

For immediate release



## **National Institute of Health Research Clinical Research Network Adopts Spiral Flow™ AV Graft Randomised Controlled Trial**

*Adoption to facilitate fast and efficient addition of new sites to the trial*

**Dundee, UK, 2 October, 2015** – **Vascular Flow Technologies**, the medical device company using proprietary Spiral Laminar Flow™ (SLF™) technology to replicate natural blood flow for enhanced patient outcomes, today announces the adoption of its randomised controlled trial (RCT) of the Spiral Flow™ AV graft for use in arteriovenous haemodialysis access in end-stage renal disease (ESRD) by the [National Institute of Health Research Clinical Research Network \(NIHR CRN\)](#).

The Spiral Flow™ haemodialysis access study will recruit 189 patients to investigate real world clinical and economic outcomes of the Spiral Flow™ AV graft when used to gain arteriovenous access for haemodialysis in patients with ESRD.

The CRN is part of the NIHR, established by the Department of Health to integrate world-leading research into the NHS. Adoption of the study by the CRN will provide a support infrastructure for the clinical trials, including funding to cover equipment costs and use of facilities, funding and training for staff to provide logistical support, and a streamlined system to enable the efficient set-up of trials at new sites. In addition, the CRN provides advice on suitable new NHS sites with the facilities and patient populations required.

Spiral Flow™ grafts use VFT's proprietary Spiral Laminar Flow™ (SLF) Technology, proven to induce natural blood flow with the use of a patented helical groove<sup>1,2</sup>. By replicating the blood's natural flow pattern, Spiral Flow™ grafts reduce turbulence and blood flow stagnation<sup>3</sup>. These disturbances in blood flow are risk factors for thrombosis, a major cause of failure in AV access grafts<sup>4</sup>.

A randomised controlled trial of the Spiral Flow™ AV graft is currently underway at St. Georges Hospital, London, UK, where the first patient has been enrolled.

Bill Allan, CEO of VFT commented, 'NIHR supporting the study means CRN's infrastructure will allow easier enrolment of patients and addition of new satellite sites, allowing us to complete the study on schedule and add to the considerable body of evidence on VFT's SLF™ technology.'

#### References:

1. Stonebridge PA, Buckley C, Thompson A, Dick J, Hunter G, Chudek JA, Houston JG, Belch JJ. Non spiral and spiral (helical) flow patterns in stenosis. In vitro observations using spin and gradient echo magnetic resonance imaging (MRI) and computational fluid dynamic modelling. In *Angiol* 2004 Sep;23(3):276-83.
2. Kokkalis E, Hoskins P, Corner G, Stonebridge P, Doull A, Houston G. Secondary flow in peripheral vascular prosthetic grafts using vector Doppler imaging. *Ultrasound in Med & Biol* 2013;39(12):2295-2307.
3. El Sayed HF. Vascular Flow Technology: Another run of the mill graft or a breakthrough technology? US experience and perspective. Presented at the 8<sup>th</sup> International St George's Vascular Access Meeting at the 35<sup>th</sup> Charing Cross international vascular and endovascular symposium, 7<sup>th</sup> April 2013, London.
4. Hodges TC, et al. Longitudinal comparison of dialysis access methods: risk factors for failure. *J Vasc Surg* 1997;26:1009-1019.

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## Notes to Editors

### About Vascular Flow Technologies

Vascular Flow Technologies is a leading innovator focused on the research, development and commercialisation of devices to improve blood flow in compromised or diseased blood vessels utilising its proprietary Spiral Laminar Flow™ (SLF™) technology. Natural blood flow has a distinctive singular spiral flow pattern and the patented SLF™ technology is the only clinically-proven design to replicate this.

VFT has two CE marked and FDA approved devices commercialised in Europe and the US, the Spiral Flow™ peripheral bypass (PV) graft and the Spiral Flow™ arteriovenous access (AV) graft. The SLF™ technology is used to create a longer lasting graft or stent, producing a better quality of life for the patient due to reduced vascular complications and improved longevity of the implant.

VFT is a privately held company with headquarters in Dundee, UK.

Further information is available at [www.vascular-flow.com](http://www.vascular-flow.com).

### About Spiral Laminar Flow

Turbulent blood flow near the area where the graft and the blood vessel are sewn together damages the cell lining in the patient's blood vessel wall and causes cell tissue growth (neointimal hyperplasia) which can result in vessel blockage. Spiral Laminar Flow™ technology generates a spiral flow within the graft, reducing turbulence at the point the blood leaves the graft and enters the patient's blood vessel. Vascular Flow Technologies' SLF™ technology is supported by numerous clinical studies and a significant patent array.

### About the Clinical Research Network

In 2006, the Department of Health set up the National Institute for Health Research to create a world-class health system within the NHS, and the Clinical Research Network is part of this wider organisation. The Clinical Research Network provides the infrastructure that allows high-quality clinical research to take place in the NHS, so that patients can benefit from new and better treatments. Its function is to help researchers to set up clinical studies quickly and effectively; support the life-sciences industry to deliver their research programmes; provide health professionals with research training; and work with patients to ensure their needs are at the very centre of all research activity. The Clinical Research Network's Portfolio is a collection of high-quality clinical studies that benefit from the infrastructure provided by the Clinical Research Network. Many of these studies are Randomised Controlled Trials – considered by many in the medical profession to be the most robust form of clinical trial – although the Clinical Research Network also support other types of well-designed research.

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