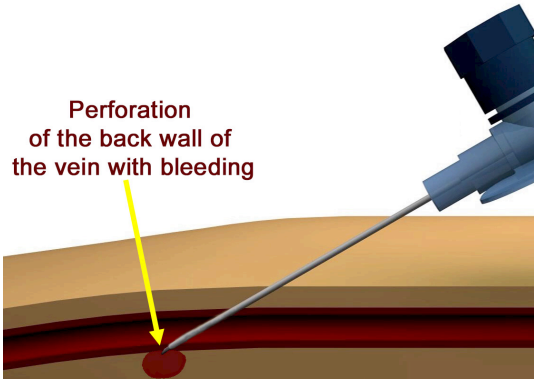
OptiVein Technology for Successful Intravascular Cannulation

Every year over 1 billion intravenous (IV) catheters are used worldwide. Insertion failures and cannulation complications remain the major concerns for clinicians and patients.

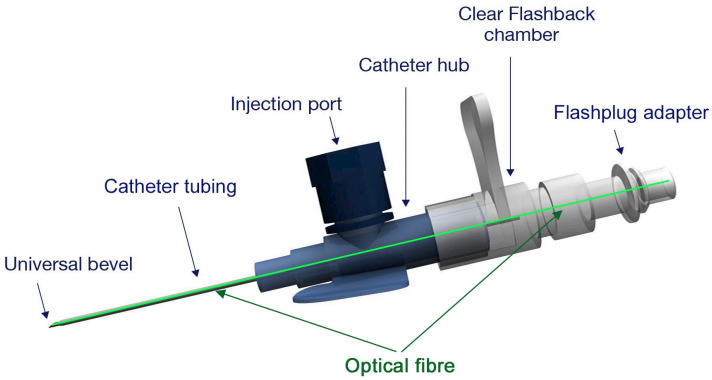
OptiVein system makes veins more perceptible as well as reduces the delay between blood vessel entry and detection of the puncture making insertion more successful.

Insertion Failures Are Common



IV catheter insertion failures are often caused by the clinicians advancing the introducer needle of the IV catheter too far into the target blood vessel. This results in a perforation of the back wall of the vessel, bleeding and a failed insertion. A new IV site must be found and prepared, a new catheter used, and valuable time lost when multiple insertion attempts are required. Placement of peripheral IV catheters in infants and children is difficult, even in skilled hands. Published data showed, that successful IV placements required an average of 2.1 punctures and more than 50% of the children required 2 or more attempts. The study furthermore discovered, that the mean time required to start the IV was over 28 minutes, highlighting the need for improved methods for IV cannulation. [Larsen, P., et al., 2010]

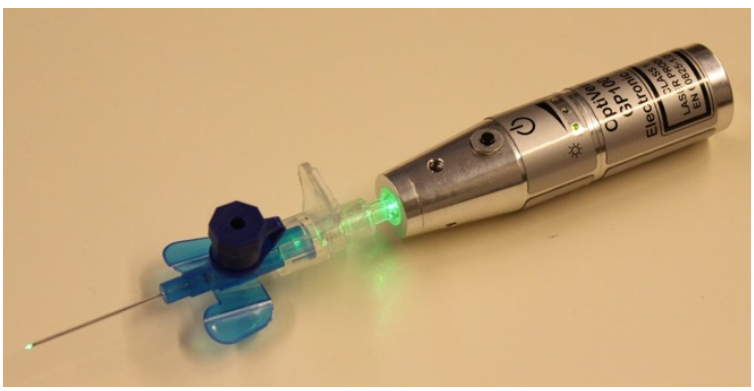
Laser Skin Transillumination Reduces Failures



OptiVein system reduces the incidence of IV insertion failures because skin transillumination through OptiVein IV catheter informs the user of the exact moment of penetration of the tip of the needle into the blood vessel. Considerable lag time between the needle tip entering the target vessel and the blood flash indicator appearing in the flashback chamber is one of the main reasons of cannulation failures, especially during cannulation of children as well as patients with small and fragile veins or low blood-pressure.

