reposition the stent graft as required. Ensure the hook markers are in the correct orientation. Figure 23. 4. Once a suitable position and orientation is achieved ensure the control collar is fully relaxed in its original position. Figure 24. **CAUTION: Repositionability may be limited by some complex anatomies. Avoid excessive rotation of the Custom Device delivery system greater than 90° in either direction.**	**A B C D E F G H I**
10	Consider performing angiography to verify the Anaconda™ (Custom made) device is now in the target landing zone.	
11	The Anaconda™ (Custom made) delivery system handle must now be stabilised, to ensure that the Anaconda delivery system does not	

Step	Stage 2. Cannulation of Contralateral Lumen of the Anaconda™ (Custom made) Bifurcate Body Device	Key
1	Stabilise the device delivery system throughout Stage 2. The Anaconda™ (Custom made) device is now unsheathed but remains attached to the delivery system until Stage 5. After unsheathing the bifurcate body, the intrinsic magnet wire (IGW) may need to be retracted until the magnet is exposed in the contralateral flare to allow connection with the contralateral magnet wire, this can be determined with the use of fluoroscopic imaging. Care must be taken not to retract the IGW too far, as this would lead to disconnection of the magnet moulding and necessitate 'freestyle' cannulation of the contralateral lumen. Note: For devices with no contralateral flare, the IGW may have to be retracted until the magnet is exposed distal to the contralateral lumen.	
2	Introduce a standard 0.035" guidewire into the contralateral arterial access point. Advance the 8Fr contralateral guiding catheter (CLGC) over the standard 0.035" guidewire until the radiopaque tip is positioned at the level of the aortic bifurcation **Figure 25**.	
3	Advance the 8Fr contralateral guiding catheter (CLGC) over the standard 0.035" guidewire until the radiopaque tip is positioned close to the aortic bifurcation. Note: Prior to introducing the 8Fr contralateral guiding catheter (CLGC), it should be flushed with sterile heparinised saline via the connector on the dilator and the stopcock on the side tube. The stopcock should then be closed.	
4	Exchange the standard 0.035" guidewire for the contralateral magnet guidewire. The standard contralateral magnet guidewire (CLMW) can be used in straight anatomy and the flexible contralateral magnet guidewire (FCLMW) can be used in selected tortuous anatomy. Note: exchange for an ultrastiff 0.035" guidewire will be required prior to introduction of the contralateral iliac delivery system. Note: The pre-loaded intrinsic magnet is designed to move on the intrinsic magnet guidewire. Normally this will only occur in the intrinsic magnet guidewire withdrawal process. However, under certain circumstances, the intrinsic magnet mould may move prematurely if it meets an obstruction such as an anatomical ledge or focal calcification. The widened section at the end of the intrinsic magnet guide wire prevents the magnet mould coming off the end of the guidewire	**A B C**
5	Manipulate the torque device on the intrinsic magnet guidewire and the contralateral magnet guidewire until the two magnets connect. **Figure 11**. Note: Ensure the ipsilateral magnet guidewire is not accidentally withdrawn from the custom device during magnet wire manipulation. Note: If the bottom of the docking zone is in close proximity to the aortic bifurcation, then the intrinsic magnet guidewire may sit within the common iliac arteries. In such a case it may be necessary to advance the intrinsic magnet guidewire before the housing magnet on the intrinsic magnet guidewire and the magnet wire can be connected. Figure 27. Note: For devices with no contralateral flare; in the event that the contralateral magnet guidewire cannot be used, freestyle cannulation of the contralateral leg may be more difficult. To ensure that the contralateral guidewire is in the lumen of the contralateral leg, visualisation using fluoroscopy should be obtained from multiple angles and checking cannulation with a balloon if necessary. **CAUTION: It is important to ensure the floppy tip of the intrinsic magnet guidewire remains above the level of the proximal ring stent at all times during the cannulation procedure however in longer devices this may not be possible, resulting in a risk that it could be advanced through the valley control loops. This may result in difficulty releasing the device from the delivery system. If such difficulty is encountered, please see Section 13 Bailout Procedures Section 13.1 Issue 7.**	

6 When the magnets have connected, carefully advance both magnet guidewires simultaneously until the magnets are visualised above the tip of the Anaconda™ (Custom made) bifurcate body nose cone. **Figure 12.**
Note: Ensure the ipsilateral magnet guidewire is not accidentally withdrawn from the bifurcate body during magnet wire manipulation.
Note: Ensure approximately 20mm of the intrinsic magnet guidewire remains distal to the delivery handle.
If the guidewire magnets disconnect during advancement through the Anaconda™ (Custom made) bifurcate body, care must be taken to reconnect the guidewire magnets outside the bifurcate body, 2-3mm below the level of the contralateral cannulation flare to minimise the risk of passing through a bifurcate body control sutures.
CAUTION: **It is important to ensure the floppy tip of the intrinsic magnet guidewire remains above the level of the proximal ring stent at all times during the cannulation procedure**

7 To disconnect the magnets, fix the flexible contralateral magnet wire and advance the intrinsic magnet guidewire the final 20mm.
CAUTION: This procedure must take place at the level of the tip of the Anaconda™ (Custom made) bifurcate body nose cone**. Figure 13.**

8 Withdraw the intrinsic magnet guidewire until the floppy tip is below the contralateral cannulation flare (if applicable). As the magnet slides along the wire there will be a small amount of resistance. This procedure must be visualised under fluoroscopic guidance to visualise that the magnet mould has reached the final position at the widened section on the end of the intrinsic magnet guide wire. **Figure 14.**

9 **Note**: If the FCLMW has been used, it must be exchanged for an ultrastiff 0.035" guidewire before advancing the contralateral iliac leg delivery system. **A B C**
Re-insert the inner dilator through the contralateral guiding catheter and advance the contralateral guiding catheter to the tip of the bifurcate body nose cone over the FCLMW.
Remove inner dilator and the FCLMW and exchange for an ultrastiff 0.035" guidewire.
Note: The magnet at the end of the FCLMW is a larger diameter than the inner dilator therefore removal of the wire should take place from the proximal end of the dilator.

Step Stage 3a. Anaconda™ (Custom made) Fenestrated Bifurcate Device: Cannulation and Stenting of Fenestrations **Key**

1 Once position of proximal ring stents and fenestrations has been confirmed and is accurate, the relevant target vessels can be cannulated through the fenestrations, this is done under fluoroscopic visualisation. **Figure 31**.

2 Following cannulation of the target vessels and insertion of the appropriately sized sheaths it is advised to take a single shot x-ray to visualise any disturbed release wires. **A B**
Note: Fenestrated Valley designs should be given extra care as they are more prone to this occurrence.
CAUTION: If disturbance is noted, it is recommended to remove the custom device release wires prior to deployment of the visceral stent grafts, and only when final position in the target landing zone is achieved.

3 The target vessels are now stented through the fenestrations. This is done under fluoroscopic visualisation. **Figure 32.**

Step 4 is for a Fenestrated Valley design only

4 The fenestration between the ring stents should not be stented at this stage. **Figure 33.** **A**

Step Stage 3b. Anaconda™ (Custom made) Cuff/AUI Device: Cannulation & Stenting of Fenestrations **Key**

1 Once position of proximal ring stents and fenestrations has been confirmed and is accurate the relevant target vessels can be cannulated through the fenestrations, this is done under fluoroscopic visualisation. As the distal portion of the graft is still within the delivery system access will need to be gained from above (brachial, subclavian approach etc.). **Figure 34.**

2 Following cannulation of the target vessels and insertion of the appropriately sized sheaths it is advised to take a single shot x-ray to visualise any disturbed control/release wires. **D E G H**
Note: Fenestrated Valley designs should be given extra care as they are more prone to this occurrence.
CAUTION: If disturbance is noted, it is recommended to remove the custom made device release wires prior to deployment of the visceral stent grafts, and only when final position in the target landing zone is achieved.

3 The Anaconda™ (Custom made) Cuff/AUI Device can now be fully unsheathed. The delivery system handle must be stabilized. Slowly pull back the sheath slider to withdraw the outer sheath. Ensure the sheath slider is docked completely at the device handle. The Anaconda™ (Custom made) Cuff/AUI Device is now unsheathed but remains attached to the delivery system until Stage 5. **Figure 35.**
Caution: At this stage, the Custom Cuff device will have limited repositionability; any attempt at repositioning the device will result in twisting of the graft fabric.

4 The target vessels are now stented through the fenestrations. This is done under fluoroscopic visualisation. **Figure 36.**

Step 5 is for a Fenestrated Valley design only

5 The fenestration between the ring stents should not be stented at this stage. **Figure 37.** **E H**

Step Stage 4a. Anaconda™ (Custom made) Iliac Leg and Flared/Tapered Iliac Leg Preparation **Key**

1 Remove the Anaconda™ (Custom made) leg delivery system from the sterile packaging and place it on a sterile table while the device is still in its clear plastic tray. Take care not to excessively bend or kink the outer sheath whilst handling the delivery system.

2 First flush the guidewire port with 30ml of sterile heparinised saline. **A B**
Following this, flush the white flushing port with 30ml of sterile heparinised saline, and then turn off the white stopcock. Some Custom made Leg devices may be provided on a 20F body delivery system, this will require flushing of both ports as per stage 1a, Step 2 **C G H I**

3 Wet along the full length of the delivery system sheath with sterile heparinised saline. Ensure the sheath remains wet throughout the procedure.
The Anaconda™ (Custom made) leg delivery system is now ready for use.

4 Ensure visualisation of the Anaconda™ (Custom made) leg markers and orientation of the device prior to insertion into the arterial system.

