U.S. Market Access: Airglove Thermal Warming Device

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The number of U.S. intravenous (IV) cannulations in 2017 is estimated at 250 million with a market value of over five billion dollars, and the catheterization growth rate is projected to increase at 4% annually for the foreseeable future due to the increasing population of individuals having multiple chronic diseases. U.S. IV cannulation primarily takes place in hospitals, surgical centers, diagnostic settings (radiology), and phlebotomy centers. IVs are indispensable to healthcare providers as it provides a quick and convenient route to administer fluids and medications. However, a significant population of persons have conditions making IV access difficult.

Difficult Vascular Access: Obesity, chronic illness, hypovolemia, IV drug abuse, vasculophy, and pediatric patients under the age of two years have difficult IV access as a rule. In the Emergency Department, first attempt success rate for placing IV catheters is 60% and takes about thirty seconds on average for insertion. For adult patients with difficult vascular access (DVA), the time to cannulation ranges from 2.5 minutes to 10 minutes. Especially difficult patients are reported to require up to 30 minutes for successful cannulation. Physicians attempting to cannulate difficult patients require 22-57 minutes, and success rates range from 23-44%.

Pediatrics: Children under the age of two are more difficult to access. Successful cannulation requires an average of 2.5 attempts with a range of 1-10 attempts. Pediatric cannulation is also labor intensive as it takes 30 minutes on average. Pediatrics are cannulated 53% of the time on the first attempt, 70% on second attempt, and 94% on the fourth attempt.

Issue: All stakeholders suffer when the time to successful IV cannulation is delayed. Patients are made uncomfortable by the needle sticks, tourniquets, and restricted positioning. Healthcare providers find DVA takes away from time that should be dedicated to other caregiving duties and the cost of supplies increases with each attempt. Nurses identify individuals as having DVA due to prior experience with the patient, or after two needle sticks. At this time, the care givers begin to utilize technology designed to aid their cannulation efforts.

Competition: Products are available to assist with venous cannulation efforts, but they are mostly unhelpful to caregivers. Vein detectors utilize laser or infrared lights to determine vein location, but "real world" device performance is sub-optimal when it comes to improving IV cannulation success rates. Scientific studies confirm this by demonstrating the Accuvein device does not improve first attempt cannulation rates, and the VeinViewer only provides statistically significant improvement for first attempt placement of IVs in the pediatric population under two years of age. Nurses report visualizing the position of the vein is not helpful if they cannot also palpate the same vein – improved cannulation rates require patient vein palpation capability.

In contrast, ultrasound assisted vein location improves vascular access without improving palpation capability. Palpation of the venipuncture site is not necessary with ultrasound because the imaging wand has a notch used to guide IV catheters to the appropriate location. Yet, ultrasound remains a tool of IV nursing teams and physicians focusing on more complex cannulations. As a result, the use of heat to improve intravascular access is the most common intervention after the first failed cannulation attempt.

Thermal Intervention: A review of IV access guidelines reveals thermal intervention is near universally recommended to aid in catheter placement. The scientific literature supports these guidelines by depicting the virtues of applying thermal intervention to promote vascular dilation in DVA patients. Evidence shows warming the limb chosen as for venipuncture dilates associated vessels thus allowing for improved viewing and palpation of the insertion site. The effects of thermal intervention are thought to be maintained for five minutes after removal of the heat source. One study reports warming reduces time to cannulation from 62 (range 50-74) seconds to 36 (31-40) seconds for neurosurgery patients. Leukemia patients receiving thermal intervention saw their time to cannulation reduced from 32 to 8 seconds, and first attempt success rates improved from 70% to 94%. Corresponding increases in patient satisfaction along with decreases in labor and supply costs are also evident. Last, the published literature also indicates the superiority of dry heat over moist heat for vascular access. First attempt success is 2.7% more likely with dry rather than moist heat.

