

For immediate release



**Vascular Flow Technologies announces collaboration with the Society for Vascular Surgery® (SVS) Patient Safety Organization (PSO) to conduct a new post market observational registry of Spiral Laminar Flow™ AV graft for use in haemodialysis access**

**Dundee, UK, 17 June, 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 a new observational registry for Spiral Flow™ arteriovenous (AV) grafts in haemodialysis access that will be conducted by the Society for Vascular Surgery Patient Safety Organization (SVS PSO) as part of their ongoing Vascular Quality Initiative® (VQI). The VQI is designed to improve vascular health care and provides an opportunity for individual providers, hospitals, and regional quality improvement groups to collect and analyze clinical data in an effort to improve patient care.

The SVS PSO evaluation of Vascular Flow Technology's Spiral Laminar Flow™ Arteriovenous Graft will objectively measure the long-term safety, efficacy and cost effectiveness when used as the primary access for patients with end stage renal disease (ESRD) requiring routine haemodialysis. By restoring natural blood flow, and eliminating turbulence that can lead to neointimal hyperplasia, Spiral Flow™ AV grafts may result in higher patency rates and fewer interventions when compared to other marketed grafts.

The Spiral flow Technology AV Access Registry (STAAR) will recruit up to 15 participating centers in the US and enroll up to 75 patients with ESRD who require synthetic graft placement for haemodialysis access. Patients will be followed for a period of up to 12 months following graft implantation.

The implanted Spiral Flow™ AV graft will be assessed for primary patency (intervention free access survival), assisted primary patency (thrombosis-free access survival) and secondary patency (access survival until abandonment), as well as any complications that arise during that time.

Dr. Barbara Bunger, Chief Clinical Officer for Vascular Flow Technologies, commented: "The STAAR post market registry will collect intraoperative and acute post-operative outcomes in addition to long term graft performance in real world clinical practice as patients undergo routine dialysis. We anticipate the resulting dataset to help confirm the hypothesis that Spiral Flow™ grafts have higher patency rates, and require fewer interventions than PTFE grafts resulting in lower costs to healthcare payers and healthcare providers."

The SVS PSO Steering Committee will independently conduct and analyze the results of the STAAR under a prospectively designed protocol. An interim analysis will be performed when 25 subjects have completed 12 months of follow-up, and based on the projected patient recruitment rate, the full 12-month dataset will be available in 2017.

The SVS PSO STAAR registry is in addition to the Spiral Flow™ AV Access Graft Clinical Registry, which was announced in 2014 and is open to any interested surgeon. This open-access registry provides data to detailing graft performance data compared to national performance and can be accessed at [www.vascular-flow-clinical-registry.com](http://www.vascular-flow-clinical-registry.com).

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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 the Society for Vascular Surgery Patient Safety Organization**

The Society for Vascular Surgery Patient Safety Organization (SVS PSO) was approved by the Agency for Healthcare Research and Quality (AHRQ) in February 2011 to oversee the data sharing partnerships and patient safety initiatives of the Vascular Quality Initiative (VQI).

Formerly the Vascular Study Group Patient Safety Organization, it was established to oversee the data sharing partnerships and patient safety initiatives of customers utilizing M2S's Clinical Data Pathways platform. Comprising MDs, analysts, and administrative personnel, the SVS PSO staff provides medical expertise, analyses, and has oversight of quality improvement activities conducted through the PSO.

### **About the Vascular Quality Initiative**

The Vascular Quality Initiative® is designed to improve the quality, safety, effectiveness and cost of vascular health care by collecting and exchanging information. It consists of a distributed network of regional quality groups that function under an AHRQ-listed Patient Safety Organization using the M2S cloud-based data collection and reporting system. It is available to all providers of vascular health care and their respective institutions.

Further information is available at [www.vascularqualityinitiative.org](http://www.vascularqualityinitiative.org)

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