Step	Stage 4b. Contralateral Anaconda™ (Custom made) Iliac Leg or Flared/Tapered Iliac Leg: Introduction & Deployment	Key
1	When working on the contralateral side, ensure the Anaconda™ (Custom made) Stent Graft System delivery system is stabilised throughout Stage 4b.	
2	Ensure that the leg delivery system is prepared as indicated in the leg delivery system preparation section 4a.	**A B C**
	CAUTION: The control collar on any of the leg delivery systems will be fixed and cannot be used to reposition the leg device. The leg delivery system handle must be stabilised whilst unsheathing to prevent shortening of device and redundant fabric, increasing the risk of thrombus developing. The release wire must not be removed before the device is fully unsheathed as this could result in breakage of the release wire.	
3	Advance the leg delivery system over the flexible contralateral magnet guidewire.	
	CAUTION: **If the FCLMW has been used, it must be exchanged for an ultrastiff 0.035" guidewire before advancing the leg delivery system.**	
4	Visualise the radiopaque docking markers on the Anaconda™ (Custom made) body device and the proximal marker of the leg device. Note: Flared/tapered legs have an additional radiopaque marker which identifies the transition zone between the flared/ tapered and straight segments of the leg device. **See Anaconda™ (Custom made) Iliac Leg diagrams in Section 2. Figures 5b & 5c.**	
	CAUTION: Do not retract the outer sheath until the position is satisfactory in relation to the Anaconda™ (Custom made) bifurcate body docking markers, i.e., when the proximal marker of the leg device is 2-3mm above the proximal radiopaque docking marker of the Anaconda™ (Custom made) bifurcate body.	**A B C**
5	Consider performing angiography to confirm the position of the leg device is in the target landing zone.	
	CAUTION: the distal radiopaque marker should be at least 5mm proximal to the internal iliac artery if this is being preserved.	
6	The proximal marker of the leg device should be 2-3mm above the proximal radiopaque docking marker of the custom bifurcate device. The distal radiopaque marker of the leg device should be at least 5mm proximal to the internal iliac artery. **Figure 38.**	
	Consider performing angiography to confirm that the position of the leg device and proximal ring stent of the custom device remain in the target landing zone	
7	When the leg device is in the target landing zone, the leg delivery system handle must be stabilized.	
	Do not unsheathe the device.	

Step	Stage 5. Deployment of the Anaconda™ (Custom made) Stent Graft	Key
1	Verify that the proximal ring stent of the Anaconda™ (Custom made) Stent Graft remains in the target landing zone and is positioned below the level of the renal arteries. Considering performing angiography to aid verification.	
Note: If the Anaconda™ Custom Stent Graft is designed to cradle a vessel in the anterior valley, lateral imaging should be performed to ensure there is sufficient clearance between the first proximal ring of the anterior valley and the respective vessel.		**A B C**
2	If minor proximal or distal repositioning of the Anaconda™ (Custom made) Stent Graft is required, see Stage 1c, Step 9.	**D E F**
	CAUTION: Following any minor repositioning, ensure adequate overlap of bifurcate body/leg and leg/leg extensions is maintained.	**G H I**
3	If repositioning was required, ensure the control collar is fully forward and the Anaconda™ bifurcate body is positioned in the target landing zone. At this point, the device remains attached to the delivery system.	
	Consider performing angiography to verify the Anaconda™ (Custom made) Stent Graft is in the target landing zone.	
4	Stabilise the Anaconda™ (Custom made) Stent Graft delivery system when the final position is confirmed.	
THE NEXT STEPS WILL FULLY DEPLOY THE ANACONDA™ (CUSTOM MADE) STENT GRAFT AND NO FURTHER REPOSITIONING IS POSSIBLE		
5	Pull the white release clip and attached wire fully out of the delivery system handle.	
	CAUTION: This eliminates the ability to open and close the ring stent.	
	The release wire should be pulled out distally, in line with the delivery system handle. **Figure 39.**	**A B C**
6	To fully deploy the Anaconda™ (Custom made) Stent Graft from its delivery system, pull the blue release clip and attached wire fully out of the delivery system handle. This releases the Anaconda™ (Custom made) Stent Graft from its delivery system. The release wire should be pulled out distally, in line with the delivery system handle. **Figure 40.**	**D E F G H I**
THE ANACONDA™ (CUSTOM MADE) STENT GRAFT IS NOW FULLY DEPLOYED AND NO FURTHER REPOSITIONING IS POSSIBLE		
7	Fully Retrieve the nose cone of the delivery system by stabilising the sheath slider and retracting the delivery system handle. Retract the custom device delivery system carefully over the guidewire, this should be performed with care as the delivery system may interact with and damage any visceral stents. Ensure the guidewire is not removed with the delivery system. This should be performed under fluoroscopy **Figure 41.**	**A B C D E F G H I**
	CAUTION: **If any resistance is experienced during the removal of the Anaconda™ (Custom made) delivery system, stop the procedure immediately. An additional stage may be required for safe removal of the delivery system. Please see additional information in1 Section 13 Bailout Procedures Section 13.1.**	
8	Leave the ultrastiff guidewire in place for advancement of the ipsilateral iliac leg delivery system.	
Step 9 is for a Fenestrated Valley design only		
9	The fenestration between the ring stents should now be stented. This is done under fluoroscopic visualisation. **Figure 42.**	**A E H**

Step	Stage 6. Anaconda™ (Custom made) Bifurcate Device Contralateral Anaconda™ Iliac Leg or Flared/Tapered Iliac Leg: Deployment	Key
1	Anaconda (Custom made) Bifurcate Device is now deployed, ensure that the leg device is still positioned accurately in the target landing zone. Consider performing angiography to confirm the position of the proximal and distal radiopaque markers of the leg device in relation to the target landing zone.	

CAUTION: The control collar on any of the leg delivery systems will be fixed and cannot be used to reposition the leg device. The leg delivery system handle must be stabilised whilst unsheathing to prevent shortening of device and redundant fabric, increasing the risk of thrombus developing. The release wire must not be removed before the device is fully unsheathed as this could result in breakage of the release wire. **A B C**

2 The leg delivery system handle must be stabilised as the leg device is unsheathed. Ensure the sheath slider is retracted completely into the delivery system handle Figure 43a/Figure 43b.

Note: The leg device remains attached to the delivery system until the release wire is removed.

3 Visualise the radiopaque docking markers on the Anaconda™ (Custom made) bifurcate body and the proximal marker of the leg device. Flared/tapered legs have an additional radiopaque marker which identifies the transition zone between the flared/tapered and straight segments of the leg device.

CAUTION: Do not retract the outer sheath until the position is satisfactory in relation to the Anaconda™ (Custom made) bifurcate body docking markers, i.e., when the proximal marker of the leg device is 2-3mm above the proximal radiopaque docking marker of the Anaconda™ (Custom made) bifurcate body.

4 Consider performing angiography to confirm the position of the leg device distal radiopaque marker in relation to the target landing zone.
CAUTION: The distal radiopaque marker should be at least 5mm proximal to the internal iliac artery if this is being preserved

5 When the leg device is in the target landing zone, the leg delivery system handle **must** be **stabilised** as the leg device is unsheathed. The leg device remains attached to the delivery system until the release wire is removed. Ensure the sheath slider is docked completely at the delivery handle.

6 To fully release the leg device, pull the blue release clip and attached wire fully out of the delivery system handle. The release wire should be pulled out distally, in line with the delivery system handle. **Figure 44a/Figure 44b.** **A B C**

7 **Note: If the CLMW is still in situ, it must be exchanged for a 0.035" guidewire before insertion of any haemostatic sheath or catheters.**
Re-insert the contralateral guiding catheter with the inner dilator in place and advance over the CLMW to the level of the tip of the Anaconda™ (Custom made) bifurcate body nose cone. Remove inner dilator and the CLMW and exchange for a stiff 0.035" guidewire.
Note: the magnet at the end of the CLMW is a larger diameter than the inner dilator therefore removal of the wire should take place from the proximal end of the dilator when removed from the arterial system.

8 If required, insert an appropriately sized sheath to achieve haemostasis at the arterial access point.

9 See Stage 7a if a further iliac leg or flared/tapered iliac leg extension is required.
See Stage 7b if a custom fenestrated leg is required.

Step Stage 7a. Anaconda™ (Custom made) Iliac Leg or Flared/Tapered Iliac Leg Extension Introduction & Deployment **Key**

1 Prepare the leg delivery system as indicated in Stage 4a.
CAUTION: The control collar on any of the leg delivery systems cannot be used to reposition the leg device. The leg delivery system handle must be stabilised whilst unsheathing to prevent shortening of device and redundant fabric which can increase the risk of thrombus developing. The release wire must not be removed before the device is fully unsheathed as this could result in breakage of the release wire.

2 Advance the leg delivery system over the 0.035" guidewire.

3 Consider performing angiography to confirm that the proximal and distal markers of the leg extension device are in the target landing zone. **Figure 46a/Figure 46b.**
CAUTION: For flared/tapered devices the transition marker on the leg extension device must not be positioned proximal to the distal marker of the leg device into which it is being docked. The flared/tapered segment of the extension should not be contained within the overlap zone.
CAUTION: Do not retract the delivery system sheath until there is a minimum overlap of 20mm between the leg device and leg extension device.
CAUTION: The distal radiopaque marker should be at least 5mm proximal to the internal iliac artery if this is being preserved.

4 Once the leg device is in the target landing zone, the leg delivery system handle must be stabilised as the leg device is unsheathed. **Figure 47a/Figure 47b.** **A B C G H I**
Note: The leg device remains attached to the delivery system until the release wire is removed. Ensure the sheath slider is retracted completely into the delivery system handle.

5 To fully release the leg device, pull the release clip(s) and attached wire fully out of the delivery system handle. The release wire should be pulled out distally, in line with the delivery system handle. **Figure 48a/Figure 48b.**

6 Fully Retrieve the nose cone of the delivery system by stabilizing the sheath slider and retracting the delivery system handle. Retract the delivery system carefully over the guidewire ensuring the guidewire is not removed with the delivery system.
Figure 49a/Figure 49b.

