

aorflux™

Endovascular Stent Graft



Instructions for Use

Bifurcated Implant and Delivery System

ATTENTION

Read these Instructions for Use before attempting to use the Aorfix™ AAA stent-graft and delivery system.

Only for use by physicians trained in the use of this device. US Federal law restricts this device to sale by or on the order of a physician



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Lombard Medical Cardiovascular Devices Division has been abbreviated to “Lombard Medical” throughout this document



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TABLE OF CONTENTS

TABLE OF CONTENTS	3
List of Figures.....	5
1 General Information.....	6
2 Product Description	6
2.1 Stent-graft.....	6
2.2 Delivery system	7
3 Indications for Use.....	8
4 Contraindications.....	8
5 Patient Selection, Treatment and Follow-up	8
6 Warnings and Precautions	9
6.1 MRI Safety	11
7 Potential Adverse Events	11
8 Planning	12
8.1 Sizing	12
8.2 Points to Consider if Neck Angulation is greater than 65°	13
9 Follow-up.....	14
10 Patient Counseling	14
11 Instructions for Use	14
11.1 General	14
11.2 Patient preparation	15
11.3 Additional equipment (not supplied with system)	15
11.4 Accessories of Aorfix™ for adjunctive procedures	15
11.5 Devices not supplied with the system.....	16
11.6 Preparation of delivery systems.....	16
11.7 Pre-deployment	17
11.7.1 Prepare the external iliac arteries for the delivery systems:	17
11.7.2 Additional Imaging Neck Angulation greater than 65°	18
11.8 Deployment of main body component	18
11.8.1 Initiate deployment.....	19
11.8.2 Engage the hooks.....	21
11.8.3 Use of the Push Rods in neck angles greater than 65°	21

11.8.4	Deploy the aortic part of the graft	22
11.8.5	Disconnecting the proximal neck from the delivery system	22
11.8.6	Pushing up the stent graft.....	22
11.8.7	Deploying the Ipsi-lateral leg	23
11.8.8	Resheathing and removal of the delivery system	24
11.9	Deployment of the contralateral limb	25
11.9.1	Insert a guidewire into the socket:	25
11.9.2	Position the delivery system	25
11.9.3	Deploy contralateral limb	26
11.9.4	Remove delivery system.....	28
11.10	Ballooning	29
12	Use of proximal, distal extenders and Converters.....	30
12.1	Deployment of Proximal Extenders (Cuffs).....	30
12.2	Positioning and Deployment	31
12.3	Distal Extenders.....	33
12.4	Use of Converter.....	35
13	Technical training	36

List of Figures

Figure 1	Position of radiopaque markers on device.....	7
Figure 2	Contralateral limb delivery system.....	16
Figure 3	Main Body Delivery System.....	17
Figure 4	Initial deployment sequence	20
Figure 5	Engaging the hooks.....	21
Figure 6	Deployment of the main body	23
Figure 7	Resheathing and removal of delivery system.....	24
Figure 8	Plug-in distal end marker	26
Figure 9	Deployment of the Contralateral limb	27
Figure 10	Removal of the contralateral limb delivery system	28
Figure 11	Completed Aorfix™ deployment.....	29
Figure 12	Cuff Deployment.....	31
Figure 13	Proximal Part of Cuff.....	31
Figure 14	Cuff Deployment.....	32
Figure 15	Tantalum markers on distal extenders.....	33
Figure 16	Ipsilateral and contralateral leg profile.....	34
Figure 17	Position of tantalum markers on the converter	35

1 General Information

The Lombard Medical bifurcated stent-graft system (Aorfix™) is used to treat aortic, aorto-iliac and iliac aneurysms. It is intended for use only by suitably trained physicians who are experienced in diagnosis and endovascular treatment of aneurysm disease. Standard techniques for the use of vascular access sheaths, angiography, guidewires and contrast media should be employed.

The device is supplied in its delivery system, sterilised by means of ethylene oxide (EtO). It is packaged in peel-open pouches. Before use inspect packaging for signs of damage and do not use if packaging is damaged in any way. Do not store at temperatures above normal room temperature (25 °C / 77 °F).

This product is designed and intended for single use only. The delivery system and graft cannot be re-sterilised. The potential for patient cross contamination and mechanical failure of the product makes it inappropriate for multiple uses.

2 Product Description

2.1 *Stent-graft*

Aorfix™ is a two-part modular implant comprising a bifurcated main body section and a straight contralateral limb section (the “plug-in”). The main body section bifurcates into a full-length ipsilateral iliac section and a contralateral short leg mating section (the “socket”). The plug-in is mated intra-operatively to the socket to form the complete bifurcated system.

Each of the two components is supplied pre-loaded into a delivery system comprising a catheter with built-in deployment handle. The self-expanding implant is fabricated from nitinol (an alloy of nickel and titanium) and a woven polyester fabric (synthetic textile). Proximal hooks, also fabricated from nitinol, are provided in the main body section to resist migration. Radiopaque markers made of Tantalum are positioned as shown in Figure 1 below.

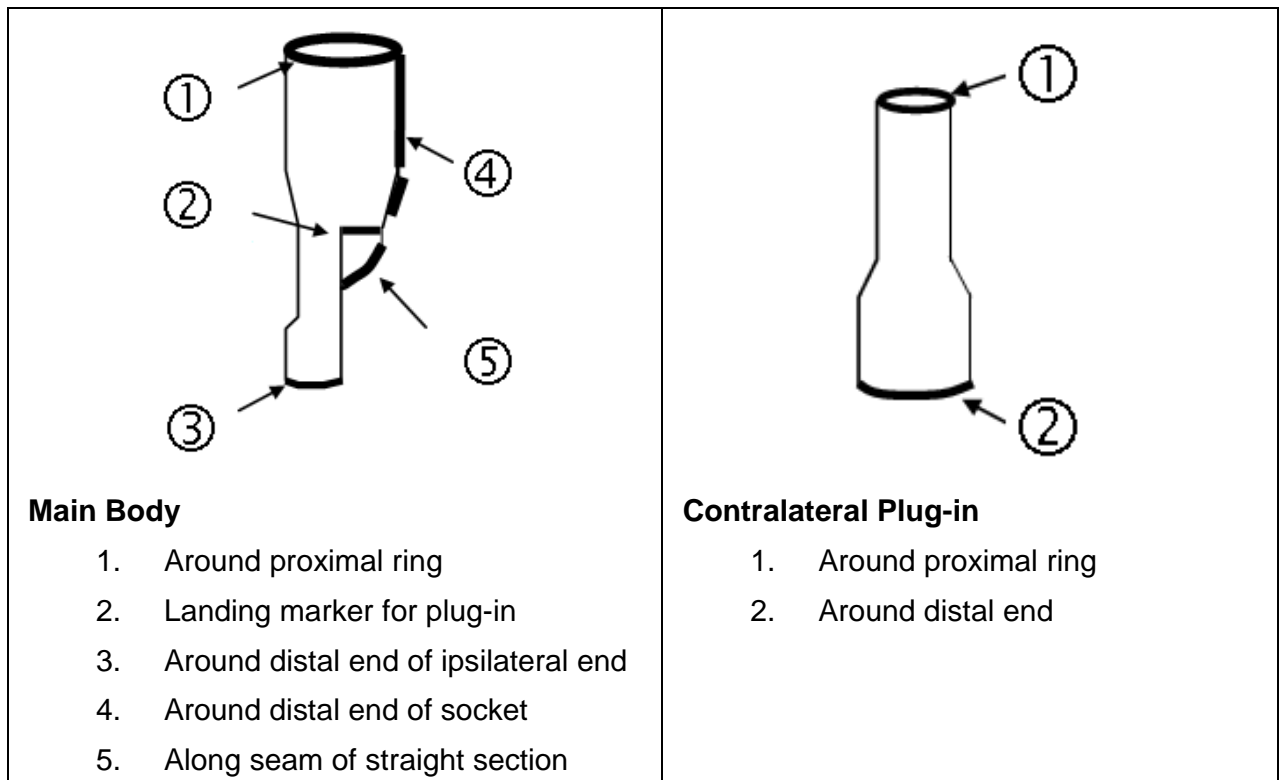


Figure 1 *Position of radiopaque markers on device*

2.2 **Delivery system**

The delivery system allows accurate endovascular placement of the stent-graft at the target site. The body-contacting materials within the delivery system are: Polyurethane (PU), Cyanoacrylate adhesive, Polyphenylenesulfide, (PPS) Stainless steel, Polyetheretherketone (PEEK), Polytetrafluoroethylene (PTFE).

For the main body delivery system, the maximum effective length (tip to handle) is 595mm. The length from handle to proximal neck of stent graft is 462mm (+/- 5mm).

For the contralateral plug-in delivery system, the maximum effective length (tip to handle) is 555mm. The length from handle to proximal neck of stent graft is 420mm (+/- 5mm).

The nominal diameter of the largest delivery catheter introduced into the body is 7.6mm (+/- 0.2mm). Please note that due to packing the shape of the catheter may take a slight oval shape, but the circumference remains the same.

The nominal diameter of the delivery catheter for the contra-lateral plug-in leg is 6.6mm (+/- 0.2mm). Please note that due to packing the shape of the catheter may take a slight oval shape, but the circumference remains the same.

Note: Traces of silicone lubricant may be present on the device.

