

Stratos Medical, a start-up medical device company based in Galway, are developing a patent-pending Arteriovenous Fistula (AVF) repeat-access sheath that aims to extend the usable lifespan of AVFs, increase the viability of long-term haemodialysis (HD), and reduce the vast costs associated with alternate vascular access modes. In addition, its solution will enable far simpler patient self-cannulation, improve the HD experience, facilitate home HD, and make daily HD more feasible. Stratos Medical was selected as one of the HIHI Open Call 2020 winners.



About Health Innovation Hub Ireland

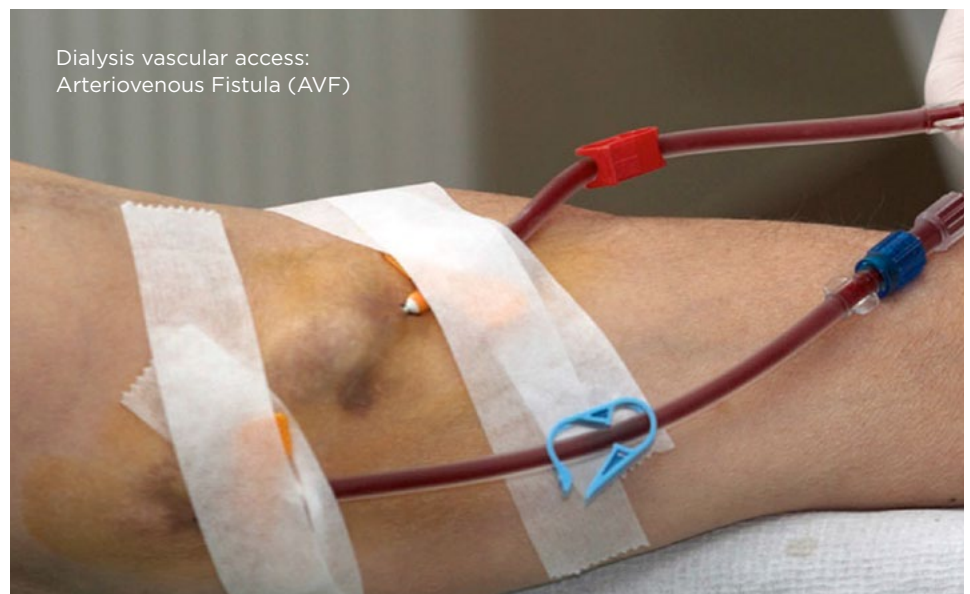
Health Innovation Hub Ireland (HIHI) was established by the Department of Business, Enterprise and Innovation and the Department of Health, supported by Enterprise Ireland (EI) and the Health Service Executive (HSE) to drive collaboration between the health service and enterprise. We offer companies the opportunity for pilot and clinical validation studies and the health service access to innovative products, services and devices that they may not otherwise be exposed to. HIHI is built on the recognition that collaboration with enterprise can benefit patient care, patient pathways and outcomes.



The Healthcare Challenge

Renal Replacement Therapies (RRTs) include treatments that replace the normal blood-filtering function of the kidneys. RRT options for those with end stage renal disease (ESRD) include dialysis or kidney transplant. The latter is an option for very few patients meaning dialysis is a life-saving treatment for most patients. Haemodialysis (HD) is the most widely used mode of dialysis. In Ireland, approximately 2,000 patients receive

HD treatment while more than 1.5 million patients globally are on HD. Although life sustaining, HD is painful and unpleasant for the patient. The Gold Standard of HD vascular access is via a native AVF, which have a primary failure rate of 30%-70% and a one-year patency rate of 40%-70%, resulting in costly complications and jeopardising HD treatment. Failing AVFs are a frustrating daily problem for clinicians, negatively affecting clinical outcomes.



Dialysis vascular access:
Arteriovenous Fistula (AVF)

The Healthcare Solution

Stratos Medical's patent-pending novel AVF repeat-access sheath system TRACKSMART™ is at the prototype stage. This device aims to reduce the repetitive sharp-needle cannulations of the AVF occurring at each HD session, which cause cumulative puncture damage to the

AVF. TRACKSMART™ entails a novel Class II device, indwelling in the AVF that acts as a conduit through which blunt dialysis needles can be advanced for access to the patient's vascular system during routine HD. The device offers significant potential to improve HD in terms of

clinical outcomes, patient treatment experience, procedure costs and simplicity of AVF cannulation. This in turn results in home HD (daily/nightly) being more accessible leading to vast health and quality of life gains, as well as cost savings to the healthcare system.



Pictured here is the external or 'point-of-patient' part of the TrackSmart™ system. Patients can easily and painlessly 'plug-in' and 'plug-out' blunt dialysis needles without the assistance of dialysis nurses.

HIHI Role

Feedback from various clinical personnel and experts was required early in the development of the device. HIHI recruited a targeted number of 10 key opinion leaders (KOLs) from the disciplines of nephrology, surgery, and nursing using the HIHI national network of clinicians and healthcare institutions throughout Ireland. HIHI facilitated interactions with the multidisciplinary group of healthcare professionals to engage with the Stratos Medical team. Relevant

information was gathered through detailed interviews and questionnaires. The Stratos Medical team sought feedback on the incidence of failed AVFs, the impact of failed AVFs on clinical outcomes, cost implications of failed AVFs and feedback on the perceived benefits and disadvantages of the TRACKSMART™ device. The data obtained from these engagements was analysed and a final report was compiled for Stratos Medical for use when engaging with funders and investors.

Outcome Report

Engaging with KOLs allowed Stratos Medical to gain valuable feedback on the TRACKSMART™ device concept. Feedback obtained highlighted that AVF complications or failure are a real issue requiring alternative solutions. Cost, time and sub-optimal clinical outcomes associated with failing AVFs were significant concerns for the KOLs. It was also identified that AVFs may last longer using the proposed TRACKSMART™ device and AVF 'needling' may be easier than traditional techniques as it may be less painful for patients, reduce the incidence of repeated needle puncture wounds and reduce trauma. A device such as TRACKSMART™ has the potential to enable a far greater HD experience and contribute to increased uptake of home HD.

Testimonial

"HIHI's assistance and support has been a tremendous asset to Stratos, in particular regarding facilitated engagements between the Stratos Medical team and clinicians in Ireland. This allowed us to gather incredibly valuable feedback and inputs directly from clinicians regarding our TRACKSMART™ device concept. Through these engagements, we were able to validate our own hypotheses about AVF complications and failure, establish the extent to which clinicians regarded this as a problem worth solving, and getting inputs on the perceived risks and challenges. HIHI's assistance helped Stratos Medical to conclude an investment from Enterprise Ireland via its Competitive Start Fund, and the team has progressed its TRACKSMART™ device concept to the prototype and proof of concept stage. Stratos Medical is interested in partnerships and in particular to explore other applications of its platform technology. We thank HIHI for being an important part of our journey."

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