7 **Note:** If the CLMW is still in situ, it must be exchanged for a 0.035" guidewire before insertion of any haemostatic sheath or catheters. Re-insert the contralateral guiding catheter with the inner dilator in place and advance over the CLMW to the level of the tip of the Anaconda™ bifurcate body nose cone. Remove inner dilator and the CLMW and exchange for a stiff 0.035" guidewire.
Note: the magnet at the end of the CLMW is a larger diameter than the inner dilator therefore removal of the wire should take place from the proximal end of the dilator when removed from the arterial system.

8 If required, insert an appropriately sized sheath to achieve haemostasis at the arterial access point.

Step Stage 7b. Anaconda™ (Custom made) Fenestrated Straight/Flared/Tapered Iliac Extension Introduction & Deployment **Key**

1 Prepare the leg delivery system as indicated in Stage 4a.
CAUTION: The control collar on any of the leg delivery systems cannot be used to reposition the leg device. The leg delivery system handle must be stabilised whilst unsheathing to prevent shortening of device and redundant fabric which can increase the risk of thrombus developing. The release wire must not be removed before the device is fully unsheathed as this could result in breakage of the release wire.

2 Advance the leg delivery system over the 0.035" guidewire. **J**

3 Visualise the radiopaque markers on the proximal and distal end of the leg extension as well as the fenestration markers.
Note: Flared/tapered leg devices have an additional radiopaque marker which identifies the transition zone between the flared/tapered and straight segments of the iliac leg device. See Anaconda™ Iliac Leg diagrams in Section 2.
The proximal, transitional (if applicable) and distal radiopaque markers are positioned as agreed at the design stage. The fenestration is marked with four equally spaced markers, one of which is a Tantalum crimp which is located at the top left quadrant of the fenestration. A radiopaque marker is also positioned at the top of the fenestration. Check position relative to the target vessel prior to unsheathing and adjust as required.

4 Consider performing angiography to confirm that the proximal and distal markers of the leg extension device are in the target landing zone. **Figure 46a/Figure 46b.**
CAUTION: For flared/tapered devices the transition marker on the leg extension device must not be positioned proximal to the distal marker of the leg device into which it is being docked. The flared/tapered segment of the extension should not be contained within the overlap zone.
CAUTION: Do not retract the delivery system sheath until there is a minimum overlap of 20mm between the leg device and leg extension device.
CAUTION: The distal radiopaque marker should be at least 5mm proximal to the internal iliac artery if this is being preserved.

5 When the leg device is in the target landing zone, the leg delivery system handle must be stabilised as the leg device is unsheathed. To achieve a more controlled deployment it is recommended to slowly unsheathe the device at this stage to ensure the alignment of the fenestration is not affected. **Figure 51.**
Note: The leg device remains attached to the delivery system until the release wire is removed. Ensure the sheath slider is retracted completely into the delivery system handle.

6 To fully release the leg device, pull the release clip(s) and attached wire fully out of the delivery system handle. The release wire should be pulled out distally, in line with the delivery system handle. **Figure 52a/Figure 52b.** **J**

7 Fully Retrieve the nose cone of the delivery system by stabilizing the sheath slider and retracting the delivery system handle. Retract the delivery system carefully over the guidewire ensuring the guidewire is not removed with the delivery system. **Figure 53.**

8 The target vessel can now be cannulated and stented through the fenestration; this is done under fluoroscopic visualisation. **Figure 54.**

9 It is recommended to smooth and model the overlap between the iliac leg and proximal portion of the custom fenestrated Iliac leg using an appropriately sized compliant or non-compliant balloon. Ensure access via the fenestration is maintained, do not balloon in the region of the fenestration.
Ensure any balloons are completely deflated prior to removal to avoid catching the stent graft material.
Note: Please refer to individual manufacturer's guidelines for size selection, preparation, and use of all balloons.

10 **Note:** If the CLMW is still in situ, it must be exchanged for a 0.035" guidewire before insertion of any haemostatic sheath or catheters. Re-insert the contralateral guiding catheter with the inner dilator in place and advance over the CLMW to the level of the tip of the Anaconda™ bifurcate body nose cone. Remove inner dilator and the CLMW and exchange for a stiff 0.035" guidewire.
Note: the magnet at the end of the CLMW is a larger diameter than the inner dilator therefore removal of the wire should take place from the proximal end of the dilator when removed from the arterial system.

11 If required, insert an appropriately sized sheath to achieve haemostasis at the arterial access point.

Step Stage 8. Anaconda™ (Custom made) Stent Graft Ipsilateral Iliac Leg or Flared/Tapered Iliac Leg Introduction & Deployment Key

1 **Prepare the leg delivery system as indicated in Stage 4a.**
CAUTION: The control collar on any of the leg delivery systems cannot be used to reposition the leg device. The leg delivery system handle must be stabilised whilst unsheathing to prevent shortening of device and redundant fabric, increasing the risk of thrombus developing. The release wire must not be removed before the device is fully unsheathed as this could result in breakage of the release wire.

2 Advance the leg delivery system over the ipsilateral guidewire.

3 Visualise the radiopaque docking markers on the Anaconda™ (Custom made) Stent Graft and the proximal marker of the leg device.
Note: Flared/tapered legs have an additional radiopaque marker which identifies the transition zone between the flared/tapered and straight segments of the leg device. See Iliac Leg diagrams in Section 2.

4 The proximal marker of the leg device should be 2-3mm above the proximal radiopaque docking marker of the Anaconda™ (Custom made) Stent Graft. The distal radiopaque marker of the leg device should be at least 5mm proximal to the internal iliac artery. **Figure 55.**

5 Consider performing angiography to confirm that the proximal and distal markers of the leg device are in the target landing zone. **A B C G H I**
CAUTION: The distal radiopaque marker should be at least 5mm proximal to the internal iliac artery if this is being preserved.

6 When the leg device is in the target landing zone, the leg delivery system handle must be stabilised as the leg device is unsheathed. Ensure the sheath slider is retracted completely into the delivery system handle **Figure 56.**
Note: The leg device remains attached to the delivery system until the release wire is removed.

7 To fully release the leg device, pull the release clip(s) and attached wire fully out of the delivery system handle. The release wire should be pulled out distally, in line with the delivery system handle. Figure **57a/Figure 57b.**

8 Fully Retrieve the nose cone of the delivery system by stabilising the sheath slider and retracting the delivery system handle. Retract the delivery system carefully over the guidewire ensuring the guidewire is not removed with the delivery system. This should be performed under fluoroscopy. **Figure 58**.

9 If required, insert an appropriately sized sheath to achieve haemostasis at the arterial access point.

10 See Stage 7a if a further iliac leg or flared/tapered iliac leg extension is required.
See Stage 7b if a custom fenestrated leg is required.

Step Stage 9. Smoothing of the Anaconda™ (Custom made) Stent Graft Fabric and Smoothing & Modelling of the Iliac Legs Key

1 It is recommended to smooth the stent graft fabric of the docking zone of the Anaconda™ (Custom made) Stent Graft by using an appropriately sized compliant or non-compliant balloon.
Note: Please refer to individual manufacturer's guidelines for size selection, preparation, and use of all balloons.

2 It is also recommended to smooth and model the full length of the iliac legs and overlaps using an appropriately sized compliant or non-compliant balloon. **A B C G**

CAUTION: Do not balloon in the region of the fenestration for Custom made Fenestrated Legs **H I**

3 Ensure any balloons are completely deflated prior to removal to avoid catching the stent graft material.

Step Stage 10. Completion Angiography and Verification of Stent Graft Placement and Seal **Key**

1 At the completion of the procedure perform angiography to assess the stent graft for proximal and distal endoleaks, and to verify position of the implanted stent graft in relation to the abdominal aortic aneurysm and renal arteries.

Note: If deemed clinically significant; leaks at the attachment of connection sites should be treated using an appropriately sized compliant balloon to remodel the stent graft against the vessel wall. Leaks between the visceral stents and Anaconda™ (Custom made) Fenestrated Device should be ballooned as required. **A B**

Note: Clinically significant endoleaks that cannot be corrected by ballooning may be treated by adding aortic or iliac extension components to the previously placed stent graft components. **C D E F**

CAUTION: **Any endoleak left during the implantation procedure must be carefully monitored after implantation.** **G H**

2 Remove all ancillary devices prior to repairing the entry site. **I**

3 Repair the entry site with standard closure techniques.

4 Regular follow-up including imaging of the Anaconda™ (Custom made) Stent Graft System should be performed in accordance with the standard of care of the treating hospital/clinician. Patients should be monitored on a regular basis for aneurysm growth, occlusion of vessels within the treatment area, pulsatility, migration, endoleaks and device integrity.

16.2 DEPLOYMENT OF ANACONDA™ (CUSTOM MADE) ILIAC STENT GRAFT SYSTEM

Step Anaconda™ (Custom made) Iliac Stent Graft Preparation, Introduction & Deployment **Key**

1 Prepare the leg delivery system as indicated in Section 12.1 Stage 4a.

2 First flush the guidewire port with 30ml of sterile heparinised saline. Following this, flush the white flushing port with 30ml of sterile heparinised saline, and then turn off the white stopcock.

3 Wet along the full length of the delivery system sheath with sterile heparinized saline. Ensure the sheath remains wet throughout the procedure. The Anaconda™ (Custom made) Iliac Stent Graft delivery system is now ready for use.

4 Having gained access using standard techniques insert an ultrastiff 0.035" guidewire into the required side.

5 Advance the Anaconda™ (Custom made) Iliac Stent Graft delivery system over the guidewire.

6 Visualize the radiopaque markers on the proximal and distal ends of the stent graft. **Figure 59.**

Flared / tapered Anaconda™ (Custom made) Iliac Stent Grafts have an additional radiopaque marker which identifies the transition zone between the flared/ tapered and straight sections of the Anaconda™ (Custom made) Iliac Stent Graft.

