Lombard MEDICAL

AORFIX™

Endovascular Stent Graft

Instructions for Use

Aorfix™ AAA Flexible Stent Graft System with

AorFlex™ Delivery Device

ATTENTION

Read these Instructions for Use before attempting to use the Aorfix™ AAA Flexible Stent Graft System with

AorFlex™ Delivery Device.

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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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.

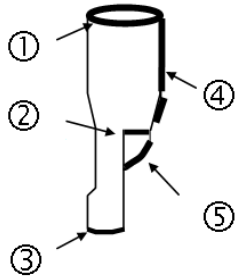
This product is designed and intended for single use only. The delivery system and graft cannot be re-sterilised. The potential for patient cross contamination and mechanical failure of the product makes it inappropriate for multiple uses.

2 Product Description

2.1 Stent-graft

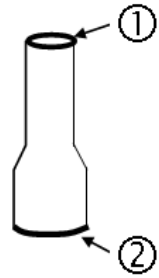
Aorfix™ is a two-part modular implant comprising a bifurcated main body section and a straight contralateral limb section (the “plug-in”). The main body section bifurcates into a full-length ipsilateral iliac section and a contralateral short leg mating section (the “socket”). The plug-in is mated intra-operatively 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 catheter for the main body section has a hydrophilic coating on its outer surface. 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.



Main Body

1. Around proximal ring
2. Landing marker for plug-in
3. Around distal end of ipsilateral end
4. Along seam of straight section
5. Around distal end of socket



Contralateral Plug-in

1. Around proximal ring
2. Around distal end

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), Polyether Block Amides (PEBA), Platinum-Iridium Alloy, Photo-reactive polyvinylpyrrolidone copolymer, Polyethylene terephthalate (PET).

For the main body delivery system, the maximum effective length (tip to handle) is 586mm. 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 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 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, including:
  - Aortic neck landing zone diameters with a range of 19mm to 29 mm
  - Common iliac landing zone diameters with a range of 9mm to 19mm
- 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, including:
  - Aortic neck landing zone diameters with a range of 19mm to 29 mm
  - Common iliac landing zone diameters with a range of 9mm to 19mm

4 Contraindications

The Aorfix™ AAA Flexible Stent Graft System is a contraindicated in:

- Patients who have a condition that threatens to infect the graft.
- Patients with known allergies or sensitivities to the implant materials (including, polyester, Nitinol and tantalum)

5 Patient Selection, Treatment and Follow-up

Key anatomic elements that may affect successful exclusion of the aneurysm include short proximal aortic neck (Refer to section 5), pre-aneurysmal neck, thrombus and/or calcium formation at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interfaces. Irregular calcification and/or plaque may compromise the fixation and sealing of the implantation sites. Necks exhibiting these key anatomic elements may give rise to graft migration or compromised durability.

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 or delivery system – see Section 2.
- 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 12, 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.
- Patients with a history of allergic reaction to hydrophilic coatings may require additional management or selection of an alternative device.
- Do not occlude the renal arteries; this may lead to renal failure.
- 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 3.0 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 0 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 (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field less than or equal to 10 T/m.
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of:
- 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
- 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

3.0 Tesla

In non-clinical testing with body coil excitation, the Aorfix™ Stent Graft produced a differential temperature rise of less than 1.0°C when exposed to a maximum specific absorption rate (SAR) of 3.5 W/kg for 15 minutes of scanning in a 3.0-Tesla MR system (Siemens Trio, SYNGO MR A30 4VA30A software, Munich, Germany). Scaling of the SAR and observed

heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

1.5 Tesla

In non-clinical testing with body coil excitation, the Aorfix™ Stent Graft produced a differential temperature rise of less than or equal to 1.0°C when exposed to a maximum specific absorption rate (SAR) of 1.5 W/kg for 15 minutes of scanning in a 1.5- Tesla MR system (Siemens Espree, SYNGO MR B17 software, Munich, Germany).

Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than or equal to 1.0°C.

Caution:

The RF heating behavior does not scale with static field strength. Implants which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

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. For additional information and the list of available model numbers, please refer to the following website address:

http://www.lombardmedical.com/files/pn02604b_sizing_insert-uk__3_.pdf. 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.		

