Call for Proposals  
For Veinplicity® Vein Dilation Device

Introduction

Rising Tide Foundation, a non-profit organization based in Switzerland, has funded the development, production and EU registration of the Veinplicity vein dilation device, which is used to aid peripheral intravenous cannulation in patients with Difficult Venous Access (DVA), a condition with a global incidence of over 330m cases per year.\(^1\,2,3\)

The company has initiated a US clinical trial for the purpose of FDA approval. Veinplicity is ready for commercialization in Europe and could be ready for commercialization in the United States within 18 months, pending a successful trial outcome.

Rising Tide is now seeking to grant Veinplicity IP and assets to an academic/healthcare/philanthropic institution that works with, or has an interest in, adults or children with difficult-to-access veins. The objective of this call for proposals is to identify an organization that will facilitate access to Veinplicity for the benefit of the many patients with DVA.

Background

The Unmet Clinical Need - Difficult Venous Access

Difficult Venous Access is one of the most common challenges in modern healthcare. With more than 80% of hospitalised patients requiring intravenous access, healthcare professionals perform more than 1 billion peripheral IV cannulations each year\(^4\). A third of patients have difficult access however and first attempt failure is high, at 26% in adults\(^4,5\) and 47% in children.\(^6\)

Cannulation is difficult in children because of the size of their veins and complicated in adults by a range of factors including obesity, old age, diabetes, vascular pathology and renal disease.

Failed attempts lead to lost productivity and increased costs for hospitals, as well as additional pain and anxiety for patients. Moreover, multiple unsuccessful attempts can lead to serious complications such as infection, infiltration, vessel damage and vein depletion\(^7\).
The Solution – Increased Vessel Size, Increased Palpability, Increased 1\textsuperscript{st} Attempt Cannulation Success

A range of technology options serve different and often complementary functions in the effort to increase first attempt cannulation success. Most tools are designed to improve vessel visibility. Palpability rather than visibility however, is considered a greater predictor of successful cannulation\(^*\), and that’s where Veinplicity comes in. Veinplicity enlarges forearm veins by 50\%\(^*\) and improves vessel tone, providing a larger, more palpable target for the clinician.

\(^*\)According to a NICE expert evaluation\(^9\) “visual inspection may be part of the process of identifying a suitable vein, but it is the palpation of that vein that is essential for deciding if cannulation should be attempted. Some patients have clearly visible veins, but without palpation of vein elasticity or ‘bounce’, they may be liable to collapse when cannulation is attempted. It is therefore important not to give undue emphasis to visualising a vein, especially if it cannot be palpated.”

Veinplicity System and Mode of Action

Veinplicity is a portable electronic device that emits a gentle current between a disposable bifurcated electrode placed on the palm and biceps. Stimulation of the nerves and muscles in the forearm result in increased blood flow and vasodilation, while stimulation of receptors in the vessel wall causes veins to stiffen. Enlarged veins are pushed towards the surface where they are better anchored, easier to palpate and less prone to rolling.

Easy to Use:

- Place the disposable gel pads on the palm and biceps and connect to the Veinplicity device
- Tell the patient they will feel a tingling sensation and see their forearm muscles twitching
- Rotate the dial to the highest comfortably tolerable position and maintain stimulation for 2-10 minutes while preparing for cannulation
- Turn the device off once the target vein is sufficiently palpable
- Apply tourniquet and cannulate as normal
Incidence and Cost of DVA

The total global incidence of DVA is over 330 million cases per year. The real cost of failed IV cannulation is hard to define as the cost of vessel trauma can’t be quantified. Most institutions consider only the cost of materials and labour, which can vary greatly between institutions and countries. The cost of a straightforward insertion has been estimated to be between $25 and $35, but the cost for a patient with DVA can be very much higher. Any increase in the number of attempts required, escalation to more highly paid staff, or need for more invasive devices and ancillary equipment has a significant cost impact.

Fredericus H J van Loon estimated the average cost of cannulation in the 700-bed Catharina Hospital in Eindhoven to be $10.29 but increased to $40.04 for patients with DVA requiring 5 attempts. A trial at the same hospital showed that Veinplicity increased first-time cannulation success by 18%.