7 Confirm the position of the Anaconda™ (Custom made) Iliac Stent Graft. Do not retract the outer sheath until the stent graft is in the desired position. The stent graft should extend at least 25mm proximally and 20mm distally to the aneurysmal lesion/s. **K**

8 Once the position is satisfactory, the Anaconda™ (Custom made) Iliac Stent Graft delivery system handle must be stabilized as the stent graft is unsheathed. Ensure the sheath slider is docked completely into the delivery system handle. **Figure 60.**

9 The Anaconda™ (Custom made) Iliac Stent Graft remains attached to the delivery system until the release wire is removed.

10 Fully release the Anaconda™ (Custom made) Iliac Stent Graft device by pulling the blue release clip and attached wire fully out of the delivery system handle. The release wire should be pulled out distally, in line with the delivery system handle. **Figure 61a/61b.**

11 Re-sheath and retract the system carefully over the guidewire. Ensure the guidewire is not removed with the delivery system.

12 If the Anaconda™ (Custom made) iliac leg is fenestrated follow Section 12.1, Stage 7b steps 8-9

13 Angioplasty ballooning technique can be used to ensure that the custom iliac leg is fully dilated

17 BAILOUT PROCEDURE

In the unlikely event of delivery system or deployment issues, the following bailout techniques may be used. It is recommended that bailout procedures are carried out in the presence of Vascutek Ltd trained personnel.

17.1 ANACONDA LOPRO90 BIFURCATE BODY AND ILIAC LEG DELIVERY SYSTEM DEPLOYMENT ISSUES		
Issue	**Potential Problem**	**Process**
1. Difficulty in advancing the Anaconda™ (Custom made) Stent Graft delivery system through access vessels ordifficulty advancing the iliac leg through access vessels or through Anaconda™ (Custom made) Stent Graft.	The outer sheath of the delivery system may extend past the widest portion of the delivery system tip exposing a lip of plastic. This may impede the advancement of the delivery system.	1. Withdraw the delivery system and check if the outer sheath has moved beyond the widest portion of the delivery system tip. If this is not the case re-advance the delivery system. 2. If the outer sheath does extend beyond the widest portion of the delivery system tip, slowly retract the sheath slider until the outer sheath is in line with the widest portion of the delivery system tip. 3. If the outer sheath cannot be withdrawn until it is in line with the widest portion of the delivery system tip, the procedure must be abandoned, and a replacement device manufactured.

2. The tip/nose cone of the contralateral iliac leg delivery system meets resistance and will not advance beyond the level of the custom made bifurcate body ring stents.	The tip of the iliac leg delivery system may catch on the custom made bifurcate body delivery system control loop, impeding the movement of the iliac leg delivery system through the custom made bifurcate body	**CAUTION: Do not forcefully advance the iliac delivery system**. If using an ultrastiff stainless steel guidewire to advance the iliac leg delivery system, consider exchanging this guidewire for a less rigid ultrastiff guidewire. Alternatively: 1. The iliac leg delivery system should be retracted until its tip is in line with the flow splitter of the custom made bifurcate body. 2. The contralateral guidewire should be retracted until its tip is aligned with the tip of the iliac leg delivery system. Care must be taken to maintain contralateral guidewire access of the custom made bifurcate body. 3. The contralateral guidewire should be re-advanced, followed by the iliac leg delivery system, which should now advance unimpeded.
3. The Anaconda™ (Custom made) Stent Graft delivery system kinks as it is introduced through the access vessels, or when the Anaconda™ (Custom made) Stent Graft ring stent is closed for repositioning. The iliac delivery system kinks as it is introduced through the access vessels.	The central core of the delivery system is flexible and relies on the stiffness of the guidewire over which it is introduced for rigidity.	Use an alternative ultrastiff guidewire to introduce the delivery system. Care must be taken to ensure that no kinking occurs when unpacking and preparing the delivery system
4. The Anaconda™ (Custom made) Stent Graft or iliac leg delivery system sheath slider becomes detached from the outer sheath when deploying.	The outer sheath fails to withdraw and expose the stent graft.	Visualise via fluoroscopy if the stent has been partially unsheathed. If no unsheathing has occurred remove the delivery system. If the graft has been partially unsheathed the following stages will fully unsheathe the graft: 1. Retract the sheath slider until it is fully docked with the delivery system handle. 2. Carefully cut a central line through the outer sheath from the handle approximately 10 cm long. 3. Attach one set of forceps to each side of the sheath ensuring the delivery system handle is stabilised. 4. Retract the outer sheath carefully under fluoroscopy ensuring the sheath is split apart well away from the vessel. 5. The sheath should be retracted until its distal end is in line with the blue tip of the fully retracted sheath slider. This will ensure that the graft is fully unsheathed. **CAUTION: Do not remove the release wires until the graft is fully unsheathed.**
5. The Anaconda™ (Custom made) Stent Graft ring stents fail to open and close when attempting to reposition the device	Snapped delivery system control loop.	The ring stent position must be confirmed in relation to the target landing zone. 1. If the position is satisfactory, then release the graft from the delivery system. 2. If the position is too high and renal arteries are occluded, consider explanting the device
6. Resistance is experienced on removal of the white (valley) release clip/wire and/or blue (peak) release clip/wire.	Release wire has become damaged/ snapped and still through control loops.	1. Perform a high resolution single shot x-ray over the proximal section of the delivery system, to visualise all release wires. Review the imaging for potential obstruction that may prevent resheathing and removal of the delivery system. 2. If no obstruction is identified, then the clinician should proceed to remove the release wires following the standard deployment sequence. If the clinician still encounters resistance, repeat step 1. 3. On removal of the release wires from the delivery system, check both release wires are intact and are similar lengths (~130 cm). 4. Perform a final high resolution single shot x-ray before removal of the delivery system ensuring no remaining parts of the release wire are still attached to the delivery system. 5. Under continuous fluoroscopic visualisation carefully remove the delivery system observing for any movement of the stent graft. If movement is noted; stop and perform further imaging to assess the proximal section of the stent graft. 6. Evaluate any other potential reasons for difficulty in removing the delivery system e.g., catheters, wires, balloons, or anatomical obstructions. 7. If the remaining portion of release wire is attached to the peak eyelets of the proximal ring stent, it may be possible to remove the remaining portion using an antegrade approach. Obtain access from an antegrade approach using an introducer sheath. Using a catheter, catch the loop of the release wire. Advance a guidewire through the catheter to facilitate snaring and removal of release wire. Snare the free end of the guidewire to secure the release wire. Close and retract the snare, guidewire and catheter into the sheath and carefully remove from the patient. 8. If the release wires are similar lengths, proceed to remove the delivery system. If the release wires are not similar lengths, perform a final high resolution single shot x-ray to ensure that no section of release wire remains. If no sections of release wire are observed, then proceed to re-sheath the delivery system and remove from the patient.

7. Resistance is met on removal of the Anaconda™ (Custom made) Bifurcate device delivery system following full deployment and release and release of the custom made bifurcate body device.	The bifurcate body delivery system control loops are caught in the eyelets of the bifurcate body device or in exceptional circumstances, a contralateral guidewire, catheter and/or balloon could have passed through a bi-furcate body control sutures. This will require their removal prior to re-sheathing of the bi-furcate body nosecone as illustrated in the following text.	**NOTE:** This procedure must be done whilst maintaining ipsilateral guidewire access throughout. 1. The bifurcate body delivery system should be advanced 10 mm proximally whilst observing the proximal rings of the bifurcate body device under fluoroscopy. 2. Slowly re-sheath and retract the delivery system over the guidewire. 3. If resistance is still experienced in removing the bifurcate body delivery system, stop immediately. 4. Any contralateral guidewire, catheter and/or balloon must be carefully retracted until their tips are within the iliac leg stent graft but distal to the contralateral cannulation flare of the bifurcate body. Following this adjunctive procedure, it should now be possible to remove the bifurcate body delivery system as normal. **CAUTION: Ensure fluoroscopic visualization is maintained throughout this procedure to observe for any movement of the bifurcate body stent graft**
8. Resistance is met on removal of the iliac leg delivery system following full deployment and release of the iliac leg device.	The iliac leg delivery system is caught in the eyelets of the iliac leg device**.**	1. The iliac leg delivery system should be advanced 10mm proximally whilst observing the proximal rings of the iliac leg device under fluoroscopy. 2. Slowly re-sheath and retract the delivery system over the guidewire.
9. Resistance is met on removal of the custom made Cuff/AUI delivery system following full deployment and release of the cuff device.	The Cuff/AUI delivery system is caught in the eyelets of the device.	1. The Cuff/AUI delivery system should be advanced 10mm proximally whilst observing the proximal rings of the device under fluoroscopy 2. Slowly re-sheath and retract the delivery system over the guidewire
10. Excessive resistance is encountered while trying to retract the sheath slider on an Anaconda™ (Custom made) Stent Graft or iliac leg delivery system or the Anaconda™ (Custom made) Stent Graft / iliac leg cannot be unsheathed.	The outer sheath of the delivery system has kinked while the delivery system was being introduced. A kink in the outer plastic sheath at the level of the compacted device may make it very difficult to un-sheath the device.	**NOTE:** Verify on fluoroscopy that the compacted device has not partially unsheathed: for Anaconda™ (Custom made) Stent Graft devices, the procedure must be abandoned, and a replacement device manufactured. 1. For non-custom devices, remove the delivery system and replace with a new delivery system 2.Take care not to kink the new delivery system while unpacking and preparing the system 3. If a NMUS or CLMW guidewire is being used to advance the delivery system, it may be advisable to exchange this for an alternative ultra stiff or super stiff guidewire. **CAUTION: If the device has partially unsheathed:** 1. Attempt to retract the sheath slider as normal If the sheath slider cannot be retracted, and the device is partially unsheathed impeding deployment or removal through access point, consider conversion to open repair to explant the device.
11. When pulling the release ring and attached wire to fully deploy an Anaconda™ (Custom made) Stent Graft or iliac leg device, the release wire breaks, or resistance is felt and the wire cannot be fully removed from the delivery system handle.	The release wire may be caught between the sheath slider and the delivery system handle.	1. Stabilise the delivery system handle. 2. Hold the sheath slider and advance the sheath slider by a maximum of 1 cm. This will ensure that the release wire is not caught between the sheath slider and the delivery system handle. 3. If the release wire is intact, attempt to pull it out fully of the delivery system handle. 4. If the release wire has broken, use sterile forceps to pull the release wire out fully out of the delivery system handle.
12. Resistance is met on removal of the Anaconda™ (Custom made) Stent Graft delivery system following full deployment and release of the Anaconda™ (Custom made) Stent Graft.	The valley control loops, or hook retractor loop may be caught on the flared section of a branch stent or other 3rd party device.	Refer to Section 13.2 Alternative Deployment Options - Alternative Deployment 2 1. Stabilise the delivery system handle. 2. Using a sterile hypodermic needle, carefully lift the 5 visible threads from the inner shaft of the delivery system handle (the 5 threads include 1x hook retractor loop and the 4 ends of both valley control loops). This should be carried out proximal to the control collar. 3. Secure each thread using small artery forceps proximal to the hypodermic needle and ensure there is a suitable area to cut the control threads. Carefully use a new scalpel to cut through the control threads between the artery forceps and the control collar. It should be noted that there is no need to follow any particular order to cut the five threads. 4. Carefully pull the threads one by one. There are 5 threads in total but only 4 threads will be able to be removed from the delivery system. 5. If resistance is felt while removing any of the other threads, stop and attempt to remove one of the other control threads. 6. This should now enable re-sheathing and removal of the delivery system. **NOTE:** The remaining thread that cannot be removed is the hook retractor thread and is designed to remain within the delivery system – cutting this thread should enable removal of the delivery system if the hook retractor loop is caught only.
17.2 ALTERNATIVE DEPLOYMENT OPTIONS		
Alternative options for deployment should an issue occur during the removal of the release wires.		
Alternative Deployment Option 1		