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),
- Standard surgical equipment.

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.

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

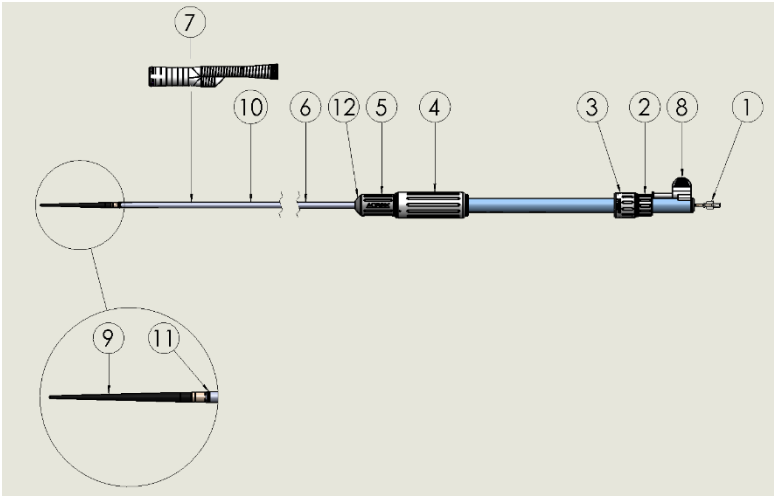
Using a sterile heparin/saline solution, flush the central lumen of the delivery system via the. luer lock. Refer to Figure 2.

Flush the graft.

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

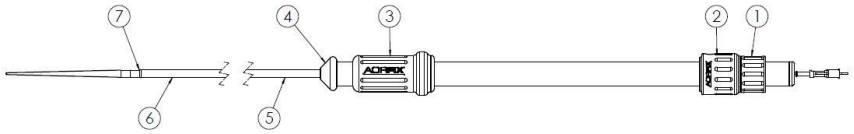
Flush with sterile heparin/saline solution via the luer lock until the solution has been seen to wet the entire graft.

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



1. Luer Lock
2. Disconnector control
3. Push-rod control
4. Sheath control
5. Handle
6. Uncoated braided sheath with links
7. Aorfix™ stent graft
8. Distal Stop
9. Flexible tip
10. Hydrophilic coated braided sheath with links
11. Radiopaque marker band (Platinum Iridium) on sheath tip
12. Seam orientation

Figure 2: Main Body Delivery System



1. Disconnector Control
2. Push-Rod Control
3. Sheath Control
4. Proximal Cap
5. Uncoated Braided Sheath
6. Hydrophilic Coated Braided Sheath
7. Radiopaque Marker (Platinum Iridium) on Sheath Tip

Figure 3: Contralateral limb delivery system

11.7 Pre-deployment

11.7.1 Prepare the external iliac arteries for the delivery systems:

Surgically expose both superficial femoral arteries. Place slings around a sufficient length of artery to enable access for appropriate clamps.

After use of vascular access instruments, insert floppy guidewires and then a 4 or 5 French catheter, into the lowest parts of both of the exposed arteries. Push each wire up to the region of the renal arteries in the aorta.

On the ipsilateral side, exchange the floppy guide wire for a 0.035" diameter, 260 cm long extra stiff guide-wire, such as a Lunderquist™ (Cook, Inc) and advance it well into the thoracic aorta. 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 embolic showers, cardiac arrhythmias or stroke.

In the contra-lateral artery, remove the guide wire to open the lumen of the catheter. [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.]

11.7.2 Angiography

Perform an appropriate angiogram to establish landmarks such as the following to be readily identified:

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

Be aware that in tortuous anatomy, significant deformation of the vessels is likely to take place on insertion of the Aorfix™ delivery system. It is usual to defer most angiography until after the delivery system is in place.

Leave the angiographic catheter in the best position to visualize the renal arteries to update the position of Aorfix™ during deployment

Center the renal arteries in the field of view of the image intensifier.

In cases with angled or tortuous necks, the plane containing the peri-renal aorta is usually significantly angled to the AP view.

It is essential that an accurate oblique angle is calculated that will place the fluoro perpendicular to the renal arteries. In this view, both left and right renal arteries should be seen at the very edge of the aorta. The oblique angle can be calculated from 3-dimensional CT reconstruction.

