

For immediate release



Vascular Flow Technologies announces new Haemodialysis Access study funded by Scottish Enterprise Grant

Dundee, UK, 20 January, 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 announced the start of a randomised controlled clinical trial at St. Georges Hospital, London, UK.

The 189-patient trial is using current best practice as the comparator, and is designed to test the hypothesis that restoring the natural spiral blood flow pattern will increase arteriovenous graft patency in patients undergoing haemodialysis, resulting in fewer interventions over a 24 month period.

The trial will assess graft patency measured as the interval between graft placement and access thrombosis, or interventions to maintain, assist or re-establish patency over the 24 month period. In addition this clinical measurement the trial will record the costs of interventions, producing data to support health economic evaluation of the Spiral Flow™ AV Graft.

Spiral Laminar Flow™ (SLF™) technology has been available since 2008 and is the only graft technology that is proven to replicate natural blood flow by generating a spiral laminar flow within the graft, reducing turbulence at the point where the blood flows into the blood vessel^{1,2}. This limits changes to the blood vessel wall that may be precursors to thrombosis³. The clinical effectiveness of SLF™ technology has been reported in a number of published studies, with high patency rates at 30 months in vascular reconstruction in the leg (81% above the knee, and 57-64% below the knee)⁴.

The trial will involve patients with end stage renal disease (ESRD) requiring dialysis, who will be randomized to Spiral Flow™ AV Graft or a standard polytetrafluoroethylene (PTFE) bridge graft. The main complication for PTFE grafts used for haemodialysis is thrombosis, which is reported to contribute to 70% of failures⁵ and these grafts show patency rates in published literature of 41-68% at one year⁵⁻⁹, and 25% at two years¹⁰.

Mr. Eric Chemla, Consultant Vascular Surgeon, St. George's Hospital, London, UK and lead investigator for the study commented: "St. George's Hospital has one of the largest dialysis units in the UK, with a team of experienced vascular access surgeons, and a high throughput of this type of procedure. We are excited to be the trial centre for this study, which will produce clinical and economic evidence on the utility of this potentially game-changing technology."

The haemodialysis access study is supported in part by a Scottish Enterprise Grant awarded to Dundee-based Vascular Flow Technologies, who are gathering evidence to support wider applications of their proprietary SLF™ technology.

Bill Allan, CEO of Vascular Flow Technologies said: “We are truly delighted to announce the first patient into this trial. We are confident in our technology and are now pursuing trials that will consolidate the clinical evidence gained to date, and provide data for health economic appraisals.”

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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.

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.

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