1.1 If the white release clip has become detached from its release wire (Figure 6) then place small artery forceps on the release wire at the distal end of the device (Figure 7).
1.2 Secure the release wire by turning the wire gently around small artery forceps to aid removal of the release wire from the delivery system (Figure 8).
1.3 If the blue release clip has become detached from its release wire (Figure 9) then place small artery forceps on the release wire at the distal end of the device (Figure 10).
1.4 Secure the release wire by turning the wire gently around small artery forceps to aid removal of the release wire from the delivery system (Figure 11).
1.5 If resistance is felt, place second artery forceps on the release wire proximal to the first artery forceps and continue to gently wind the wire (Figure 12 & 13). This will ensure no added forces are applied to the wire distally. Please note there is no need to specifically orientate the artery forceps on the wire.
1.6 This maneuver should facilitate the complete removal of the release wire and it should now be possible to re-sheath the delivery system as per Anaconda™ IFU.
1.7 If any release wire should break, please refer to Alternative Deployment Option 2.

Figure 6

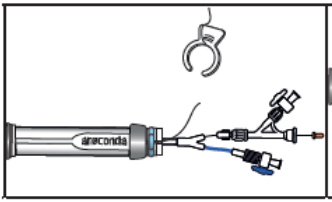


Figure 7

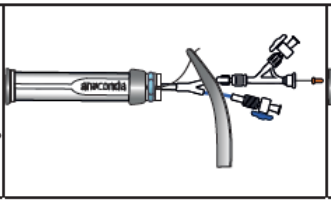


Figure 8

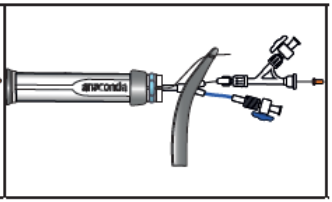


Figure 9

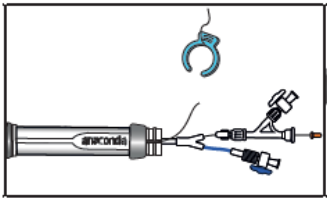


Figure 10

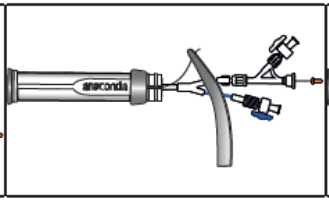


Figure 11

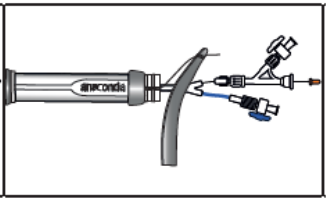


Figure 12

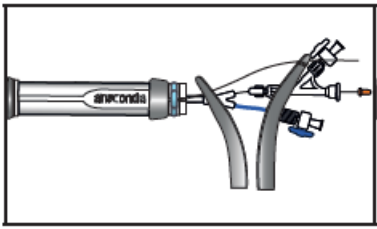
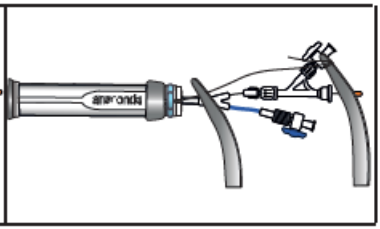


Figure 13



17.3 ALTERNATIVE DEPLOYMENT OPTION 2

2.1. On removal of the release wires confirm that the release wires are of approximately the same length.
If one release wire is substantially shorter than the other, then cut the bottom control threads to facilitate release of the stent graft from the delivery system. Using a sterile hypodermic needle, carefully lift the 5 visible threads from the inner shaft of the delivery system handle (the 5 threads include 1x hook retractor loop and the 4 ends of both valley control loops). This should be carried out proximal to the control collar (Figure 14).
2.2. Secure each thread using small artery forceps proximal to the hypodermic needle and ensure there is a suitable area to cut the control threads. Carefully use a new scalpel to cut through the control threads between the artery forceps and the control collar (Figure 15 & 16). It should be noted that there is no need to follow any order to cut the five threads (Figure 17).
2.3. Carefully pull the threads one by one. There are 5 threads in total but only 4 threads will be able to be removed from the delivery system. The remaining thread that cannot be removed is the hook retractor thread and is designed to remain within the delivery system. If resistance is felt while removing any of the other threads, stop and attempt to remove one of the other control threads (Figure 18).
2.4. This should now enable re-sheathing and removal of the delivery system.
2.5. If resistance is still met, please refer to Section 13.1 Delivery System Deployment Issues, Issue 7.
2.6. Note: The removed bottom control loops should be measured to approximately 170 cm.

Figure 14

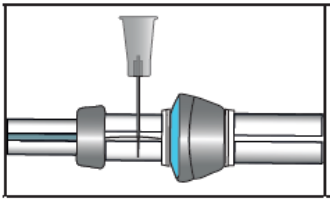


Figure 15

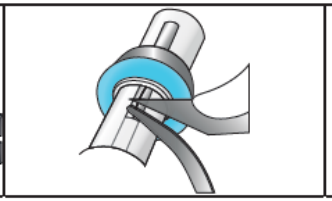


Figure 16

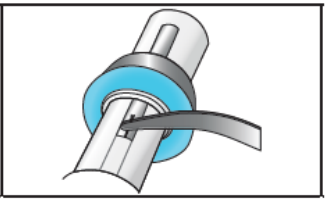


Figure 17

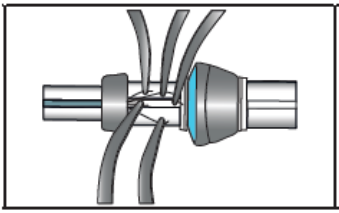
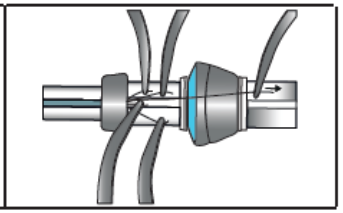


Figure 18

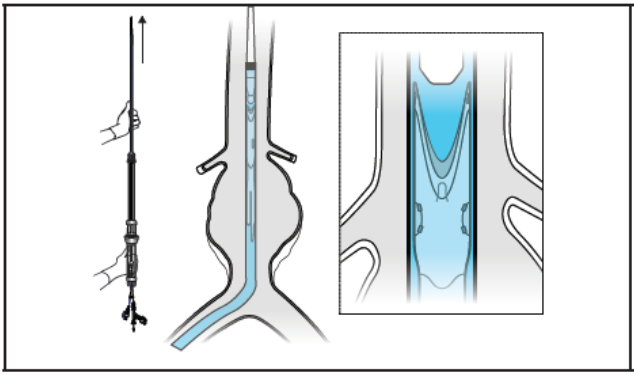


17.4 IPSILATERAL GUIDEWIRE ISSUES		
Issue	Potential Problem	Process
1. Accidental removal of the ipsilateral guidewire when removing the custom made bifurcate body delivery system.	Ipsilateral guidewire access is required to advance the ipsilateral iliac leg delivery system into the bifurcate body.	A. Perform a cross-over procedure from the contralateral side: 1. Exchange the contralateral angiography catheter for a suitably shaped guiding catheter for crossover technique. 2. Manipulate the catheter so that its tip passes above the flow splitter and enters the contralateral lumen of the custom made bifurcate body. 3. Introduce a suitable flexible guidewire and advance down through the ipsilateral lumen of the custom made bifurcate body. 4. Use a snare device or forceps to gain control of the wire, on the ipsilateral side. **CAUTION: Great care must be taken to maintain contralateral access while performing this procedure. Ensure this whole procedure is carried out under fluoroscopy, taking care that the bifurcate body is not displaced.** OR B. Use a brachial approach to pass a suitable guidewire down through the ipsilateral lumen of the bifurcate body. A snare device should then be used to gain control of this wire on the ipsilateral side. **CAUTION: When ipsilateral access has been achieved, ensure the new guidewire is in the correct lumen of the Anaconda™ (Custom made) Stent Graft before deploying any iliac leg into the docking zone.**
17.5 MAGNET CANNULATION SYSTEM ISSUES		
Issue	Potential Problem	Process
1. The magnets connect but the magnet guidewires meet resistance and cannot be advanced through the custom made bifurcate body.	The magnet on the intrinsic magnet guidewire may catch on an anatomical ledge or control sutures inside the custom made bifurcate body, impeding the advancement of the magnet guide wires through the custom made bifurcate body.	1. Manipulate the magnet guidewires so that the magnets disconnect as per instruction in Stage 2 Step 7 of Section 2 Deployment Procedure. Gently rotate the intrinsic magnet guidewire and advance it independently of the flexible contralateral magnet guidewire, to ensure that it can pass through the bifurcate body. If the intrinsic magnet guidewire can be advanced, reattach the magnets outside of the stent graft, distal to the contralateral cannulation flare and advance both guidewires simultaneously. If the magnet guidewires can be partially advanced through the bifurcate body, it may be possible to advance the CLGC, or similar catheter, over the flexible contralateral magnet guidewire to achieve contralateral cannulation. 2. If the intrinsic magnet guidewire cannot be advanced independently, or both guidewires still cannot be advanced simultaneously, consider abandoning the magnet system and performing a freestyle cannulation of the bifurcate body contralateral lumen. **CAUTION:** Due to the unsupported nature of the Anaconda™ (Custom made) Stent Graft, extra care must be taken to verify that freestyle cannulation has been successful. **CAUTION:** When contralateral access has been achieved, ensure the new guidewire is in the correct lumen of the Anaconda™ (Custom made) Stent Graft before deploying any iliac leg into the docking zone.

