Uploaded to the VFC Website

2018

This Document has been provided to you courtesy of Veterans-For-Change!

Feel free to pass to any veteran who might be able to use this information!

For thousands more files like this and hundreds of links to useful information, and hundreds of "Frequently Asked Questions, please go to:

Veterans-For-Change

If Veterans don't help Veterans, who will?

Note: VFC is not liable for source information in this document, it is merely provided as a courtesy to our members & subscribers.

Velano Vascular obtains FDA clearance for modified version of novel blood draw device

Published on January 27, 2016 at 11:52 AM

Velano Vascular, a medical technology company transforming and enhancing the care experience for hospitalized patients and their practitioners, announced today that the company received U.S. Food and Drug Administration (FDA) clearance for a modified version of its novel, needle-free blood draw device. The Velano device is designed to reduce blood draw-related discomfort and anxiety for hospital inpatients, provide a safer work environment for healthcare providers, and standardize today's fragmented approaches to inpatient blood draws.

This second FDA clearance of the company's patented technology includes two modifications designed to enhance the product's usability for inpatient blood draws, one of the most common medical procedures performed today: The addition of a clamp for use with syringe draws, a frequent practice in pediatric patients, and a refinement to the Indication for Use (IFU). The Velano device is attached to a peripheral IV catheter to draw blood directly into a vacuum tube or a syringe; the revised IFU removes a limitation in the earlier clearance that specified when the device could be used with in-dwelling peripheral IV catheters.

"We rapidly implemented and pursued FDA clearance for these modifications based on input from patients and medical professionals who are using and systematically assessing our blood-draw technology," said Eric M. Stone, co-founder and CEO of Velano Vascular. "These enhancements reflect our customer-centric approach to introducing our technology into medical practice, both in terms of product enhancements and clinical use patterns."

Velano Vascular is working closely with clinical and non-profit partners including Brigham and Women's Hospital, Intermountain Healthcare, Griffin Health, The University of Pennsylvania Health System, The Children's Hospital of Philadelphia, Children's National Hospital, and Planetree to capture patient and practitioner input regarding today's approaches to inpatient blood draws and how the Velano technology could eventually become a standard of care.

The Need for New Blood-Draw Technology

Roughly 760 inpatient blood draws are conducted every minute in the United States alone. Despite their ubiquity, blood draws create tremendous disruption for patients and clinicians alike, and are associated with significant direct and indirect costs. Twenty-eight percent of adult venipunctures and 44 percent of pediatric venipunctures require more than one stick to successfully draw blood, and around 10 percent of children aged 3 to 10 years old must be physically restrained to endure a needle-based blood draw. Published data suggest that U.S. healthcare professionals endure an average of 200 needle-related injuries each day. Aside from the significant physical and emotional toll of these injuries and any related seroconversion, studies suggest that accidental needle sticks cost hospitals upwards of $50 million per year.

Source:
Velano Vascular