U.S. Market Access Notes

- ✓ The Airglove is a Class I medical device in the eyes of the FDA. Regulatory approval should be relatively timely and assured if the required documentation is properly prepared. Class I medical devices receive minimal scrutiny from the FDA.

- ✓ Reimbursement is not an issue. Payers do not reimburse healthcare providers for devices utilized to optimize IV access. As a result, healthcare systems, surgical centers, diagnostic clinics, and phlebotomy centers are the buyers of such devices.

- ✓ Buyers considering adopting the Airglove will require a higher standard of evidence regarding device performance than what the FDA will require to provide regulatory approval. Know this, vein finders were purchased by healthcare providers prior to the availability of scientifically derived performance evidence. Healthcare providers feel they were taken advantage of by the manufacturers, and it is likely providers will take steps to prevent repeating this mistake.

- ✓ Without scientific evidence of vein finder efficacy, buyers had to rely on rational thinking when evaluating the devices for purchase. This led some buyers to believe viewing veins and knowing their location would lead to improved IV success rates and reduced insertion time. But this is not true, had the buyers waited for the appropriate science to be performed, the time and money invested in such devices could have been salvaged.

- ✓ Expect buyers to demand scientific evidence of device efficacy prior to purchasing the Airglove. Since the introduction of the vein finder devices, the healthcare providers who buy such items have become increasingly sophisticated regarding the use of science to guide their purchasing decisions.

- ✓ Existing literature provides evidence supporting the use of thermal stimulation, yet this information may **NOT** be extrapolated to the Airglove. A simple trial comparing Airglove to the standard(s) of care will be required.

Analysis

After examining the Airglove and the Secure devices, it appears the thermal intervention device will lead the Green Cross Medico entry into the U.S. market. In contrast to Secure, the Airglove device only requires conversion to the North American electrical system and a simultaneous effort to discover and test the device's impact on IV access issues important to customers – hospitals, surgery centers, diagnostic centers, and phlebotomy centers.

Each customer segment shares the overarching goal of reducing expenses by reducing the time to cannulation and supply costs. However, it is essential to discover the specific issues each customer segment considers vital to the purchasing decision when evaluating novel IV access devices for uptake. It is Green Cross' obligation to discover the issues vital to segmented purchase decisions, evaluate Airglove's potential to impact the concerns, and provide scientific evidence demonstrating the impact.

While Airglove is being adapted to operate on the U.S. electrical grid, the Green Cross organization should begin discovering the issues governing purchase decisions in order to design a business plan outlining precisely "how" the vital issues will be investigated. Potential avenues to achieve the desired results are:

1. Proactively identify vital purchase issues and conduct modest clinical trials to evaluate device impact. Present device and the potential to impact vital issues simultaneously to buyers.

2. Introduce the Airglove device to buyers, obtain their thoughts, identify the issues essential to a purchase decision, and partner with the potential customer to evaluate performance in the customer's own "real world" patient population.

3. Enter the U.S. market without issue related performance evidence - knowing full-well this is the tough path to success. Not only will it be difficult to sell the device initially, but taking this action results in failure to establish the" barriers to entry" necessary to defend future market share. Novel competitors entering the market with scientific device performance evidence could quickly diminish Green Cross' market share.

Guidance: The U.S. healthcare system does not know it, but it is primed and ready for a thermal intervention device with scientific evidence regarding vital issue performance. The initial novel device presented to U.S. buyers as having the potential to reduce costs by speeding IV catheter placement while concomitantly reducing the supplies required to service the DVA population will have the opportunity to exploit the market. Thus, time is of the essence.

Proposed Next Steps: 1.) Interview decision makers from each market segment and determine the universal issues vital to the decision to buy. 2.) Determine which of these universal issues the Airglove has the potential to impact. 3.) Partner with healthcare providers to evaluate Airglove's impact on vital issues. 4.) Present results to the customer and publish the resulting evidence to support further sales. 5.) Once a scientific body of evidence is accumulated, customer trials will no longer necessary and a widespread sales campaign can be initiated.

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