Vascular Flow Technologies

Technical Information Brochure

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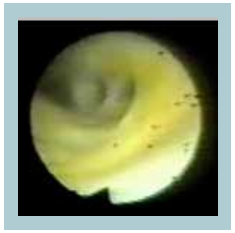
The Concept: Spiral Laminar Flow™

The Natural Blood Flow Pattern

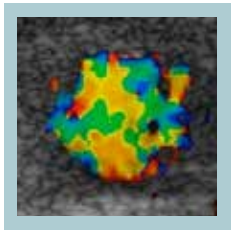


Blood leaves the left ventricle of the heart, ascending into the aortic arch with a distinctive single spiral flow pattern[1] called Spiral Laminar Flow™ (SLF™). This flow pattern has been reported by numerous observers and is propagated within the arterial system by the spiral configuration of the arterial luminal layers[2].

The Physiological Benefit of SLF™

SLF™ reduces static wall pressures at the arterial intimal layer, providing efficient and effective blood flow throughout the vasculature[3]. This forward directed rotationally stable spiral flow transports blood through the tapering and branching vascular tree while maintaining cohesion with less energy. Studies have shown where SLF™ is lacking, arterial disease severity and progression are greater[4].

Disruption of SLF™ - Turbulent Flow



If SLF™ is disrupted, through the progression of arterial disease, trauma or use of a plain, straight tubular prosthetic implant, turbulent blood flow results. Endothelial cells in native arteries experiencing this turbulence at, or beyond, the distal anastamosis, trigger flow mediated signals that lead to vascular remodelling. This remodelling, caused by smooth muscle cells, creates neointimal hyperplasia (NIH) leading to restrictions in blood flow over time and eventually results in vascular complications[5].

SLF™ - The Technology

Vascular Flow Technologies has developed a platform technology that restores the blood outflow pattern from arterial implants to its natural state – Spiral Laminar Flow™.
A precisely engineered flow inducer imparts a rotational force on the blood flow.

SLF™ Patient Benefit

With the reduction in downstream NIH leading to reduced disease severity and progression in native vessels, the patient should enjoy the benefits of a longer device patency and the associated improvement in quality of life.

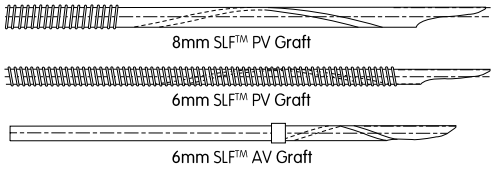
Implant Considerations for the Spiral Flow™ Graft

Special Features of the Spiral Flow™ Graft

Spiral Flow™ Grafts are unique in their construction and the distal portion differs from all other prosthetic vascular grafts.
Near the distal end of the graft is a ridge that remodels the turbulent flow inside the graft into the natural pattern of blood flow. It is called a **SPIRAL FLOW™ INDUCER**. The inducer is formed by injection molding of Chronoflex 80® polyurethane onto the outside of the graft. This creates an ePTFE helical form within the graft lumen.

Spiral Flow™ Graft Construction

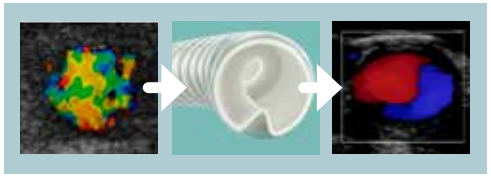
The distal end of all Spiral Flow™ Grafts features a Spiral Flow™ Inducer Segment



and a Distal Cuff separated by a 3-5mm area called the Trim Gap.

What Makes The Spiral Flow™ Graft Different?

The Spiral Flow™ Graft remodels the turbulent flow pattern and pressure created by diseased vessels and conventional grafts into the normal, spiral flow pattern seen throughout the body as shown in the transverse colour Doppler ultrasound image on the right. The Spiral Flow™ Graft eliminates turbulent flow as a cause of neointimal hyperplasia.



Implant Recommendations

Implantation of the Spiral Flow™ Graft requires no new tools or techniques different from what is normally used to implant a standard graft. The following recommendations will make the implant more efficient.

Perform the Distal Anastomosis First

- Graft can be tailored for length on proximal end only
- Distal cuff is customizable up to the Spiral Inducer Segment
- We recommend that a segment of the TRIM GAP remain for clamping the graft to achieve haemostatic control.

Align heel of vessel to the end of the Spiral Inducer Segment to provide the correct geometry for the Spiral Laminar Flow™ (SLF™) column of blood to enter the distal vessel.