It is also important to select an appropriate cranio-caudal (CC) angle for fluoroscopy as the aortic neck is usually angled antero-laterally. The CC angle will maximize the visible length of the neck to allow placement as precise as possible around the renal arteries.

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

11.8 Deployment of main body component

Wet the external surface of the delivery system catheter to activate the hydrophilic coating.

Prior to insertion of the delivery system, orientation of device can be determined by identifying the seam orientation marker on the handle of the delivery system and rotating the delivery system so that the mark is anterior. In this orientation, the jaws of the mouth of the implant can be positioned around the renal arteries.

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

Insert the delivery system over the stiff guidewire so that the proximal end of the implant is initially positioned proximal (cephalad) 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, orientate the proximal end of the stent graft by viewing it directly under fluoroscopic control. It is helpful to identify the oval marker for the contralateral gate, or the irregular RO marker line that lies within the seam of the aortic component, as both should lie on the anterior face of the graft. The anterior position of these structures can be checked by using a more lateral view, or, if the position of the fluro must be held, rotation of the delivery system towards the patient's left side should be accompanied by those markers also moving to the patient's left.

Ensure correct anterior positioning of the irregular, longitudinal opaque braid in the seam of the implant 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.

While watching the fluoroscopic image, start to rotate the Sheath Control anti-clockwise slowly. The sheath will withdraw in short steps, signaled by distal movement of the RO marker ring at the tip of the sheath and accompanied by clicks.

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

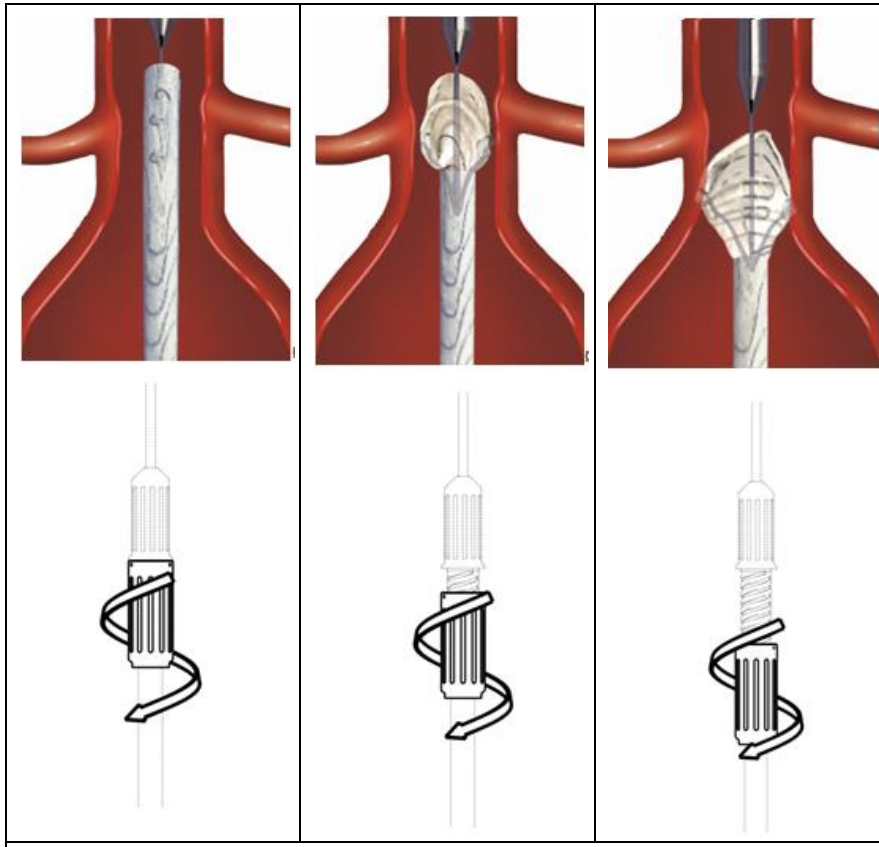
Align the tops of the jaws of the fishmouth so that they lie anterior and posterior.

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 aneurysmal neck after this point.