Note: Throughout this document 'proximal' refers to that part of the implant, delivery system or other device that lies closest to the heart

3 Indications for Use

Aorfix™ is indicated for:

- the endovascular treatment of infra-renal abdominal aortic, iliac and abdominal aorto-iliac aneurysms with peri-renal neck angles up to and including 65 degrees.
- the endovascular treatment of infra-renal abdominal aortic, iliac and abdominal aorto-iliac aneurysms with peri-renal neck angles up to 90 degrees in case of undue risk of open surgical repair.

4 Contraindications

There are no known contraindications for this device.

5 Patient Selection, Treatment and Follow-up

The safety and effectiveness of Aorfix™ stent-graft has not been evaluated in patient populations with the following characteristics:

- Infra-renal non-aneurysmal neck less than 20mm in length.
- Proximal aneurysm neck diameter less than 2mm smaller than the diameter of the device being used.
- Iliac artery diameter less than 1mm smaller than the distal device diameter.
- Distance from the lower margin of the SMA to the distal end of the neck less than 20mm in length.
- Aneurysms extending around or above the renal arteries.
- Aneurysms with a proximal neck that has significant thrombus.
- Patient co-morbidities which deny vascular access, including small access vessels.
- Acute or chronic aortic dissections or mycotic aneurysms (defined by localised asymmetric aneurysm sac).
- Current non-localised infection.
- Allergies to the components of the implant – see Section 7.
- Allergies to contrast media or anti-coagulation treatment, e.g. heparin.
- Clinically obese such that diagnostic and in-procedure imaging is impaired.
- Congenital degenerative connective tissue disease such as Marfans Syndrome or Ehlers-Danlos syndrome.
- Bleeding diathesis or dyscrasia.
- Pregnant or nursing.
- Growth is incomplete

The risks and benefits should be carefully considered for patients with the following characteristics:

- Diameter of the aneurysm is less than 5.0cm, unless aneurysm growth is more than 5mm in the previous 6 months.
- Aneurysm is symptomatic, but the diameter is less than 4.5cm in diameter.
- Short conical aortic necks
- Ruptured aneurysm.
- Renal failure, serum creatinine greater than 2mg/dL
- Less than 60 years who are suitable for open repair.
- Unfit for bail-out surgery and appropriate anaesthesia.
- Peri-renal neck angles greater than 65 degrees

6 Warnings and Precautions

- Do not use Aorfix™ without fully reading and understanding the instructions for use.
- This device is only intended to be used by competent and suitably qualified and trained physicians and teams – see Section 13, Technical training.
- Single use only - do not reuse.
- Do not attempt resterilisation.
- Do not use this device for patients who are unsuitable for angiography or similar pre- or post- operative imaging.
- Do not occlude the renal arteries; this may lead to renal failure.
- Long-term efficacy of Aorfix™ has not been established. Consequently, patients should be followed up routinely, and monitored for endoleak, aneurysm growth and evidence of device migration.
- Ensure that an appropriate vascular surgical team and facilities are available in case of the need for revision to open repair.
- Proximal necks of aneurysmal, or near aneurysmal size (over 29mm in diameter) may lead to endoleak or device migration.
- Bowel/pelvic ischaemia may result from:
 - inability to maintain patency of at least one internal iliac artery;
 - presence of an indispensable and patent inferior mesenteric artery; this may also lead to an endoleak.
- Aneurysm necks with greater than 3mm increase in diameter from renal arteries to the aneurysm may be aneurysmal and give rise to a subsequent endoleak.
- Common iliac arteries of aneurysmal or near aneurysmal proportions may lead to an endoleak.

- Size the proximal diameter of the stent-graft to the largest diameter of the neck. Always oversize the diameter of the stent-graft to aneurysmal neck diameter by at least 10% but no more than 30%, (see Section 8.1, for recommended over sizing dimensions).
- Oversize the device in the distal iliac target by at least 1mm, but no more than 20%.
- Ensure that an adequate distal 'landing zone', of at least 20mm and free from important arterial branches, is available for the distal portion of the device. Failure to allow such a distance may result in endoleak.
- Avoid reliance on 'road mapping' in imaging systems because introduction of the delivery system can significantly modify the shape of vessels.
- The use of magnification during deployment of the neck is strongly recommended.
- Lombard Medical recommends careful assessment of the use of MRI imaging post-operatively: Aorfix™ may be used in an MR environment for whole body imaging with fields of 1.5 Tesla or less. MR images may be distorted, particularly if the distance to the device is less than the device diameter.
- The position of the neck is not considered fixed until the barbs have been engaged after ballooning. At all time during the procedure take care to ensure that the proximal neck is not displaced, proximally or distally.
- Use of the device in iliac arteries that are less than 7 mm in diameter poses an increased risk for device complications and use of the Aorfix endovascular graft is not recommended in such cases.
- The distal landing zone should be a minimum of 9mm in diameter to avoid difficulty when withdrawing the delivery system.
- If difficulty is encountered in inserting the device, care must be taken to detect angulation of the device tip with respect to the rest of the device (multiple views may be needed to detect such angulation). If focal angulation over 45 degrees is detected at the junction of the tip with the center tube of the delivery system or excessive force is required to advance the device, there is an increased risk of complications. Other options than use of the Aorfix endovascular graft should be considered.
- If the vessel is narrow enough to grip the tip, the tip can be drawn out of the sheath when the handle is slightly withdrawn. This leaves a space between the sheath and the tip creating a possible risk of damage to the vessel wall by the exposed end of the sheath.
- Take extra care in angulated necks not to displace the implant when withdrawing the delivery system.
- Highly angulated necks offer unique challenges please refer to Section 8.2 for advice.
- Care must be taken in those patients where the aneurysm proximal neck, distal landing zones, or iliac arteries are calcified and tortuous.
- The long term safety and effectiveness of this implant has not been established. All patients with endovascular aneurysm repair must undergo periodic imaging to

evaluate the stent graft, aneurysm size, and occlusion of vessels in the treatment area. Significant aneurysm enlargement (>5 mm) the appearance of a new endoleak, evidence of perigraft flow, change in aneurysm pulsatility, or migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.

6.1 **MRI Safety**



Non-clinical testing has demonstrated that the device Aorfix™ is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla
- Spatial gradient field of 200 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 16 minutes of scanning.

In non-clinical testing, the Aorfix™ produced a temperature rise of less than 1°C at a maximum whole body averaged specific absorption rate (SAR) of 2W/kg for 16minutes of MR scanning in a 1.5T Signa Horizon GE MR scanner. The maximum whole body averaged specific absorption rate (SAR) was determined by calorimetry

The image artefact extends approximately 10mm from the device, both inside and outside the device lumen when scanned in nonclinical testing using sequence: gradient echo and spin echo in a 1.5T Signa Horizon GE MR system with standard body coil.

7 **Potential Adverse Events**

Potential adverse events related to the procedure or device malfunction include, but are not limited to:

- Death,
- Conversion to open repair,
- Vessel damage, including at the point of access and AV fistula formation,
- AAA enlargement and/or rupture,
- Endoleak,
- Cardiac complications e.g. myocardial infarction,
- Nerve damage or neurological disorders that may lead to paraplegia,
- Lower limb and bowel/pelvic complications such as ischaemia, incontinence and impotence,
- Renal problems, including failure,
- Pulmonary complications,
- Vascular access site healing complications,
- Infection and fevers,
- Emboli and subsequent tissue / organ impairment or failure,

- Thrombosis and/or occlusion of the native vessel or implant,
- Anaesthetic complications,
- Hypotensive complications,
- Post implantation syndrome,
- Blood loss,
- Failure to advance delivery system to intended location,
- Unable to deploy,
- Unable to withdraw (part or all of) delivery system, or
- Allergic reaction to implant or delivery system material

All adverse incidents should be reported to your local Aorfix™ supplier, or direct to Lombard Medical.

8 Planning

8.1 Sizing

Lombard Medical provides a wide range of sizes of Aorfix™ to match individual patients. Physicians should employ adequate diagnostic techniques, including CT imaging, to fully evaluate the individual patient needs. Lombard Medical recommends that Table 1 be consulted to assist in sizing of the implant. This is not however intended to replace the clinical judgment of the physician.

Use of the device in iliac arteries that are less than 7 mm in diameter poses an increased risk for device complications and use of the Aorfix endovascular graft is not recommended in such cases. The distal landing zone should be a minimum of 9mm in diameter to avoid difficulty when withdrawing the delivery system.

Table 1 Recommended Sizing dimensions

Vessel Size (mm)	Smallest Implant	Largest Implant
19	24	24
20	24	25
21	24	26
22	24	27
23	25	28
24	26	30
25	27	31
26	28	31
27	29	31
28	30	31
29	31	31

Note: that all diameters are internal.



Warning!

Do not use body devices with dimension L1=81mm or L1=96mm in neck angles significantly above 65 degrees

8.2 Points to Consider if Neck Angulation is greater than 65°

This section provides advice gained from experience with use of the device in aortic necks with angles greater than 65°. Use in this patient population is more challenging and clinicians should consider the following:

- Good visualisation of the anatomy in three dimensions.
- The disease is often more advanced, increasing the presence of calcification and thrombus.
- Changes can occur in the anatomy during and after the deployment of the stent graft.
- The use of a stiff guide wire and delivery system rarely straightens out an angled neck.
- There is an increased risk of the proximal end landing obliquely. This can be compensated for by additional oversizing of the stent graft.
- Plan for ipsilateral to be the side where the delivery system encounters fewer changes in direction during insertion.

