FDA Grants De Novo Clearance to Bluegrass Vascular Technologies for the Surfacer® Inside-Out® Access Catheter System

First device to reliably and repeatedly achieve central venous access from the inside-out in patients with venous obstructions

SAN ANTONIO, Feb. 11, 2020 /PRNewswire/ -- Bluegrass Vascular Technologies (Bluegrass Vascular), a private medical technology company focused on innovating lifesaving devices and methods for vascular access procedures, announced today that the U.S. Food and Drug Administration (FDA) has granted a De Novo classification order for its Surfacer® Inside-Out®Access Catheter System. The Surfacer System is intended to obtain central venous access to facilitate catheter insertion into the central venous system for patients with upper body venous occlusions or other conditions that preclude central venous access by conventional methods. The Surfacer System employs a novel Inside-Out approach.

"The Surfacer System offers a safe and effective approach to reliably preserve and restore critical upper body vascular access sites," stated Mahmood Razavi, MD, Interventional Radiologist at St. Joseph Hospital in Orange, California and lead principal investigator of the SAVE-US (Surfacer®System to Facilitate Access in VEnous Occlusions – United States) IDE study. "This is an unmet clinical need for patients who require life-saving therapies, such as dialysis, and who have limited options due to venous obstructions."

The Surfacer System is the first FDA cleared medical device to facilitate upper body central venous access in patients with venous obstructions or other conditions that preclude access by conventional methods. Approval is based on the results of the SAVE-US trial. Of the thirty enrolled patients, 90% met both the primary and secondary efficacy endpoints despite a complex patient population comprised largely of Type 3 and 4 obstructions (3 or more obstructed vessels). No device related adverse events were reported, confirming the safety and performance of the Surfacer System.

"Thoracic central venous obstruction (TCVO) is a costly problem associated with increased patient morbidity and reduced quality of life," stated Bart Dolmatch, MD, Interventional Radiologist at The Palo Alto Medical Foundation. "We've recently published reporting standards that create a common language for understanding and describing signs, symptoms, functional impairment, and anatomy of TCVO. BVT incorporated elements of these reporting standards into the SAVE-US trial, demonstrating the clinical impact of the Surfacer System. Now that it has been FDA cleared, the Surfacer will be part of the treatment algorithm for my patients with TCVO."

Thoracic central venous obstruction occurs in roughly 40% of patients where hemodialysis is performed via a central venous catheter.1 While permanent arteriovenous fistulas are the preferred form of vascular access for hemodialysis patients, central venous catheters continue to serve as an important bridge to securing long-term access for life-saving hemodialysis treatment. The current approach for most patients with central venous obstructions is to use an alternative vein, which reduces the ability to place and mature a functioning fistula, resulting in increased catheter days and costs.

"We are thrilled BVT has reached this important milestone. For the first time ever, physicians in the U.S. can offer patients a reliable and repeatable solution to treat central venous obstructions and restore access to the right internal jugular vein – the preferred access site," stated Gabriele Niederauer, Ph.D., CEO and President of Bluegrass Vascular. "Through our experience in Europeand other international sites, the Surfacer System has consistently demonstrated a positive clinical impact. We are eager to bring the Surfacer System and its important benefits to patients in the US."

The Surfacer System will be available in select U.S. centers in the coming months. The system received CE Mark in 2016 and is available in Europe, Canada, Singapore and Middle East.

About the Surfacer® Inside-Out® Access Catheter System
The Surfacer System is designed to reliably, efficiently and repeatedly gain central venous access by inserting the Surfacer System through the right femoral vein and navigating it up through the patient's venous system with an exit point in the right internal jugular vein, the optimal location for placing a central venous catheter. This proprietary Inside-Out approach allows for the placement and maturation of permanent arteriovenous access options that are associated with improved patient outcomes and reduced cost of care for both hospitals and hemodialysis providers. The Surfacer System is CE marked and distributed in Europe by Merit Medical, a global distributor of medical devices.

About Bluegrass Vascular Technologies
Bluegrass Vascular Technologies is a medical technology company dedicated to developing and commercializing lifesaving devices and methods that address shortcomings in vascular access procedures. For more information, please visit www.bluegrassvascular.com.

Source: https://www.prnewswire.com/news-releases/fda-grants-de-novo-clearance-to-bluegrass-vascular-technologies-for-the-surfacer-inside-out-access-catheter-system-301002285.html

February 11th 2020