Warning Do not push the whole system proximally as this may distort the device neck and in turn lead to an endoleak.		
Slowly rotate the Sheath Control anti-clockwise.	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.	As the sheath is withdrawn, manipulate the delivery system so 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.

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.

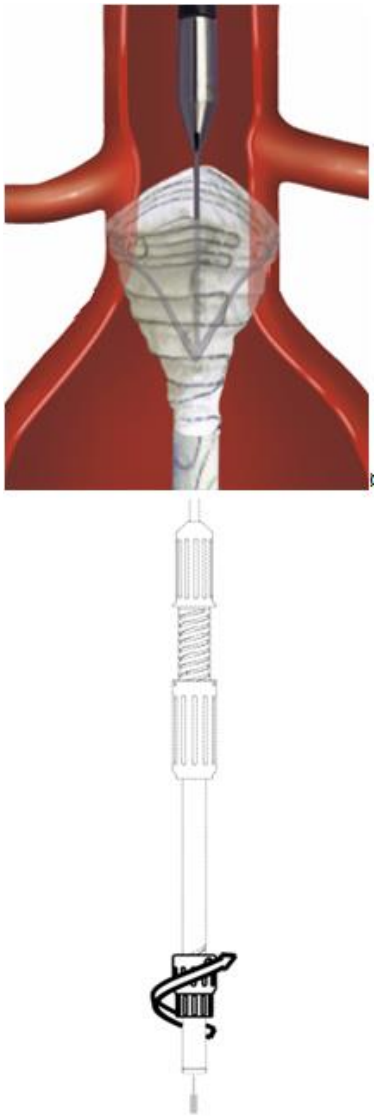


Figure 5: Engaging the hooks

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.

Remove the distal stop.

Unscrew the Disconnector 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 maneuver 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. Note that the hydrophilic coating on the outside of the catheter may make the device more prone to being pushed out of the patient by arterial pressure.

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).

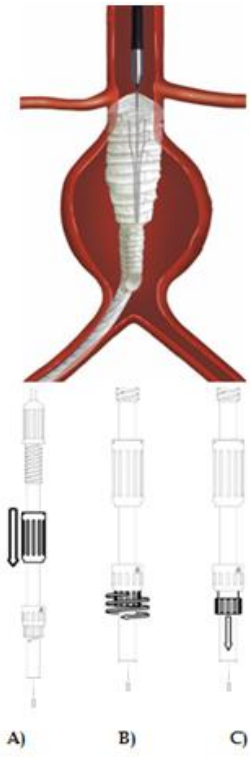
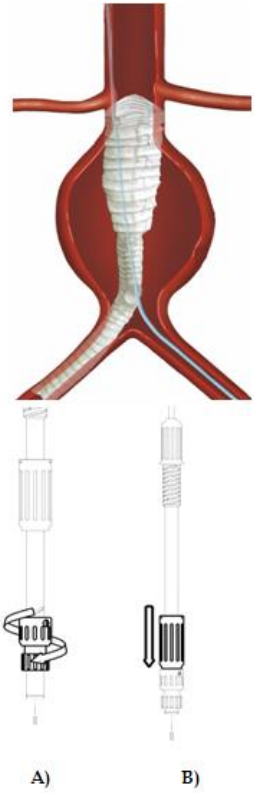
Deployment Aortic Part Main Body	Deployment Ipsi-lateral Leg
	
Deploy the aortic part of the graft: A) Pull back the sheath control until the socket has been released. Remove the distal stop. Release the graft from the delivery system: B) Turn the Disconnector Control six full revolutions in an anti-clockwise direction C) Pull the Disconnector Control distally.	Deploy the rest of the ipsilateral leg: 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.