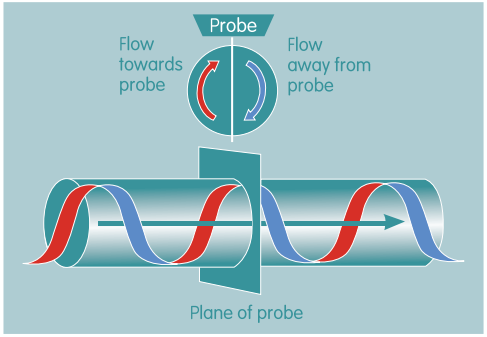
Tunneling

A pull through tunneler may be used although a sheath tunneler of sufficient internal diameter is recommended. Never tie cuff/inducer end of graft to the tunneler.

Discerning Spiral Flow™

Observing Natural Flow

Natural blood flow occurs in a spiral fashion throughout the body[2]. Aortoiliac and peripheral artery duplex ultrasonography provides a highly accurate, reproducible, noninvasive method of evaluation of the peripheral arterial vasculature. This method employs real-time B-mode, colour and spectral Doppler imaging. The combination of these modalities is important providing both anatomical and haemodynamic information.



Peripheral arterial duplex ultrasonography is performed using a commercially available duplex ultrasound system. The system must be equipped with colour and spectral Doppler, and a recording device. At least two transducers with a range of frequencies (3-8MHz) are required to allow a full interrogation of lower limb vessels.

Observing Spiral Laminar Flow™ with Colour Doppler Ultrasound

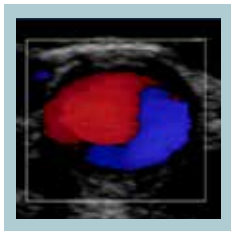
No preparation is required for examining the peripheral arteries or grafts. For vessels in legs, the subject is normally supine. The leg under examination is adducted and externally rotated to allow effective access to the groin. For AV grafts, the subject can be supine or sitting with the accessed extremity extended away from the body.

In addition to the standard longitudinal assessment of the vasculature or graft, the following describes the acquisition of transverse colour Doppler ultrasound imagery of the artery, vein or graft:

1 **NOTE: The presets of the ultrasound should be on "venous" protocol. This is because the velocity ranges of the spiral flow are lower than the longitudinal velocities normally observed.**

2 The probe is held transverse to the vessel/graft. In order to gain a true transverse 90 degrees to the longitudinal plane in both the anteroposterior and right to left directions, the probe needs alterations to the angles in right to left and anteroposterior planes. The aim is to reduce the longitudinal component of the velocity so that only the transverse components are visualised.

3 The process can be repeated at different sites from the proximal artery through to the distal runoff. Where natural flow exists, a characteristic "red/blue split" will be seen.

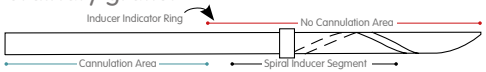


The Spiral Flow™ Graft remodels the turbulent flow pattern and pressure created by conventional grafts into the normal, spiral flow pattern seen throughout the body.

The Spiral Flow™ Graft eliminates turbulent flow as a cause of neointimal hyperplasia.

Cannulation Guidelines For The Spiral Flow™ Graft

On the outside of the graft near the venous end just over the leading edge of the **SPIRAL FLOW™ INDUCER** is a raised ridge called an **INDUCER INDICATOR RING**. It can be palpated (felt) through the skin. Do not cannulate between the **INDUCER INDICATOR** RING and the graft/vein anastomosis. This no cannulation area may be longer than what is seen on ordinary grafts.



By avoiding cannulation in this area, you will help eliminate the risk of disrupting the Spiral Flow™ Inducer. This will extend the useful life of the graft.

Cannulating the Spiral Flow™ Graft

Like other grafts, the Spiral Flow™ Graft should be cannulated using established asceptic technique.

The needle should be held at a 35° to 45° angle to the graft, adjusted for graft depth.

Upon entering the graft, you should level off and insert the needle up to its hub providing there are no obstructions or resistance. Flipping of the needles is not recommended.

De-cannulating the Spiral Flow™ Graft

When withdrawing the dialysis needle, make sure the needle is completely out of the graft before you compress the site. Spiral Flow™ Grafts cannulated within two weeks of implantation should have post treatment needle hole compression times extended to minimise the risk of bleeding and oozing.

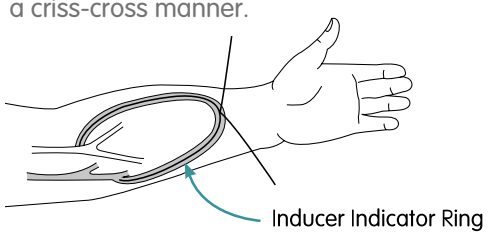
Use the two-finger technique recommended by K/DOQI for needle site compression.