- Initiate deployment of the proximal end of the stent graft in the straight section of the aorta above the renals.
- Deploy the stent graft at a slow pace continuously observing the position of the proximal end ('fish mouth') of the stent graft.
- The renal arteries may become temporarily occluded by the delivery system during the procedure.
- The primary role of the push rods is to stabilize the proximal end of the stent-graft during deployment. The push-rods may function differently in angulated necks and dilation of the graft may not always be achieved (refer to Section 11.8.3 for further details).
- Ensure that the seam does not lie on the inside of an extremely sharp bend.

9 Follow-up

As noted elsewhere, endovascular surgery as an alternative to open AAA repair has yet to be fully proven in the long-term. With this, and individual patient needs in mind, the physician should devise an appropriate follow up regime. Typically this should involve examination prior to discharge, then at 3, 6 and 12 months, then at yearly intervals unless an endoleak is detected. In the latter instance, more frequent follow up at 3 monthly intervals and possible intervention should be considered.

10 Patient Counseling

Each patient should be advised, by the physician, about the following issues:

- The nature of open and endovascular repair and their respective risks and benefits.
- Further interventions may be required, either open, or endovascular.
- The possibility that revision to open repair may become imperative.
- The fact that long-term evaluation of endovascular repair has not yet been completed and that after surgery, regular follow-up visits for the lifetime of the patient are necessary.

The physician should notify the patient of these considerations, in writing, as appropriate.

11 Instructions for Use

These instructions are not intended to replace a physician's clinical judgement, but rather to provide general guidance on the use of the device.

11.1 **General**

Check that packaging is undamaged and that seals are intact.

Check that the components supplied match the patient's requirements.

Ensure that the "use by" date has not been exceeded. Should this date have passed, contact your Lombard Medical supplier for further information.

11.2 Patient preparation

The patient should be subject to an anti-coagulant regime during the procedure using typically 5000 units of systemic heparin. Specific anti-coagulation regimes should be tailored to individual patients and given when all necessary catheters and sheaths are in place. It is not normally necessary to anti-coagulate the patient post-operatively.

11.3 Additional equipment (not supplied with system)

- 18/19 gauge needles,
- 7 Fr sheaths of 11+cm length,
- Guidewires: 0.035" diameter, 260cm long extra stiff guidewire, such as a Lunderquist™ wire,
- Catheters: diagnostic, radiopaque graduated and angiographic catheters as required,
- Moulding, sometimes called compliant, balloon,
- A 16Fr sheath equipped with a haemostatic valve. This is required for balloon insertion over a guidewire.
- Contrast media (injector mechanism recommended, do not use in conjunction with Aorfix™™ delivery system),
- C-arm Fluoroscope,
- Radiopaque markers, e.g. marker board, graduated radiopaque rule.
- Heparinised saline solution (suggested: 5000 units in 50ml for device flushing, 5000 units in 1000ml for general flushing and 5000 units in 20 ml for patient heparinisation),
- Lubricant such as sterile silicone or appropriate surgical lubricant,
- Standard surgical equipment.

<p>Note: The procedure should be conducted in an operating theatre or catheter lab environment. The C-arm should be covered with a sterile hood. Other equipment has not been evaluated with this system.</p>
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11.4 Accessories of Aorfix™ for adjunctive procedures

- Proximal extender (cuff)
- Distal extender (x 2)
- Converter

11.5 **Devices not supplied with the system.**

These components, provided by other manufacturers, are commonly used in endovascular surgery but are not specifically approved for use with Aorfix™.

- Contralateral iliac occluder
- Delivery sheath for occluder
- Giant Palmaz stent and balloon
- Renal stent and balloon
- Cross-over graft for femero-femoral perfusion
- Snaring kit

11.6 **Preparation of delivery systems**

The plug-in delivery system is illustrated in Figure 2 and the main body delivery system is illustrated in Figure 3.

Both the main body delivery system and the plug-in leg delivery system should be flushed with a sterile heparin/saline solution. The process is described below:

Remove the delivery system from the pouch.

Using a sterile heparin/saline solution, flush the central lumen of the delivery system via the luer lock. Refer to Figure 3.

Flush the graft.

Place a finger or thumb on the end of the flexible tip to temporarily block its lumen.

Flush with sterile heparin/saline solution via the luer lock until the solution has been seen to wet the entire graft.

Ensure that the items referred to in Section 11.3 are readily to hand.

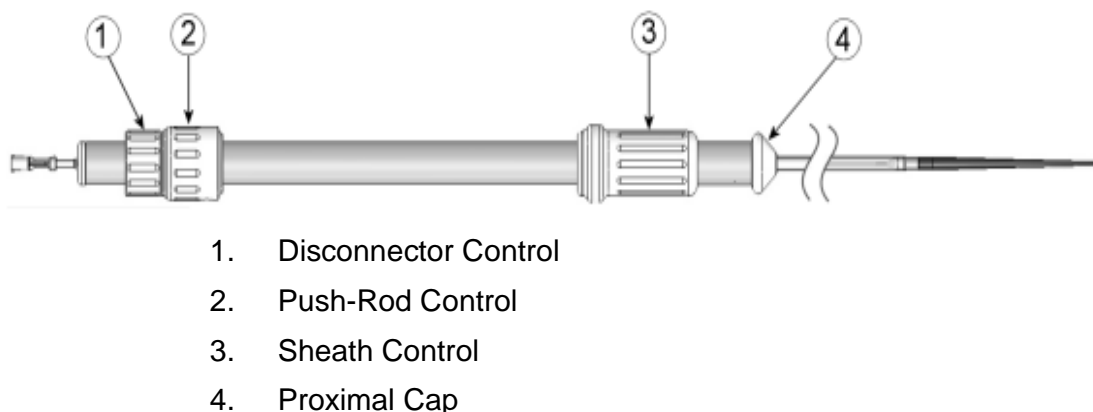


Figure 2 *Contralateral limb delivery system*

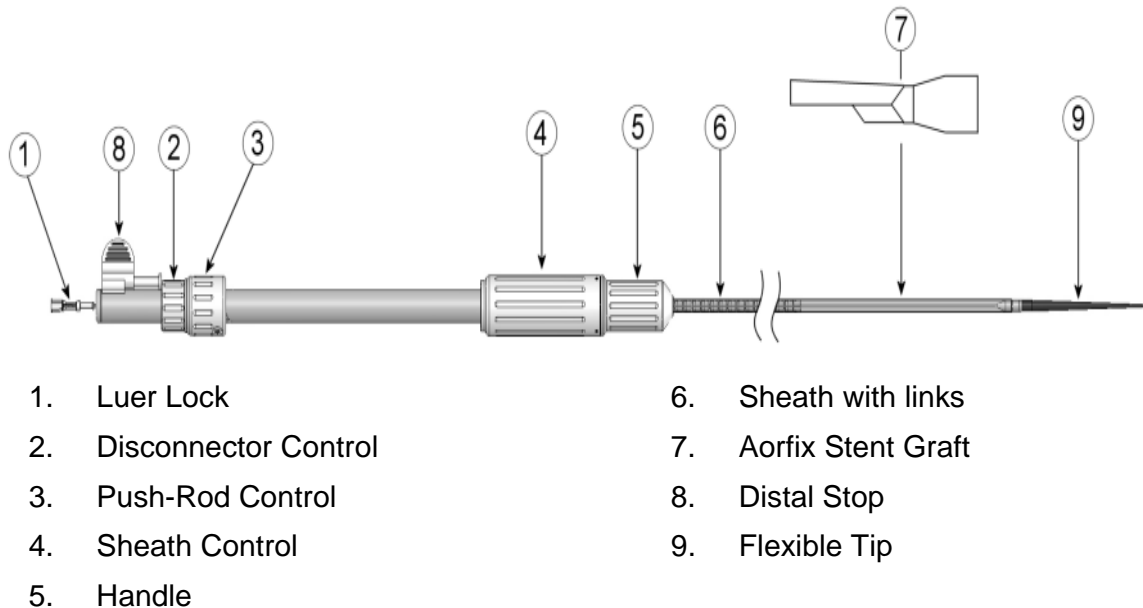


Figure 3 Main Body Delivery System

11.7 Pre-deployment

11.7.1 Prepare the external iliac arteries for the delivery systems:

Surgically expose both external iliac arteries. Tape a sufficient length of artery to enable access for appropriate clamps to allow a subsequent arteriotomy to be closed surgically.

Insert guidewires and then a 4 or 5 French catheter, into the lowest parts of both of the exposed arteries. Push each catheter up to the bifurcation of the aorta. This facilitates identification of the site of the bifurcation of the aorta and of the position of the internal iliac arteries, which is required for accurate landing of the distal part of the stent graft.

Insert 0.035" diameter, 260cm long stiff guidewire, such as a Lunderquist™ wire through needles placed in the centre of the exposed arteries and advance to a point well above the renal arteries on both sides.

Remove the access needles.

Insert vascular access sheaths of 7 Fr ID on both sides.

In the contralateral artery, insert a 7 Fr diagnostic angiography catheter, over the guidewire to a point above the renal arteries.