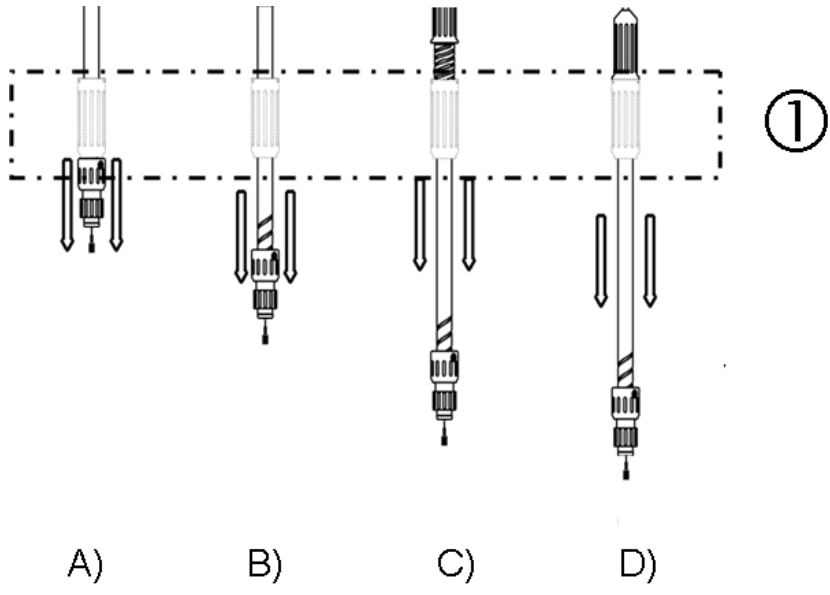
Pull the delivery system back so that the proximal end of the delivery system is clear of the implant before resheathing.

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



1. The Sheath Control remains stationary

A) Hold the Sheath Control stationary

B) → C) Pull the shaft of the delivery system distally.

D) The Sheath Control meets the Handle as the shaft is pulled distally.

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 3. 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. (Illustrated in Figure 8)

Appropriately lubricate the flexible tip.

Wet the external surface of the delivery system catheter to activate the hydrophilic coating.

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.

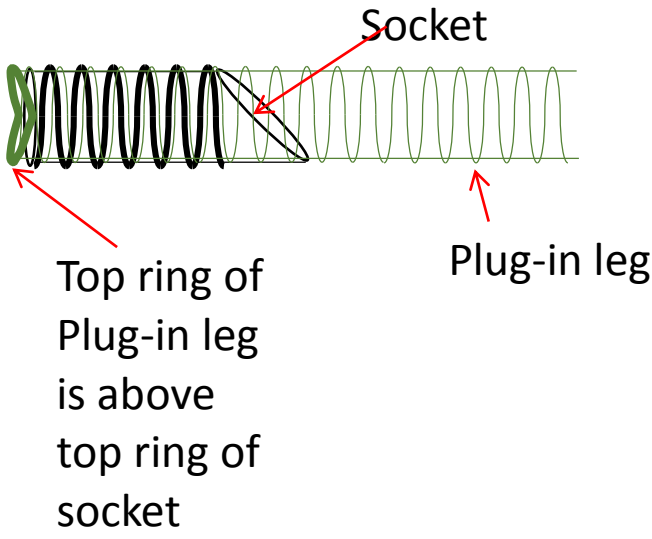


Figure 8: Location of Plug in Leg to Contralateral Socket

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 Disconnector 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.

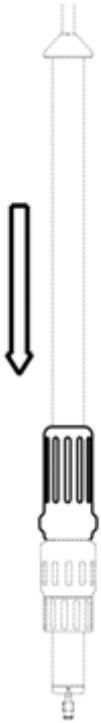
		
Hold shaft between the Sheath Control and the Proximal Cap		
Pull back the Sheath Control.	Unscrew the Disconnector Control, anti-clockwise for six full revolutions.	Pull the Disconnector Control distally The proximal end of the graft is no longer attached to the delivery system.

Figure 9: Deployment of the Contralateral limb

11.9.4 Remove delivery system

(Illustrated in Figure 10)