2. The magnets connect, but repeatedly separate when advancing magnet guidewires through the custom made bifurcate body.	The magnet guidewires are not being advanced simultaneously. OR Tortuous access vessels are causing the flexible contralateral magnet guidewire to deflect from the intrinsic magnet guidewire	1. One operator should advance both guidewires simultaneously, with one hand, to reduce the chance of separation. 2. Some slack should be introduced in the FCLMW before advancing the guidewires simultaneously.
3. The contralateral lumen of Anaconda (Custom made) bifurcate body cannot be cannulated using the magnet system, as the magnet on the intrinsic magnet guidewire does not move as expected when manipulating or advancing the intrinsic magnet guidewire.	The seal between the intrinsic magnet guidewire and the magnet molding loosens, causing the magnet to slide freely on the intrinsic magnet guidewire.	1. If cannulation of the contralateral lumen of the custom made bifurcate body using the magnet system is unsuccessful, abandon the magnet system. 2. The contralateral limb should be cannulated using a freestyle technique via the contralateral access vessels, or by a brachial approach as per Section 13.3.1B in these bailout procedures.
4. Unable to fully withdraw the intrinsic magnet guidewire so that the floppy tip of the guidewire is across the contralateral cannulation.	A high force may be required to loosen the seal that holds the magnet molding in place on the intrinsic magnet guidewire. This seal must be loose in order to allow the magnet molding to slide along the wire.	1. If the magnet molding seal is proving difficult to loosen by hand, withdraw the intrinsic magnet guidewire as far as possible, ensuring the magnet molding is below the contralateral cannulation flare. Deploy the contralateral leg. 2. When removing the custom made bifurcate body delivery system, observe the contralateral leg where it docks with the custom made bifurcate body to ensure the contralateral leg is not displaced. 3. Always retract the intrinsic magnet guidewire under fluoroscopy, stopping when the floppy tip of the intrinsic magnet guidewire sits across the contralateral cannulation flare.
5. The intrinsic magnet guidewire has accidentally not been retracted before deploying the contralateral iliac leg. The magnet remains proximal to the Anaconda™ (Custom made) bifurcate body flow splitter, resulting in difficulty retracting the intrinsic magnet guidewire/ Anaconda™ (Custom made) bifurcate body delivery system.	The magnet drags on the contralateral iliac leg when the intrinsic magnet guidewire is retracted, or the custom made bifurcate body delivery system is removed. The force required to retract the intrinsic magnet guidewire / custom made bifurcate body delivery system can result in distal displacement of the contralateral iliac leg or bifurcate body.	**CAUTION:** Do not use force to withdraw the intrinsic magnet guide wire or custom made bifurcate body delivery system. Using excessive force may result in the contralateral iliac leg or custom made bifurcate body being displaced. If the custom made bifurcate body has not been fully deployed, DO NOT deploy at this time. First, attempt to retract the intrinsic magnet guidewire while carefully observing the contralateral iliac leg / custom made bifurcate body. If the wire cannot be retracted until the magnet molding is below the bifurcate body, attempt the following: 1. Remove the torque device from the distal end of the intrinsic magnet guidewire. 2. Fully deploy the custom made bifurcate body and carefully remove the custom made bifurcate body delivery system (IFU Section 12.1, Stage 5), leaving behind the intrinsic magnet guidewire and magnet mold, as the delivery system is removed. 3. Carefully advance the CLGC or other suitable 8Fr catheter (preferably with an inner dilator to ease advancement of the catheter) over the intrinsic magnet guidewire. Continue to advance the catheter until the tip of the catheter passes between the contralateral iliac leg and the bifurcate body. Once the tip of the catheter is at the level of the bifurcate body flow splitter, making contact with the magnet mold, carefully retract the intrinsic magnet guidewire and catheter simultaneously. If Stage 3 is unsuccessful in retrieving the intrinsic magnet wire and magnet mold an alternative procedure can be utilised: 1. Remove from a proximal approach using snaring techniques.

18 APPENDIX I DEPLOYMENT SCHEMATICS (FIGURES 19-61B)

19



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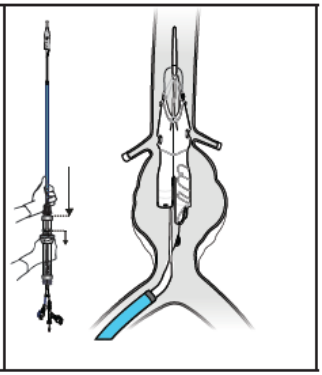

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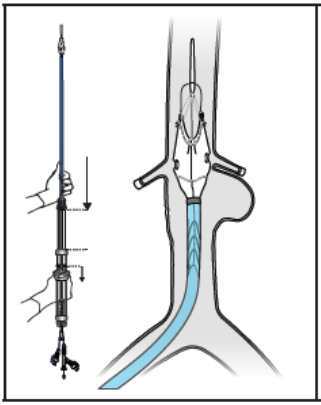

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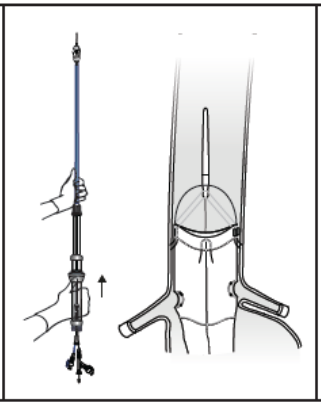

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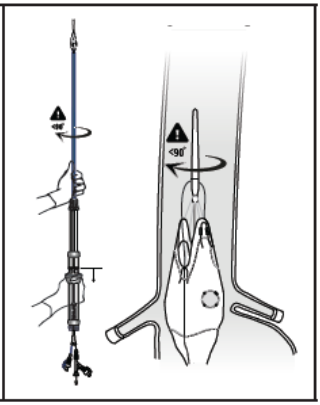

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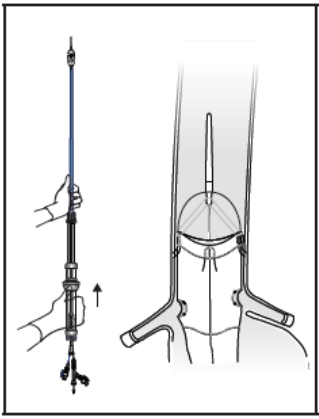

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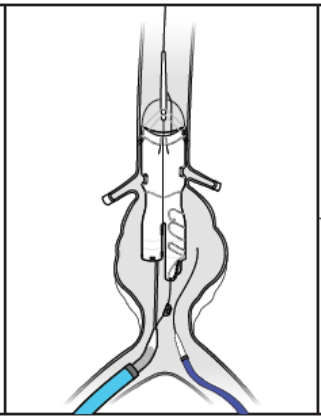

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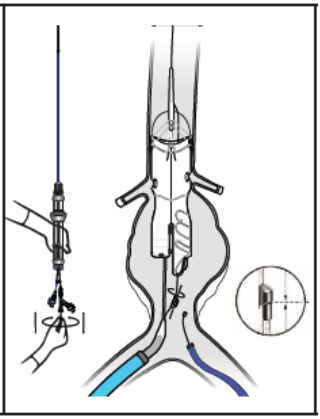

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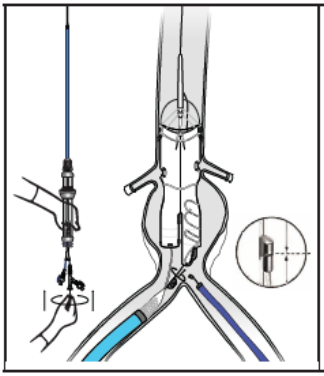

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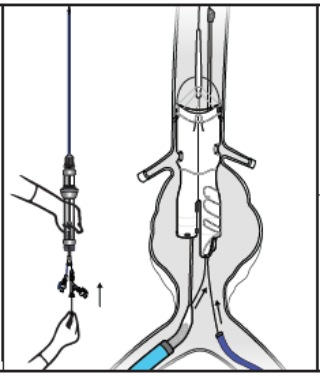

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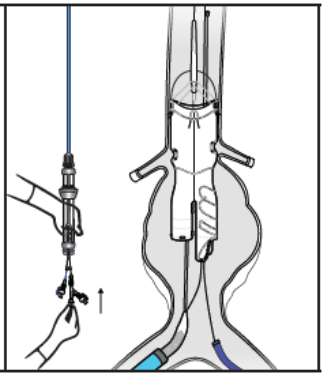