Note: A 5 Fr diagnostic catheter may be used for angiography if a pump injector is used.
A 7 Fr catheter allows easy hand injections.

In the ipsilateral artery, exchange the previously inserted guidewire for a stiff wire such as a Lunderquist™ wire to lie well up into the thoracic aorta, with its top, floppy end close to the aortic arch.

Mark the end of the Lunderquist™ wire on the table. Clamp the wire in position if necessary to ensure that no movement towards the heart is possible, as this may induce cardiac arrhythmias or stroke.

Perform appropriate angiograms to establish landmarks such that the following may be readily identified:

- Renal arteries
- Target deployment regions – both proximal and distal,
- Site of aortic bifurcation, and
- Iliac bifurcations.

Leave the angiographic catheter in the best position to visualise the renal arteries.

Data from the above may be used to update the position of radiopaque markers, if used.

Centre the renal arteries in the field of view of the image intensifier of the C-arm.

Note: Centres possessing the appropriate expertise may wish to employ intravascular ultrasound (IVUS) as an adjunct to angiography.

11.7.2 Additional Imaging Neck Angulation greater than 65°

In cases of neck vessel angulation and/or tortuosity, adjusted angle angiography views are recommended.

Correct orientation of the mouth of the graft is best achieved by arranging imaging so that the origin of the target renal artery is shown in profile. This usually involves an antero-oblique view. It may also be necessary to correct for cranio-caudal angulation of the aorta at the renal arteries.

Remove the access sheath leaving the stiff wire in place.

Insert the main body delivery system as detailed in the following pages.

11.8 Deployment of main body component

Lubricate the flexible tip of the delivery system with an appropriate lubricant, such as KY Jelly, prior to insertion.

Prior to insertion of the delivery system, orientation of device can be determined by examination through the transparent sheath. The distal end of the socket, the seam of the aortic component and the jaws of the mouth of the implant should be clearly identified and the orientation of the delivery system adjusted so that the seam lies anteriorly in the patient. In this orientation, the jaws of the mouth of the implant can be positioned around the renal arteries.

It may be helpful to mark the Handle with sterile tape or a skin marker to indicate correct orientation of the delivery system.

Ensure the stiff guidewire is positioned well above the renal arteries in the aorta.

Ensure the distal stop (Figure 3) is attached to the main body delivery system prior to commencing deployment activities.

Insert the delivery system over the stiff guidewire so that the proximal end of the implant is initially positioned proximal to the renal arteries.

If resistance is encountered when inserting the device, particularly if the delivery system is seen to kink in the vessel, **DO NOT USE UNDUE FORCE**. Withdraw the device and dilate the vessel using conventional dilation techniques such as a Coons dilator.

Minimize torquing the delivery system when inserting to reduce the stress on the catheter tip joint and other structures in the system.

Once the delivery system has been inserted, orientation can be monitored by screening under the image intensifier.

Orientate the proximal end of the device by viewing it directly under fluoroscopic control.

Ensure correct positioning of the longitudinal opaque braid in the seam of the device is achieved before further deployment.

11.8.1 Initiate deployment

The initial deployment sequence is illustrated in Figure 4.

Initiate deployment of the proximal end of the stent graft in the straight section of the aorta above the renals.

To begin deployment place one hand on the proximal Handle and the other on the Sheath Control.

Hold the proximal Handle firmly so that the delivery system neither rotates nor slides into or out of the patient.

Whilst watching the fluoroscopic image, start to rotate the Sheath Control anti-clockwise slowly. The sheath will withdraw in short steps punctuated by clicks.

Keep rotating the Sheath Control until the fishmouth is seen to start opening.

Align the tops of the jaws of the fishmouth so that they lie anterior and posterior.

As the sheath is withdrawn, manipulate the delivery system so that the proximal end of the stent graft is aligned with the renal arteries.

Ensure that the fishmouth will not occlude any part of the renal arteries when fully deployed and that the hooks lie infra-renally.

When satisfied with the position of the neck, rotate the Sheath Control further until it spins freely.



Warning!

Do not manipulate the aneurismal neck after this point.



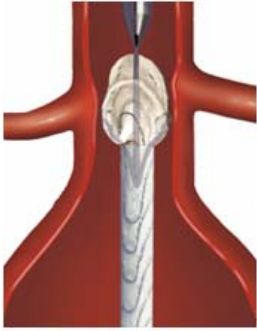

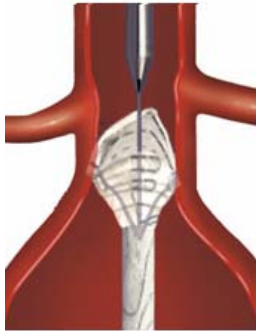


 	 	 
 <p>Warning! Do not push the whole system proximally as this may distort the device neck and in turn lead to an endoleak.</p>		
<p>Slowly rotate the Sheath Control anti-clockwise.</p>	<p>Rotate the Sheath Control until the fishmouth is seen to start opening. Align the tops of the jaws so that they lie anterior and posterior.</p>	<p>As the sheath is withdrawn, manipulate the delivery system such that the proximal end of the stent graft is aligned with the renal arteries. When satisfied, rotate the Sheath Control until it spins freely. Do not manipulate the neck after this point.</p>

Figure 4

Initial deployment sequence

11.8.2 Engage the hooks

This is illustrated in Figure 5

Stabilise the Sheath Control by holding it firmly against the exposed threads.

Rotate the Push-Rod Control clockwise while screening. Observe the fishmouth levelling.

Once the proximal end of the graft has stopped changing shape, stop rotating the Push-Rod Control (it is not always necessary to rotate it the full length of its travel).

11.8.3 Use of the Push Rods in neck angles greater than 65°

If the push rods appear to be holding the graft away from the vessel wall, operate the push rod control cautiously and monitor the effect on the mouth of the implant.

If it continues to push the graft away from the vessel wall, stop advancing the push rods. Otherwise use as normal.

If releasing the stent graft without using the push rods, position the troughs of the fish mouth so that they are infrarenal by a few mm., and firmly balloon the mouth as soon as the socket has been cannulated.

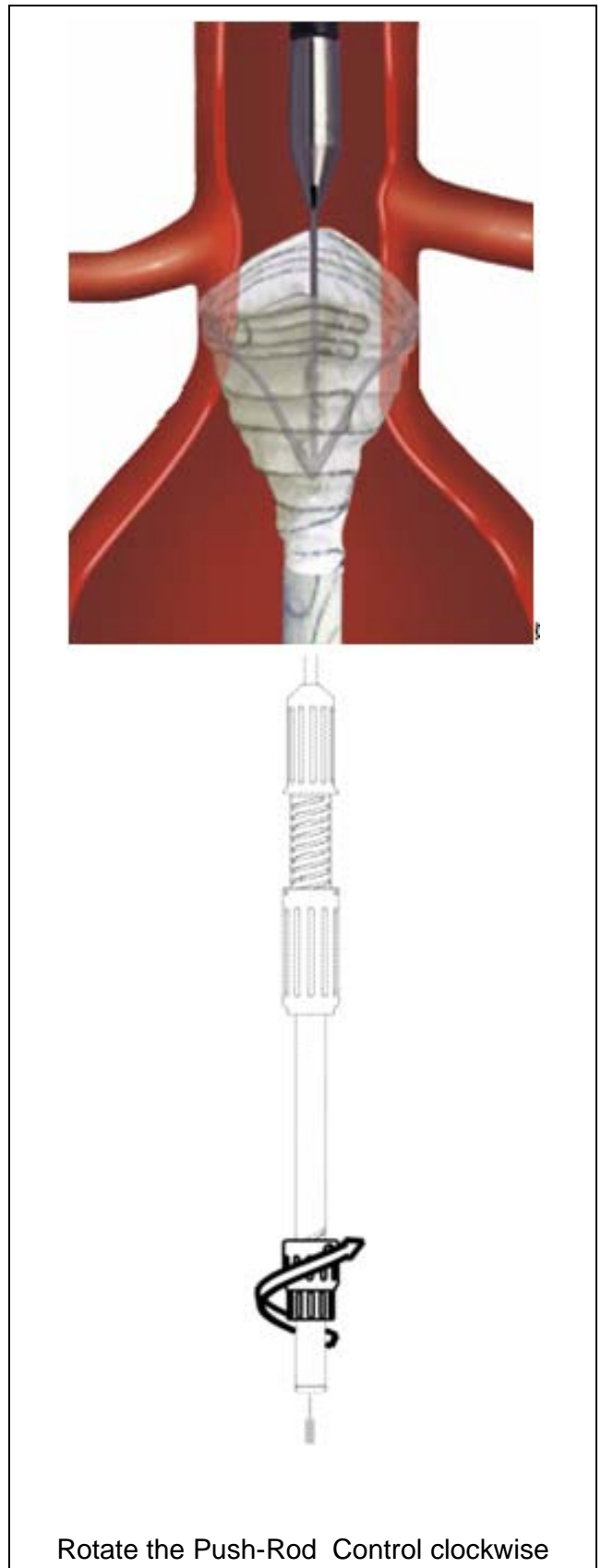


Figure 5

Engaging the hooks

11.8.4 Deploy the aortic part of the graft

Carefully pull the Sheath Control distally while holding the Push-Rod Control in position (illustrated in Figure 6).