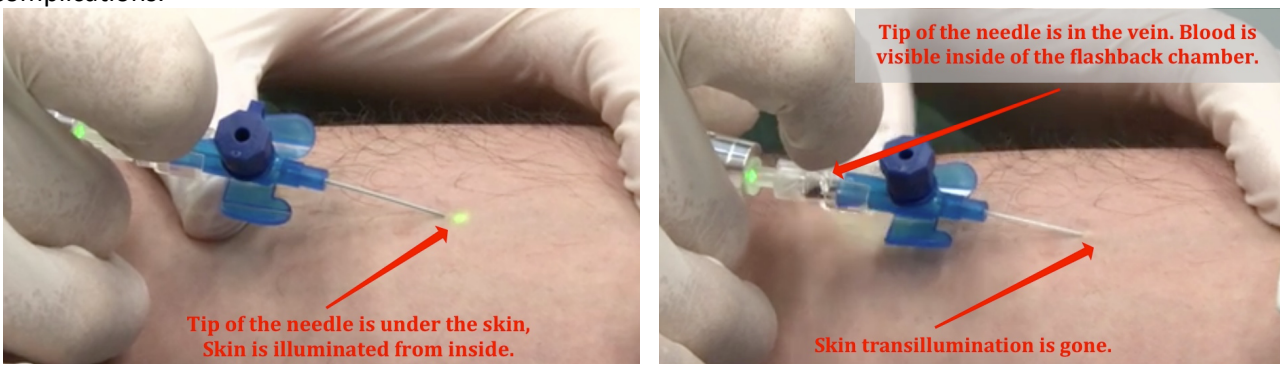
OptiVein system consists of OptiVein IV catheter and OptiVein electronic unit. The introducer needle of OptiVein IV catheter includes a thin optical fiber.

The electronic unit generates visible light, which is released from the tip of the needle into the soft tissue around the tip of the needle. Skin transillumination makes the tip of the needle and surrounding veins visible.



OptiVein system which includes OptiVein IV catheter and OptiVein electronic unit

The OptiVein system informs the clinician of the exact moment of penetration of the tip of the needle into the blood vessel. Hemoglobin in blood strongly absorbs visible light of specific wavelengths, so when the needle enters the blood vessel, the light is instantly absorbed by blood, which causes instant fading of skin transillumination. The instant disappearance of tissue illumination indicates successful insertion. This optical confirmation comes much faster than the traditional observation of blood in the flashback chamber of the needle, which informs clinician to stop forward movement of the needle. Appearance of blood in flashback chamber may take 1 to 2 seconds or even longer. This time difference in confirmation of entry can be critical in avoiding vein back wall punctures, thus increasing successful cannulation rate and decreasing complications.



OptiVein Cannulation. Left: spot of light is visible, needle is under the skin; Right: light is gone, needle is in the vein.

Clinical Trial Results

Tartu University Children's Hospital clinical trial (2017) demonstrated that use of OptiVein system improves cannulation success rate, especially for children with small and difficult to cannulate veins. The use of OptiVein system is also associated with smaller number of side effects.

Next Development Phase

Based on the experiences from the clinical trials, the OptiVein system can be enhanced by redesigning the electronic unit to make the cannulation experience more intuitive and by using yellow laser light to improve visibility of blood vessels prior to puncture. This aids in locating vein and assessing size to aid in choosing the best vein to cannulate.

Marketing Strategy

The global market for IV catheters approaches $2 billion per year and is growing steadily. OptiVein system can capture a significant portion of pediatric, emergency and oncological cannulation segments of this market due to the superior performance and functionality of the product driving both clinician and patient demand as well as cost savings.

Regulatory

According to the Council Directive 93/42/EEC OptiVein IV catheter is a class IIa medical device. OptiVein electronic unit is an accessory, a class I device.

According to EN ISO 10993-1:2009, OptiVein IV catheter is an external communicating device, circulating blood, prolonged exposure (under 30 days) while the introducer needle is an external communicating device, circulating blood, limited exposure (up to 24 hours).

OptiVein system is a class 1 laser product.

Intellectual Property

OptiVein system is patent protected: US 9,700,697 B2 (approved), July 11th, 2017 and in Europe.

We are looking for business partners.

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