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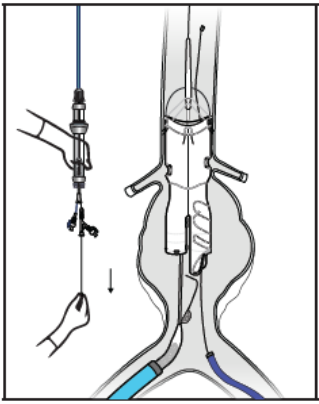

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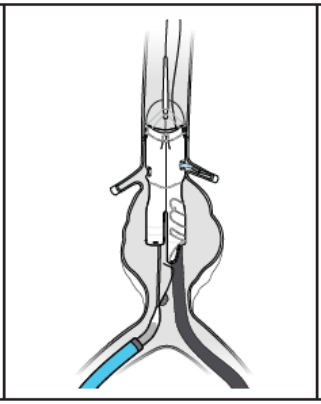

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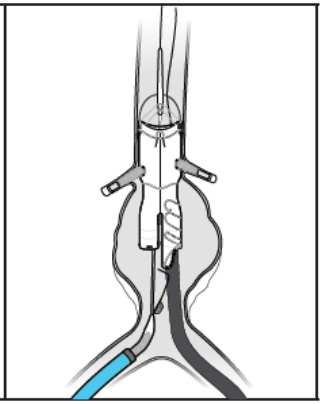

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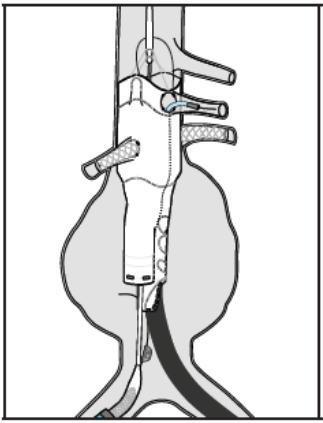

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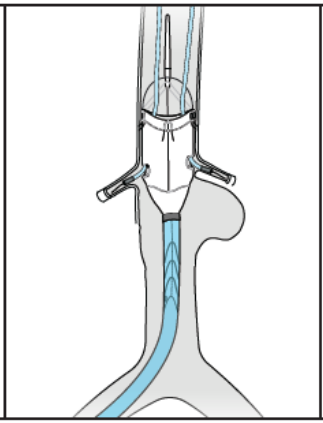

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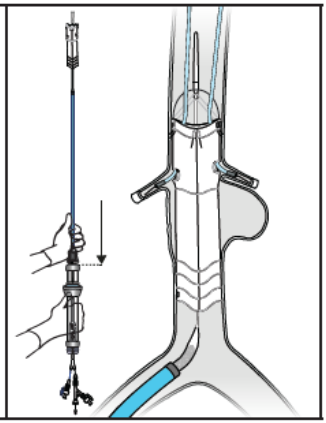

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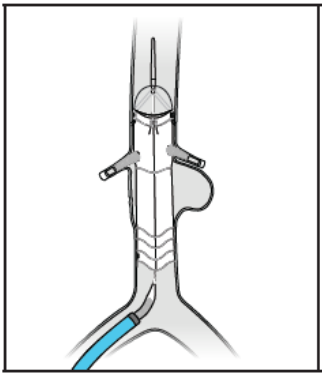
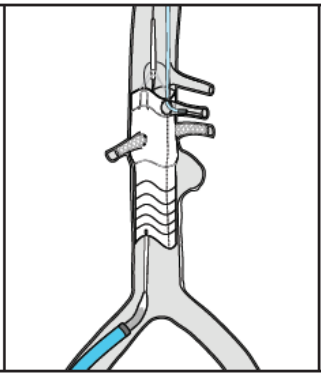


37



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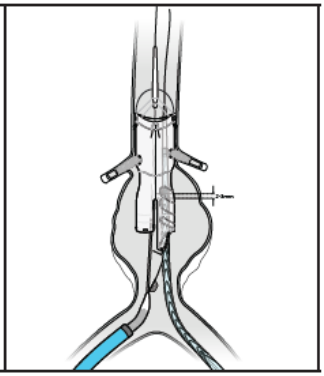

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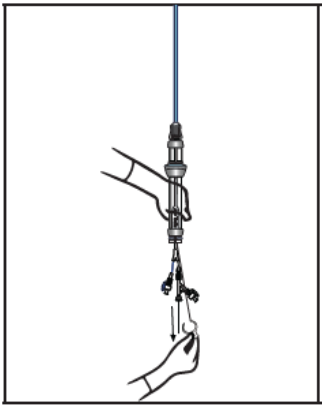

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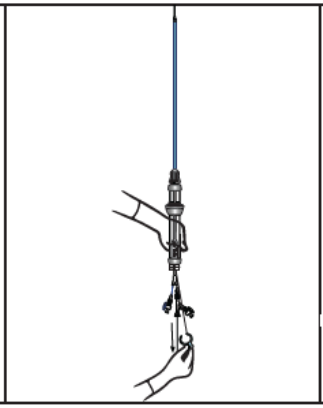

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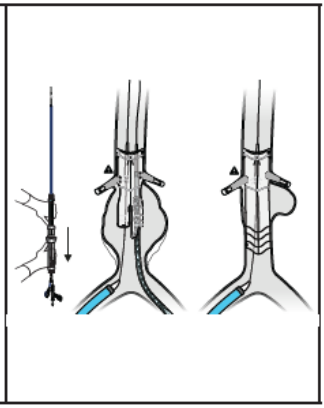

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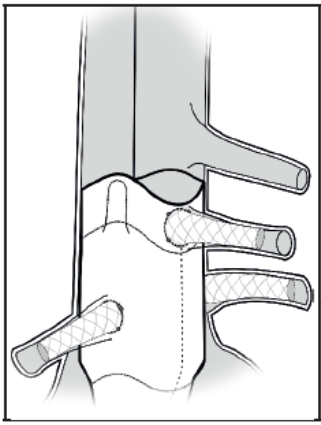
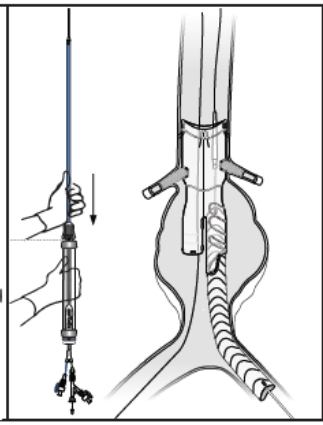
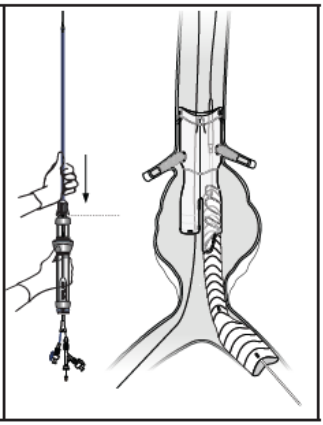


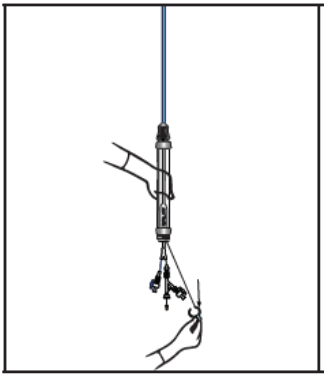
43a (43α)



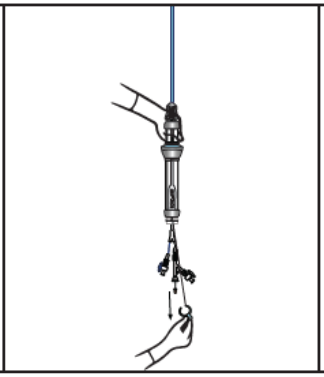
43b (43β, 43б)



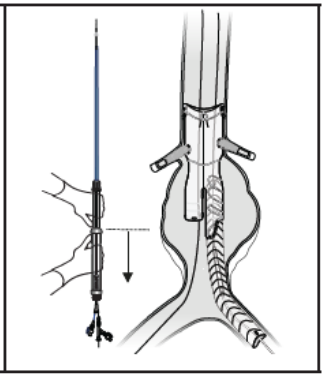
44a (44α)



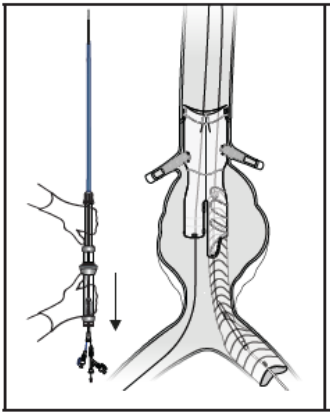
44b (44β, 44б)



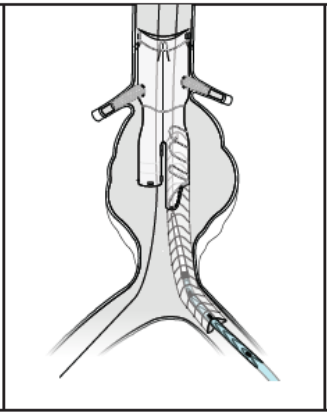
45a (45α)



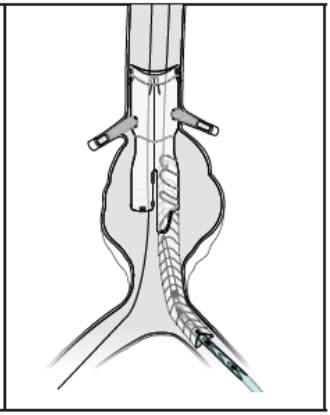
45b (45β, 45б)



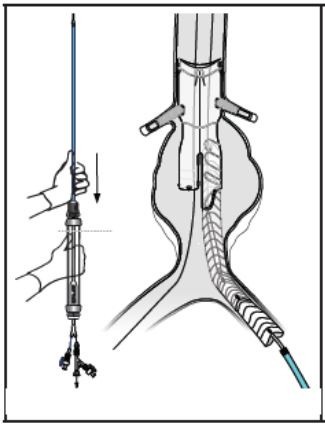
46a (46α)