Continue withdrawing the sheath until the socket has been fully released.

11.8.5 Disconnecting the proximal neck from the delivery system

Withdraw the angiography catheter as illustrated in Figure 6.

Remove the distal stop.

Unscrew the Disconnecter Control from the Push-Rod Control by turning it anti-clockwise six full revolutions and then pulling it distally. The delivery system is no longer connected to the proximal end of the stent graft.

11.8.6 Pushing up the stent graft

If desired, it is possible at this stage to slowly move the delivery system proximally to ensure that the distal end of the socket is within the aneurysm and the distal end of the ipsi-lateral leg is proximal to the internal iliac. This manoeuvre may also be used to relieve tension to allow the graft to fully expand.

The position of the proximal end of the stent graft should be monitored at this stage particularly when the device is being implanted into a tortuous vessel or a highly angled neck.

Note: At the discretion of the user, the delivery system may be left inside the patient whilst the socket is being cannulated as described in 11.9.1



Warning!

If the delivery system is left inside the patient whilst the socket is cannulated, the ipsilateral circulation will be occluded. It is advised that this situation should not be maintained for more than 10 minutes!

11.8.7 Deploying the Ipsi-lateral leg

Deploy the rest of the ipsilateral leg by withdrawing the Sheath Control to the distal end of the Handle (illustrated in Figure 6).

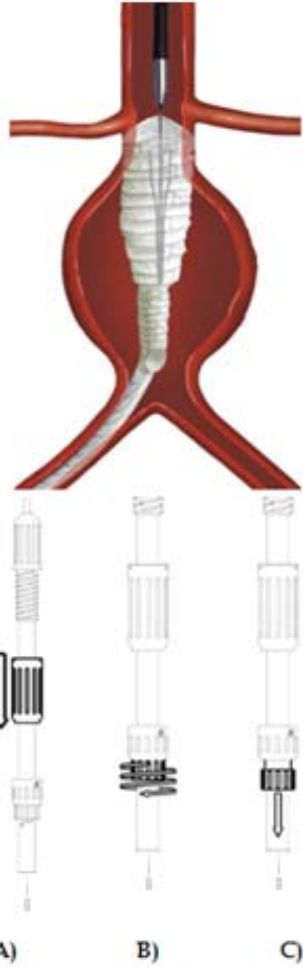
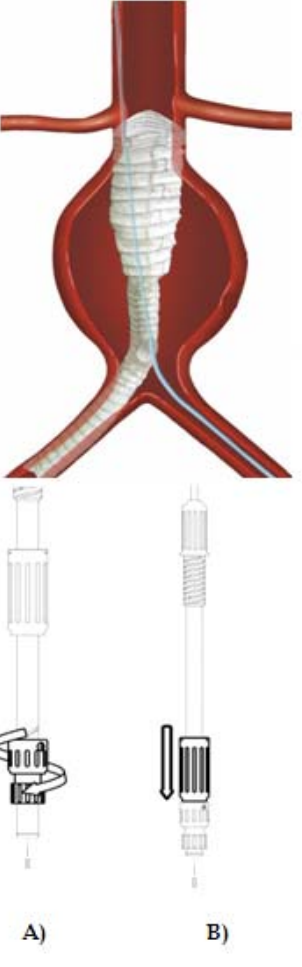
Deployment Aortic Part Main Body	Deployment Ipsi-lateral Leg
	
<p>Deploy the aortic part of the graft:</p> <ul style="list-style-type: none"> A) Pull back the sheath control until the socket has been released. Remove the distal stop. <p>Release the graft from the delivery system:</p> <ul style="list-style-type: none"> B) Turn the Disconnecter Control six full revolutions in an anti-clockwise direction C) Pull the Disconnecter Control distally. 	<p>Deploy the rest of the ipsilateral leg:</p> <ul style="list-style-type: none"> A) Rotate the Push-Rod Control anti-clockwise. B) Withdraw the Sheath Control to the distal end of the Handle.

Figure 6

Deployment of the main body

11.8.8 Resheathing and removal of the delivery system

(illustrated in Figure 7)

Ensure that the guidewire remains in place during the following steps.

Pull the delivery system back by 1cm to so that the proximal end of the delivery system is clear of the implant before resheathing.

Hold the Sheath Control stationary relative to the patient and pull the shaft of the delivery system distally until the Sheath Control is fully mated with the Handle.

Ensure that the Sheath is fully redocked and the Push Rods are captured inside the Sheath.

Withdraw the delivery system

Balloon the device as described in Section 11.10

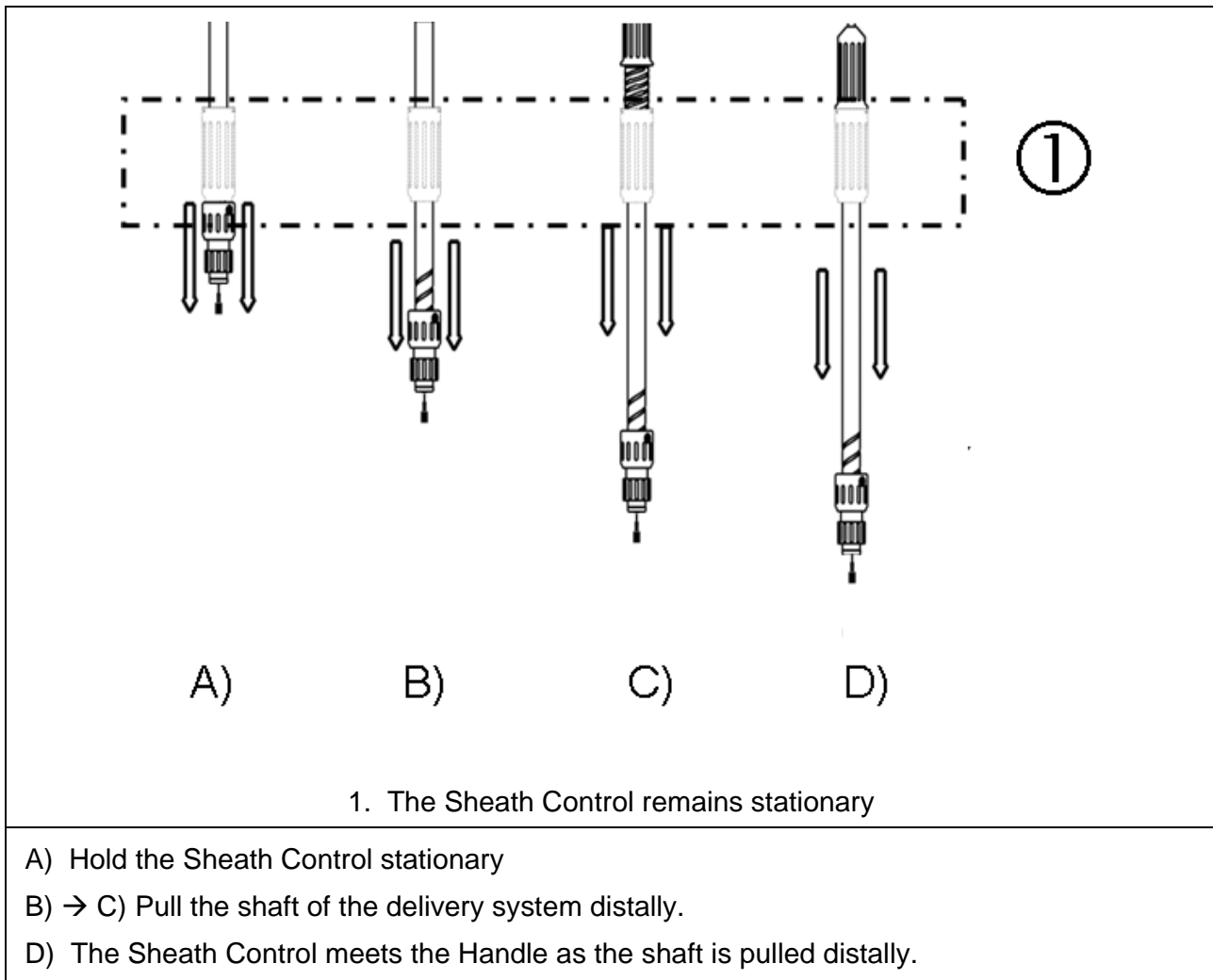


Figure 7

Resheathing and removal of delivery system

11.9 Deployment of the contralateral limb

The delivery system for the contralateral limb is illustrated in Figure 2. Prepare the delivery system as outlined in Section 11.6.

11.9.1 Insert a guidewire into the socket:

Insert a floppy guidewire through the catheter inside the contralateral sheath and into the open end of the socket. If canulation is being attempted before full deployment of the ipsilateral leg has been completed, ensure that the ipsilateral vessels do not thrombose by limiting the time of occlusion to 10 minutes. Gently push the guidewire up through the main body of the graft and into the thoracic aorta.

Ensure that the catheter is well advanced inside the implant, and exchange the floppy guidewire for a stiff wire, such as a Lunderquist™ wire. Remove the catheter and contralateral sheath.

Mark the end of the wire on the table and clamp in position if necessary to ensure that no movement towards the heart is possible, as this may induce stroke or cardiac arrhythmias.

Ballooning the proximal neck of the device, as described in Section 11.10, may be desirable at this stage.



Warning!