Veinplicity is the only device to have a physiological effect on veins. It is easy to use. No special training is required. It has no direct competition and can be used in conjunction with other cannulation aids. It has synergies with visualisation devices and adjacent vascular access products such as IV peripherals, ultrasound and infrared.

Assets and IP

- Stock of 150 devices and 1500 electrodes in stock
- 3 patents approved and a further 30 pending
- CE Mark
- Certified Quality Management System
- Physeon GmbH and Veinplicity websites
- Marketing collateral and training material

Indications and Regulatory Status

Veinplicity is a CE Mark Class 11a medical device. It is indicated for any patient over the age of two, provided they do not have an implanted electrical device.

A limited launch was conducted in the UK to gather feedback from vascular access experts and shape the clinical trial program prior to a full, pan European launch.

Trials in the UK and Netherlands have shown that Veinplicity increases vessel size and first-time cannulation success. Both trials have been peer reviewed and published in the Journal of Vascular Access.

At the end of 2018, a clinical trial was initiated in the United States for the purpose of FDA approval. Per protocol analysis at the halfway stage has demonstrated superiority over standard of care.
Veinplicity versus heat treatment for vein dilation: A randomised cross-over study

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Veinplicity dilatory effect is 38% greater than Heat Pack

In a study conducted at Frimley Health NHS Foundation Trust, the dilatory effect of Veinplicity was compared to that of commonly used Heat Packs. Healthy volunteers were randomised to receive either application of heat followed by stimulation with Veinplicity, or the same two treatments in the reverse order. Using ultrasound to measure the mean maximum vein diameter increase it was found that Veinplicity dilated veins by 50% on average, while heat packs dilated veins by 36%.

Figure 1: Ultrasound images of vein diameter measurements at baseline (left) and after stimulation with Veinplicity (right). The white dot shows a 22G cannula occupying the cross-sectional vein image.

Veinplicity dilatory effect lasts almost two times longer than Heat Pack

The same study showed that the dilatory effect was not only greater, but significantly longer. Veinplicity dilation lasted 9.7 +/- 3.9 mins (versus 4.9 +/- 2.2 min for Heat Pack) giving practitioners valuable extra time to perform difficult cannulations.

Figure 2: Mean vein diameter increase from baseline over time. Standard deviations are represented with error bars.
Veinplicity significantly improves palpability and 1st attempt cannulation success

Results from a non-randomised clinical trial comparing 1st attempt cannulation success in patients with medium risk of failed cannulation* confirm that Veinplicity was significantly better than tourniquet alone for improving vessel palpability and cannulation success.

**Figure 1:**
89.6% of patients had a palpable target vein when Veinplicity was used prior to the application of tourniquet, versus 82.2% when tourniquet was used alone.

**Figure 2:**
92% of patients who were stimulated with Veinplicity prior to tourniquet were cannulated on first attempt, versus 78% who had tourniquet alone.
About Rising Tide

Rising Tide is an independent foundation with a global reach, enabling breakthrough developments in the fields of clinical cancer research and libertarianism. The foundation collaborates with global leaders and co-funders to seek out cutting-edge projects and optimise impact. Financial independence guarantees a level of risk-taking freedom in return for accelerated change. Rising Tide has approved funding for over 100 projects in the past 9 years.

The team abides by the highest ethical and moral standards and are passionate about the work and purpose of the organization, believing deeply in the impact they can bring to society and the people they are privileged to serve.

Rising Tide has achieved what it set out to do 5 years ago, when it chose to address one of the most common problems in healthcare, failed cannulation. The organization has developed a product that has been shown to increase vessel size and improve first attempt cannulation success. Further, the product has been registered in the EU and evidence of its efficacy has been published in the Journal of Vascular Access.

Having achieved its goal, the board of the Rising Tide Foundation wish to divest the business as planned, and free up resources to incubate other opportunities.

Further Information

For more information visit the Veinplicity site.

Submission Deadline and Review Process

Rising Tide is now seeking to grant Veinplicity IP and assets to an academic/healthcare/philanthropic institution that works with, or has an interest in, adults or children with difficult-to-access veins. Preference will be given to an organization that will facilitate access to Veinplicity for the benefit of the many patients with DVA.

- Expressions of interest should be submitted to tina.leggett@risingtide.ch by the 28th February 2020
- Following the execution of non-disclosure agreements, sensitive information will be made available to enable a short list of candidates to make full applications
References