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

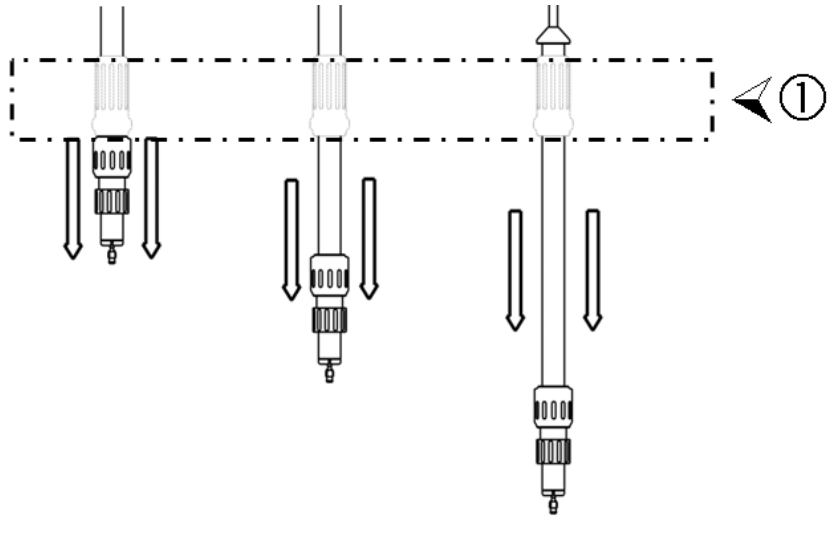
Hold the Sheath Control still against the patient and draw the delivery system back through the sheath.

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



① Hold the Sheath Control still and draw the delivery system back through the Sheath

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.

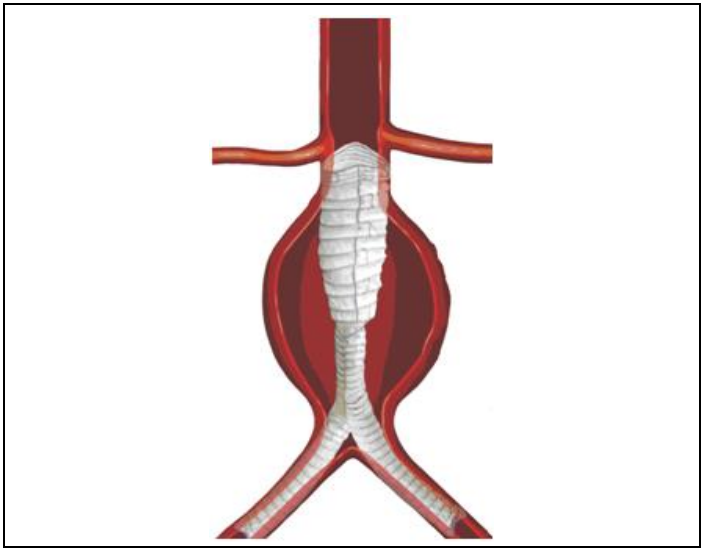


Figure 11: Completed Aorfix™ deployment

11.11 Proximal Cuff

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 and includes a hydrophilic coating. 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.

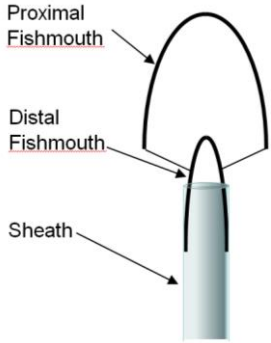


Figure 12: Proximal Extender, Part Deployed

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.

11.12 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.

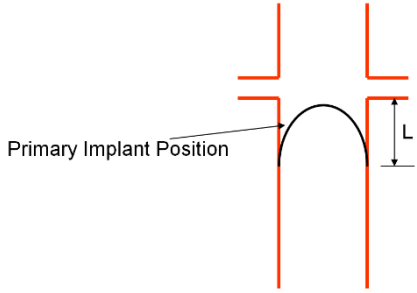
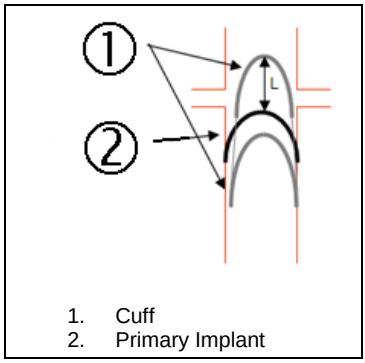


Figure 13: Measurement of malpositioned Primary Graft

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.



1. Cuff
2. Primary Implant

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 3rd or 4th 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.