Take care not to insert the Guidewire between the stent graft fabric and a suture or wire support otherwise the delivery system will snag.



Warning!

The position of the neck is not considered fixed until the barbs have been engaged after ballooning. Take care to ensure that the proximal neck is not displaced, proximally or distally.

11.9.2 Position the delivery system

Note: A radiopaque ring on the socket marks the lowest point at which the proximal rung of the plug-in can be positioned.

Appropriately lubricate the flexible tip.

Ensure that the sheath control is at its most proximal position by ensuring that the proximal end of the sheath is in contact with the tip connector (stainless steel section of the flexible tip).

Grip the sheath control and blue delivery system tube together with one hand, to prevent the sheath control from sliding backwards, while introducing the delivery system over the stiff guidewire and into the socket.

If resistance is felt, remove delivery system and check that the end of the sheath has not been pushed back and exposed during introduction.

If resistance is encountered when inserting the device, particularly if the delivery system is seen to kink in the vessel, **DO NOT USE UNDUE FORCE**. Withdraw the device and dilate the vessel using conventional dilation techniques such as a Coons dilator.

Minimize torquing the delivery system when inserting to reduce the stress on the catheter tip joint and other structures in the system.

Ensure that the entire Radiopaque Marker at the proximal end of the plug-in is positioned above the radiopaque ring at the proximal end of the socket. The most distal part of the marker on the plug-in should be in line with the radiopaque marker on the socket.

The distal end marker on the plug-in must be properly sited in the contralateral iliac artery without occluding the internal iliac vessel.

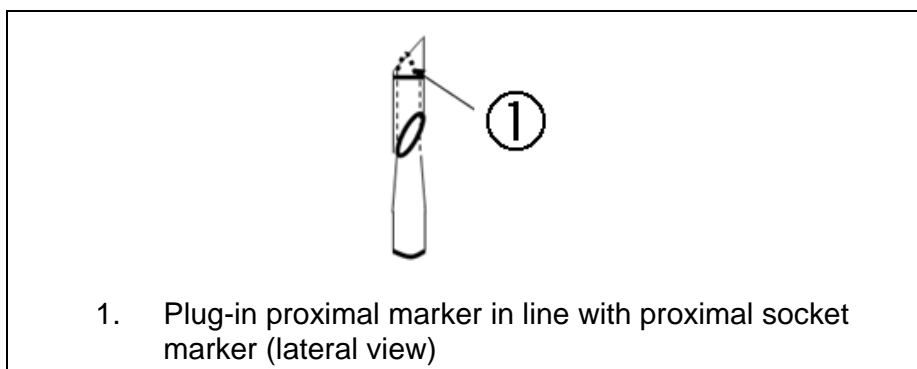


Figure 8

Plug-in distal end marker

11.9.3 Deploy contralateral limb

(Illustrated in Figure 9)

Grip the shaft of the delivery system to stabilise it against the patient.

Pull back the Sheath Control until the device is fully deployed.

Unscrew the Disconnecter Control from the Push-Rod Control by turning it anti-clockwise six full revolutions and then pulling it distally. The delivery system is no longer connected to the proximal end of the stent graft.

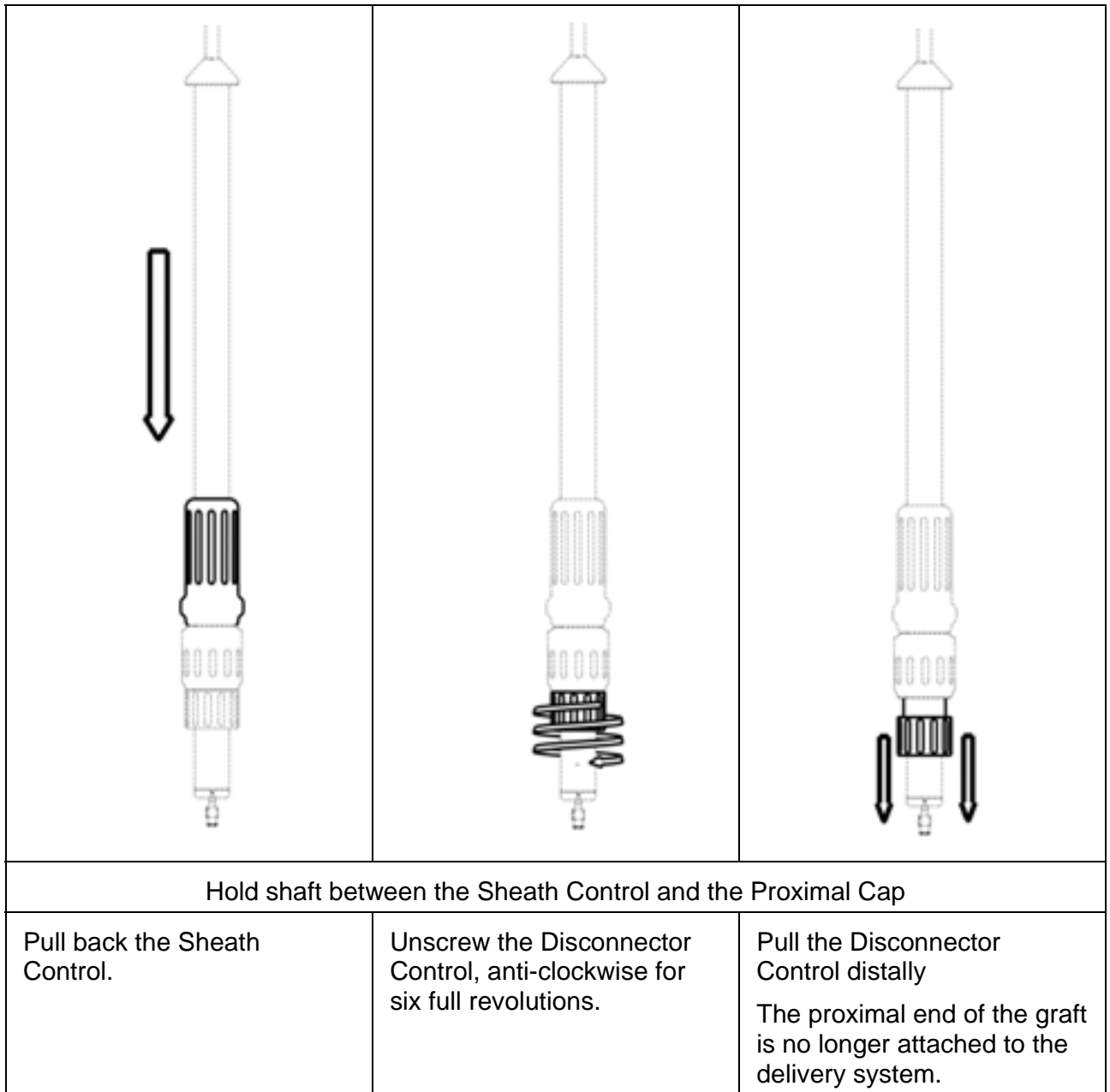


Figure 9

Deployment of the Contralateral limb

11.9.4 Remove delivery system

(Illustrated in Figure 10)

Pull the delivery system back by 1cm to so that the proximal end of the delivery system is clear of the implant before resheathing.

Hold the Sheath Control still against the patient and draw the delivery system back through the sheath.

Ensure that the Sheath is fully redocked and the Pusher Rods are captured prior to withdrawal of the delivery system.

Ensure the guidewire remains in place in the patient.

If not already removed, complete the deployment of the Body Component as described in Sections 11.8.4 to 11.8.6.

Balloon the device as described in Section 11.10.