Thrombectomy & Thrombolysis of The Spiral Flow™ Graft

Thrombectomising the Spiral Flow™ Graft

When using a balloon for thrombectomy, the Spiral Flow™ Inducer can inhibit complete contact between the balloon and the graft wall. Therefore, when thrombectomy is required, a pharmaco-mechanical technique is preferred.

In addition to surgical thrombectomy, many percutaneous techniques are suitable for use on the Spiral Flow™ Graft. These include; pulsed spray thrombolysis, balloon thrombectomy, catheter directed thrombolysis and the use of brushes. For percutaneous thrombolytic procedures accessing the graft should be performed in a criss-cross manner.



Perform an outflow venogram. If the outflow tract is suitable, perform the thrombus extraction procedure per its standard instruction.

When withdrawing balloons or brushes from the venous side, the **INDUCER INDICATOR RING** is a reliable marker that indicates the area of full graft internal diameter from the segment containing the **SPIRAL FLOW™ INDUCER**. Remove the arterial plug with an embolectomy balloon.

Post Treatment Imaging of the Spiral Flow™ Graft

Upon completion of thrombolysis and thrombectomy, contrast enhanced imaging of the venous outflow all the way to the right atrium should be performed to identify any significant lesions, which should be corrected.

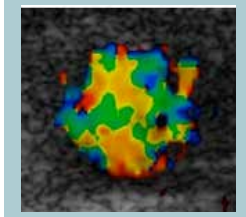
In addition to the contrast enhanced imaging, we strongly recommend a transverse color Doppler ultrasound image of the SLF™ Graft distal anastomosis. Observing the "red/blue split", indicating the presence of normal flow, ensures that the **SPIRAL FLOW™ INDUCER** is free of thrombus and the graft is performing as designed.

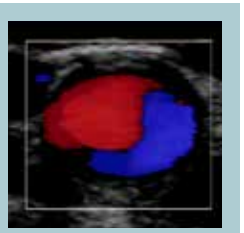
What Makes The Spiral Flow™ Graft Different?

The endothelial lining of arteries and veins are very similar. The primary cause of failure in prosthetic grafts is neointimal hyperplasia (NIH) usually occurring at the distal anastomosis. NIH is caused in large part by turbulent flow and pressure created by conventional grafts damaging the endothelial cell lining of the host vessel.

The Spiral Flow™ Graft remodels the turbulent flow pattern and pressure created by conventional grafts into the normal spiral flow pattern seen throughout the body as shown in the transverse colour Doppler ultrasound image, above, on the right.

The Spiral Flow™ Graft eliminates turbulent flow as a cause of intimal hyperplasia.


Turbulent flow


'Red/blue split' of normal flow

Surgical Revision & Angioplasty of the Spiral Flow™ Vascular Graft

Surgical Revision of the Spiral Flow™ Graft

NOTE: When revising the graft by any means, the form, length and integrity of the inducer must be maintained.

For surgical revision and implantation, it is recommended that no adjunctive procedures distal to the **SPIRAL FLOW™ INDUCER** are used. These procedures would include; any vein or prosthetic cuffs, collars or patches and distal AV fistulae.

These procedures may have been shown to have some efficacy when used alone. However, when used with the Spiral Flow™ Graft, they;

- Have not been proven to have any benefit
- May disrupt the Spiral Laminar Flow™ created by the Spiral Flow™ Graft

The Spiral Flow™ Graft has excellent physical and handling properties. Patch angioplasty should occur substantially over the host vessel and not the Spiral Flow™ Graft.

Balloon Angioplasty of the Spiral Flow™ Graft

Balloon angioplasty of the Spiral Flow™ Graft should only be done in areas **outside** the **SPIRAL FLOW™ INDUCER** segment.

Radial expansion of the graft wall could cause disruption of the inducer which would prevent the creation of Spiral Laminar Flow™. This would render the graft's performance equal to that of other grafts.

References

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2. Spiral laminar flow in arteries?;The Lancet. 1991 Nov 30;338 (8779): pp1360-1. Stonebridge PA, Brophy CM.
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4. Spiral laminar flow in the abdominal aorta: a predictor of renal impairment deterioration in patients with renal artery stenosis? Nephrol Dial Transplant (2004) 19; 1786-1791, Houston JG, Gandy SJ, Milne W, JBC Dick, JJ Belch, Stonebridge PA
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Additional information on the Spiral Flow™ Graft and the location of your local distributor can be downloaded from:

www.vascular-flow.com

If you have additional questions, email us at info@vascular-flow.com.

Vascular Flow Technologies Ltd
Prospect Business Centre,
Gemini Crescent,
Dundee, DD2 1TY, UK

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