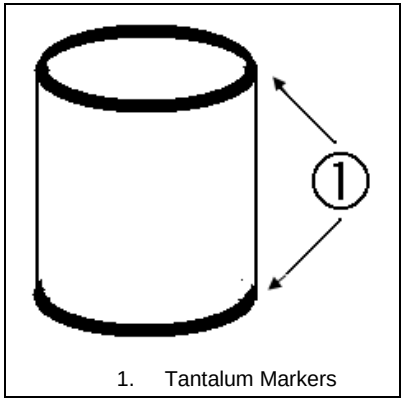
Note:	On delivery system withdrawal, it may be necessary to rotate the sheath control as the shaft of the handle is pulled distally out of the patient.

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

11.13 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.



1. Tantalum Markers

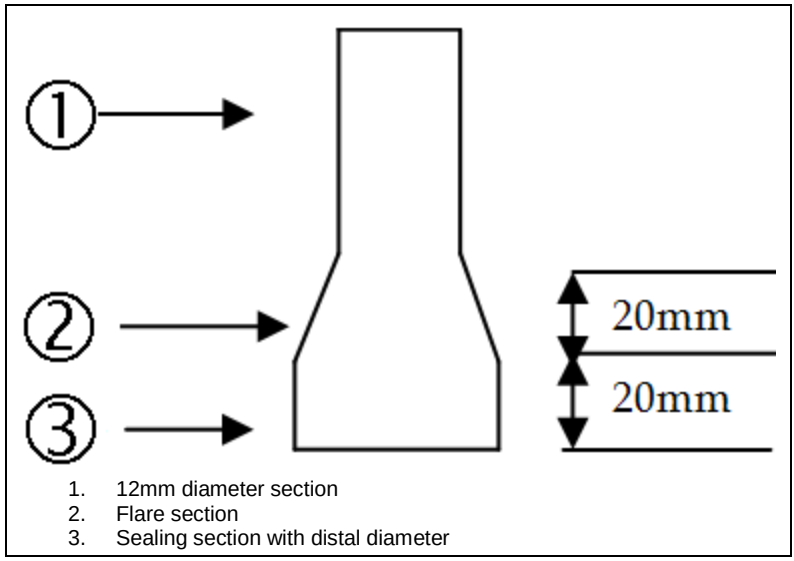
Figure 15: Tantalum markers on distal extenders

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:	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.



1. 12mm diameter section
2. Flare section
3. Sealing section with distal diameter

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 11.8

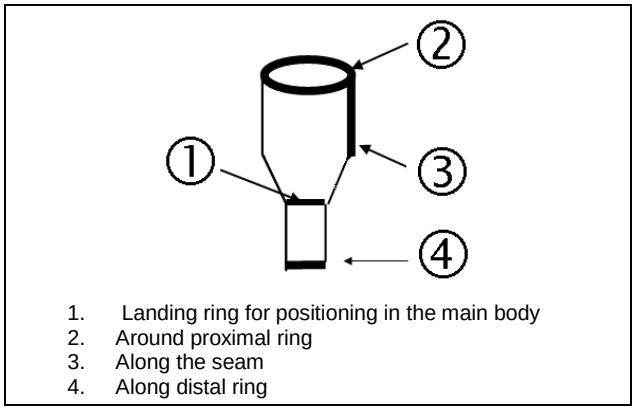
Perform appropriate angiograms to establish landmarks such that the target deployment region may be readily identified.

Distal extenders are deployed as described in Section 11.8.

11.14 Uni-Iliac 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.



1. Landing ring for positioning in the main body
2. Around proximal ring
3. Along the seam
4. Along distal ring

Figure 17: Position of tantalum markers on the converter

Prepare the device and delivery system as described in Section 11.8

The converter is supplied in the same delivery system as the main aortic implant and includes a hydrophilic coating.

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.

12 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.

13 Disposal

At the end of the procedure care must be taken to ensure safe disposal of the Aorfix™ AAA Flexible Stent Graft System. Each operating team must ensure local and national regulatory requirements for the disposal of contaminated clinical waste are adhered to.

14 Symbol Legend

Symbol	Definition
	Do not re-use, single use only
	Catalogue number
	Batch Code
	Use-by Date
	Consult instructions for use
 0297	CE mark Notified Body No. 0297
	Sterilized using ethylene oxide
	Non-pyrogenic
	Do not use if package is damaged
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Manufacturer
	MR Conditional (Applicable to implant only)