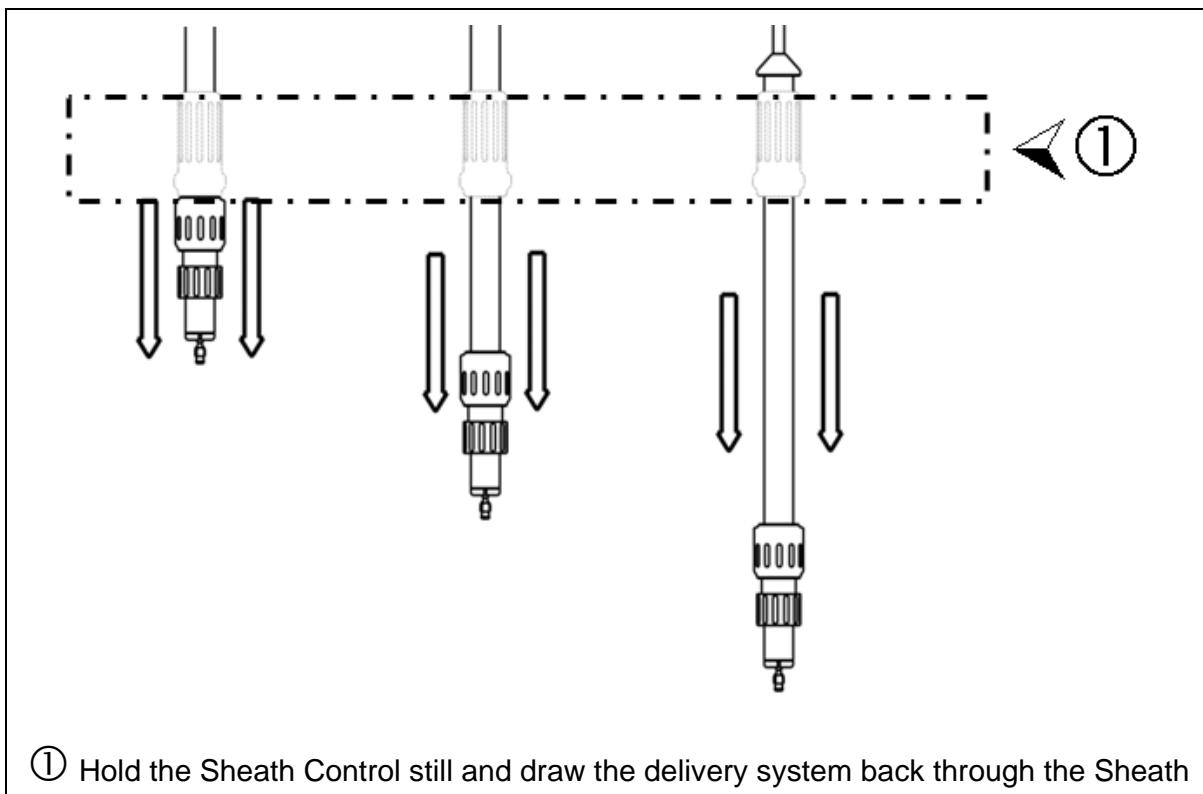


Figure 10

Removal of the contralateral limb delivery system

11.10 **Ballooning**

Insert a suitable sheath over the guidewire in the ipsilateral limb to allow insertion of the balloon.

Insert an oversize moulding balloon over the guidewire. Position the balloon at the landing site in the proximal aorta.

Inflate the balloon to seal the device fully. Deflate the balloon and move it down within the graft. Repeat ballooning process down the length of the graft, finishing at the distal landing site of the ipsilateral limb.



Warning!

Exercise care when ballooning. Close to the landing sites ballooning can displace thrombus and ballooning the aortic body within the aneurysm may displace the implant.

Remove the balloon, leaving the guidewire in place.

Repeat the ballooning process for the socket and contralateral limb to straighten and ensure seal.

Insert a diagnostic catheter over the guidewire, remove guidewire and perform completion angiography. Ensure the graft, renal arteries and hypogastric arteries are patent and that there is no evidence of endoleak.

Remove catheters from both femoral arteries and close the wounds in the normal manner.

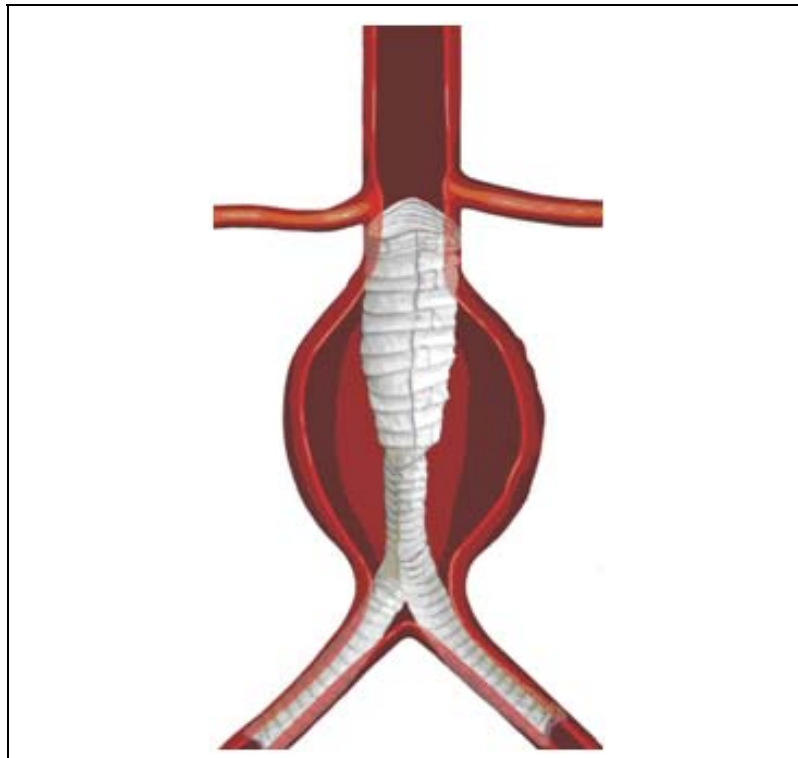


Figure 11

Completed Aorfix™ deployment

12 Use of proximal, distal extenders and Converters

12.1 *Deployment of Proximal Extenders (Cuffs)*

Information about the Aorfix Proximal Cuff

Note: Deployment generally follows the description in 11.8 above, but be advised of variations listed below.

The cuff is supplied in the same delivery system as the main aortic implant. It has an outside diameter of 22 French. (7.6mm).

The cuff has a length of 38mm and is required to have a minimum overlap with the primary graft of 20mm. Thus the cuff is able to extend the primary graft proximally by a maximum of 18mm.

The diameter of the cuff should be the same as the diameter of the primary graft to ensure the highest attachment strength between the cuff and the primary graft.

The cuff is intended to be used after the primary graft has been deployed to correct mis-positioning of the primary graft.

The cuff is a short implant which has four pairs of barbs, a seam and a fishmouth shape identical to the primary graft. The fishmouth at the proximal end of the cuff should be deployed with the same orientation as that of the primary graft.

The cuff has radio-opaque marker wires around the proximal and distal circumferences and down its seam.

The apex of the fishmouth which contains the longitudinal seam is slightly stiffer than the opposite apex and tends to lie slightly higher in the artery. The cuff can be placed with the seam lying either anteriorly or posteriorly.

The cuff is prepared identically to the primary graft and is introduced over a guidewire.

The push rod control should not be used. The effect of this control is to move the entire cuff proximally.



Warning!

The distal end of the cuff also has a fishmouth shape, the proximal part of which deploys shortly after the distal end of the proximal fishmouth. This makes repositioning the cuff impossible once half the cuff has been deployed.

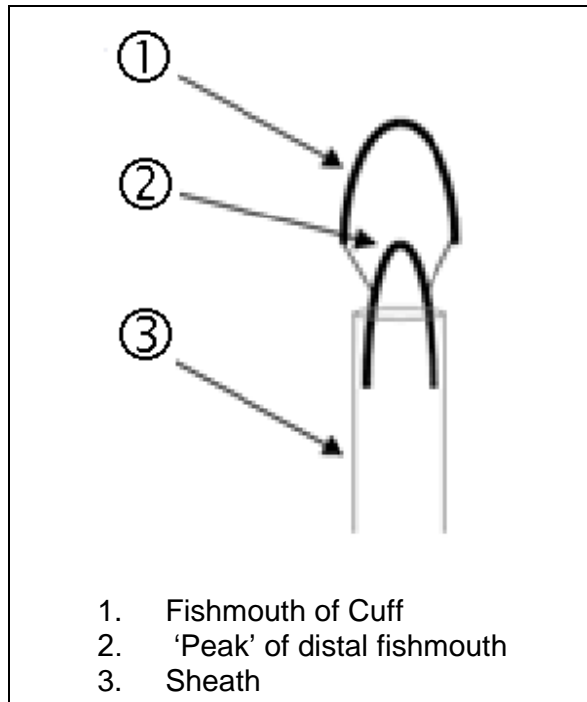


Figure 12 Cuff Deployment

Deployment of the cuff occurs very rapidly. The cuff is fully deployed by the sheath control while it is being rotated past the click stops. It is not possible to slide the sheath control after the clicking action has been completed.

12.2 Positioning and Deployment

The cuff is intended to provide stent-graft coverage of an additional, proximal portion of the aorta. The length of additional coverage required (the extension, L) should be measured using appropriate diagnostic angiographic techniques; frequently this will be the distance from the distal margin of the distal renal artery to the trough of the fishmouth of the primary implant.

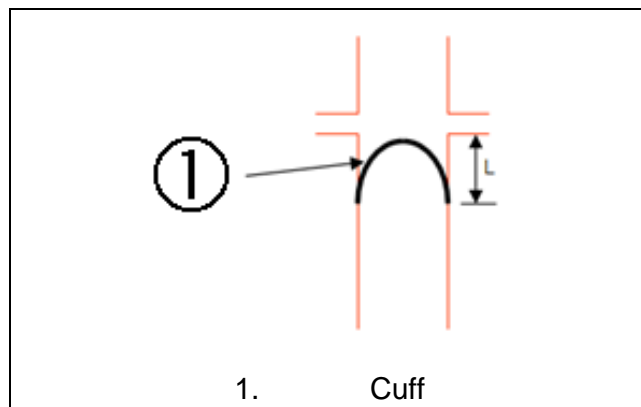


Figure 13 Proximal Part of Cuff

The cuff in its delivery system should be introduced over the guidewire and advanced until the most proximal part of the cuff, visible through the sheath of the delivery system, lies proximal to the apices of the primary graft by the required extension length (L). It may be helpful to draw a mark on the fluoro screen that indicates the intended position of the apex of the cuff.



Warning!

It is essential that the extension distance is measured apex to apex rather than trough to trough. This is because the troughs of the cuff move slightly proximally during final ballooning.