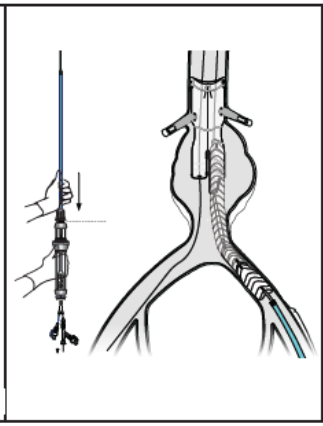
46b (46β, 46б)



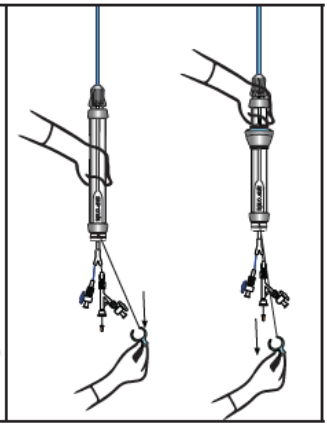
47a (47α)



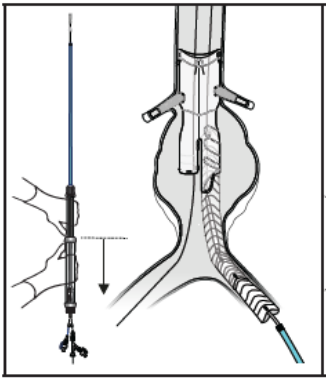
47b (47β, 47б)



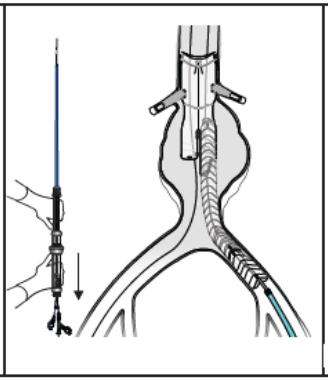
48a+b (48α+β, 48a+б)



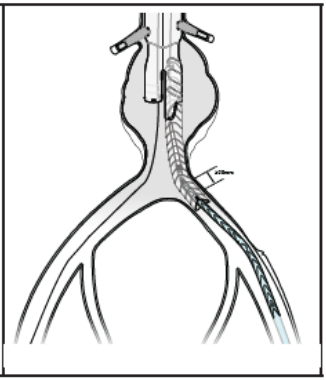
49a (49α)



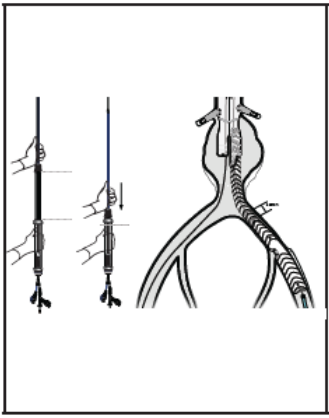
49b (49β, 49б)



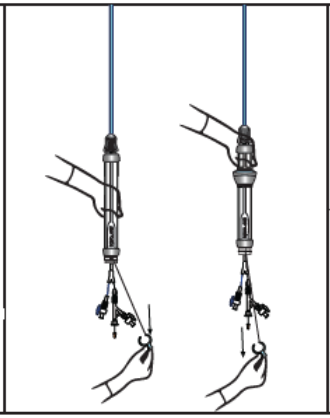
50



51



52a+b (52α+β, 52a+б)



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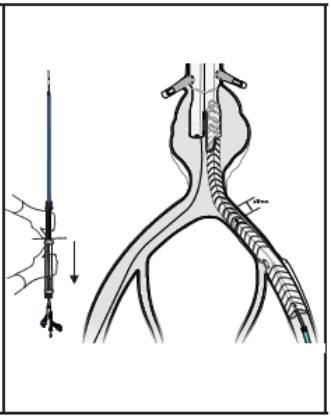
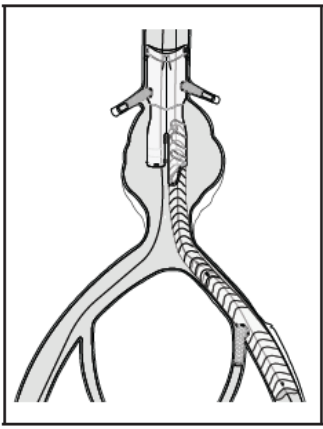


54



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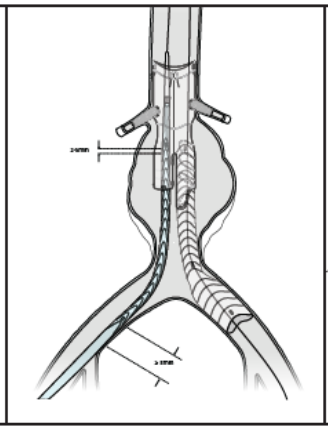
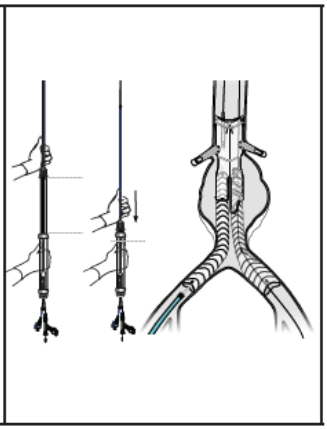
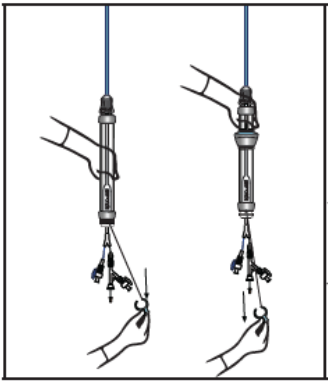


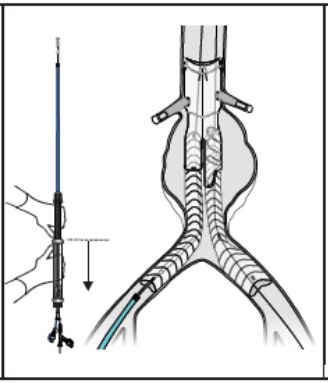
56



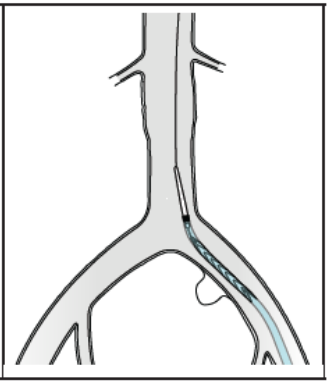
57a+b (57α+β, 57a+б)



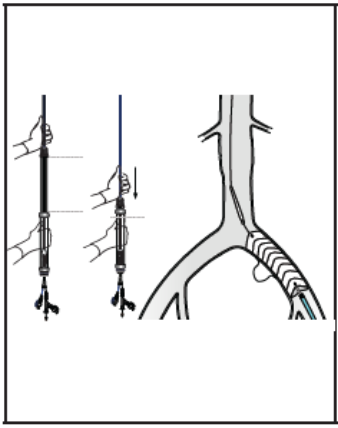
58



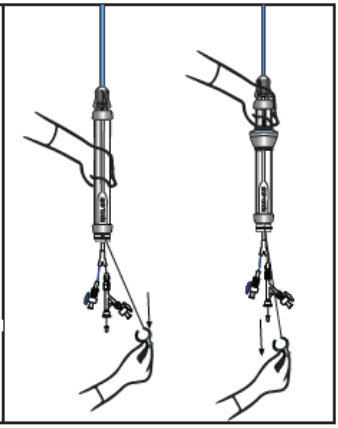
59



60



61a+b (61α+β, 61a+б)



19 APPENDIX II EXPLANATION OF SYMBOLS ON PRODUCT LABELLING

The below symbols have been used on the device labeling. The table below shows the symbol, its title and a reference to the relevant international standard the symbol has been taken from. The full designations and titles of the standards listed below are:

- ISO 15223-1:2021 - Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- ASTM F2503 - 20 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance).

Symbol	Meaning	Ref	Symbol	Meaning	Ref
	Use-by Date	ISO 15223-1 5.1.4		Latex-free	N/A
	Batch Code	ISO 15223-1 5.1.5		Catalogue Number	ISO 15223-1 5.1.6
	Serial Number	ISO 15223-1 5.1.7		Sterilized using ethylene oxide	ISO 15223-1 5.2.3
	Do not re-use	ISO 15223-1 5.4.2		Consult electronic instructions for use	ISO 15223-1 5.4.3
	Diameter	N/A		Usable Length	N/A
	Date of Manufacture	ISO 15223-1 5.1.3		Manufacturer	ISO 15223-1 5.1.1
	Do not use if package is damaged and consult instructions for use	ISO 15223-1 5.2.8		Double sterile barrier system	ISO 15223-1 5.2.12
	Do not resterilise	ISO 15223-1 5.2.6		MR Conditional	ASTM F2503 Figure 5
	Unique Device Identifier	ISO 15223-1 5.7.10		Patient information website	ISO 15223-1 5.7.4
	Medical Device	ISO 15223-1 5.7.7		Keep away from sunlight	ISO 15223-1 5.3.2

Symbol	Meaning	Ref	Symbol	Meaning	Ref
	Keep dry	ISO 15223-1 5.3.4		Caution	ISO 15223-1 5.4.4
	CAUTION: Federal Law restricts this device to sale by or on the order of a physician.	CFR Title 21 § 801.109		Authorized representative in the European Community /European Union	ISO 15223-1 5.1.2
	Patient identification	ISO 15223-1 5.7.3		Temperature limit	ISO 15223-1 5.3.7
	Health care centre or doctor	ISO 15223-1 5.7.5		Date	ISO 15223-1 5.7.6
	Authorised representative in Switzerland	ISO 15223-1 5.1.2			

Terumo Europe NV
Interleuvenlaan 40
3001 Leuven
Belgium



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