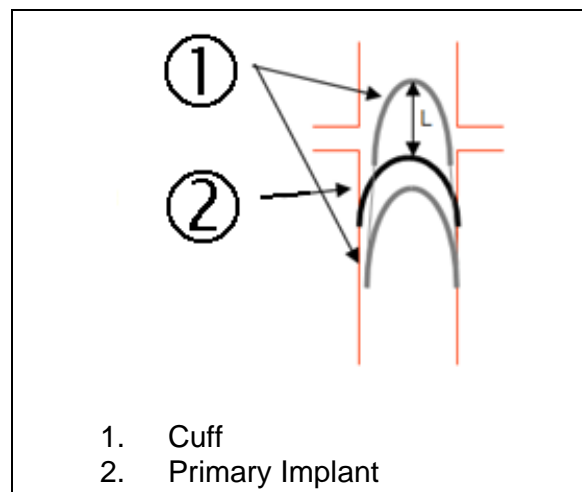


Figure 14 Cuff Deployment

Exact orientation of the fishmouth of the cuff is difficult to achieve until it has been slightly deployed. Keeping the delivery system in place longitudinally, start to operate the sheath control by rotating it anti-clockwise one click at a time. The cuff will start to deploy at the 6th or 7th click and as soon as the implant is seen to start to emerge from the sheath, rotation of the sheath control should be halted and the orientation of the cuff should be checked.

The posterior and anterior apices should be adjusted to overlay each other by rotating the handle of the delivery system. Ensure that the proximal tips of the apices are aligned with the desired landing point.

Continue to operate the sheath control, rotating anti-clockwise after each click, adjust the alignment and position of the cuff.

The cuff will be fully deployed 6 or 7 clicks after its first movement.

If the alignment of the apex of the cuff is in the desired position, do not operate the push rod control.

Operate the push rod **release** control to disconnect the delivery system from the cuff.

Remove the delivery system by pulling the blue handle of the delivery system distally by 10mm. Then hold the sheath control stationary against the patient and pull the blue handle of the delivery system slowly distally, monitoring the movement of the tip of the delivery system through the patient using fluoro.

Note: On delivery system withdrawal, it may be necessary to rotate the sheath control as the shaft of the handle is pulled distally out of the patient.

Balloon the cuff using an over-sized moulding balloon such as a Coda™ or Reliant™.

12.3 *Distal Extenders*

Distal extenders for extending the distal legs, are supplied pre-packed in delivery systems. The distal extender system is identical to the plug in leg delivery system.

The position of the radiopaque markers are shown in Figure 15 below.

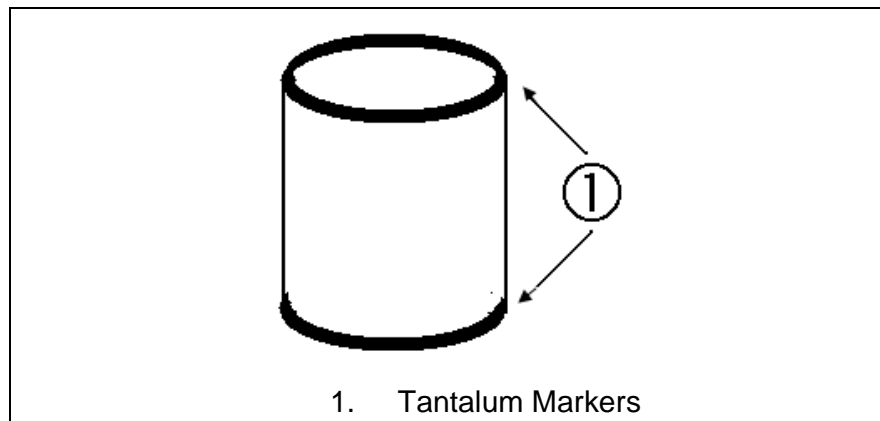


Figure 15

Tantalum markers on distal extenders

Distal extenders are 51mm long or 82mm long and are parallel-sided tubes.

Distal extenders have the highest attachment strength when mated with a leg OF THE SAME DIAMETER AS THE EXTENDER.

Distal extenders require a minimum overlap with the primary implant of 20 mm.

Note: Note that both ipsilateral and contralateral legs of the primary graft are 12mm in diameter apart from the distal 40 mm which flare out to the nominal distal diameter of the implant. The most distal 20 mm of the implant have the nominal distal diameter of the implant. See Figure 16.

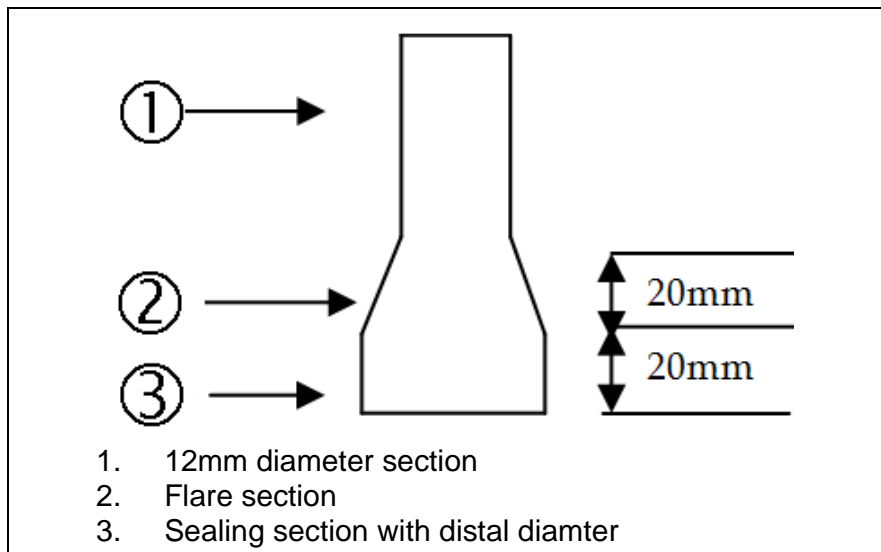


Figure 16 *Ipsilateral and contralateral leg profile*

For example an implant with an attached ipsilateral leg of 80 mm length and 20 mm distal diameter will have 40 mm of proximal leg that is 12mm in diameter, followed by a 20 mm flared section which dilates distally from 12 mm to 20 mm, which, in turn, is followed by the final, distal, section of the implant which is parallel sided and has a diameter of 20 mm.



Warning!

A large diameter distal extender can occlude a limb of the primary graft if it is placed within the 12 mm section of the limb of the primary graft. This situation will occur if the overlap of the graft and extender is more than 40 mm.

Prepare the device and delivery system as described in Section 11.6.

Perform appropriate angiograms to establish landmarks such that the target deployment region may be readily identified.

Distal extenders are deployed as described in Section 11.9.

12.4 Use of Converter

Converters are used after implantation of the bifurcated body, if implantation of the contralateral limb proves impossible. The system converts the bifurcated main body into an aorto uni-iliac stent graft. If revising to a mono-iliac approach, use a femero-femoral cross-over graft to perfuse the contralateral side and occlude the contralateral common iliac artery. The converter delivery system is identical to the body delivery system.

Radiopaque markers are positioned as shown in Figure 17 below.

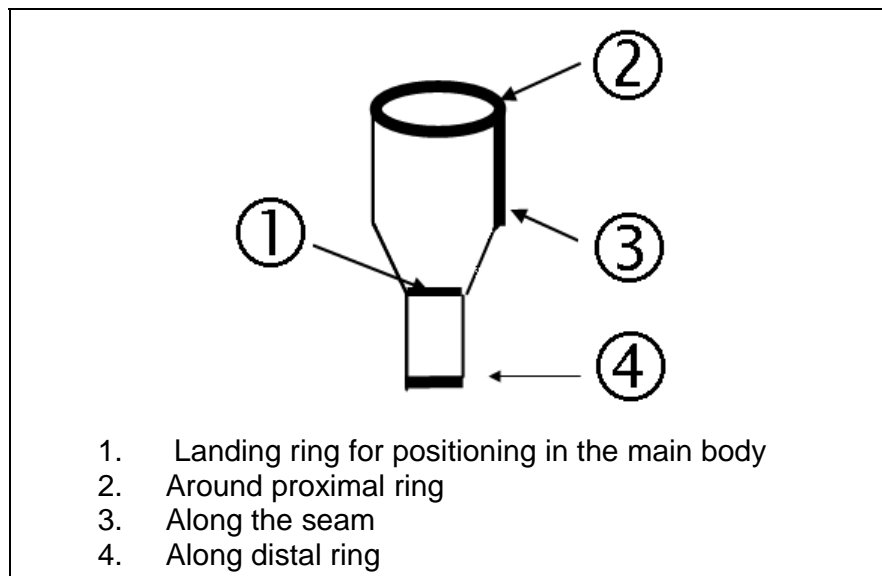


Figure 17 *Position of tantalum markers on the converter*

Prepare the device and delivery system as described in Section 11.6

Introduce the delivery system over the guidewire so that the radiopaque ring on the contralateral limb of the bifurcated body is laterally aligned with the radiopaque ring in the centre of the converter.

Deploy the converter as described in Section 11.8.

13 Technical training

Lombard Medical supports all users of the stent graft system in order to realise its optimum performance. Support will be in the form of technical training given by clinicians who have experience of the system and by the provision of training materials, as required. Details of support are available from your Lombard Medical distributor on request.

Lombard Medical requires that medical practitioners using the system are adequately trained in surgical and in particular endovascular techniques.