



Bluegrass Vascular Announces Enrollment Completion of International Post-Market SAVE Registry with Early Positive Results

SAN ANTONIO, TX – October 15, 2018 – [Bluegrass Vascular Technologies](#) (Bluegrass Vascular), a private medical technology company focused on innovating lifesaving devices and methods for vascular access procedures, announced today it has successfully completed enrollment of its prospective, multicenter, post-CE Mark, international SAVE (Surfacer® System to Facilitate Access in VEnous Occlusions) Registry. In addition, the company also announced expanded patient enrollment and study sites in the SAVE-US (Surfacer System to Facilitate Access in VEnous Occlusions – United States), a pre-market investigational device exempt (IDE) Study. Positive results and trends were respectively demonstrated in both studies with use of the Surfacer® Inside-Out® Access Catheter System, a novel device designed to facilitate reliable upper body central venous access suitable for patients with upper body venous occlusions or other conditions that preclude central venous access by conventional methods.

“Completing the post-market SAVE study reinforces the Surfacer System as the standard of care for central venous obstruction, a serious challenge in the management of hemodialysis patients,” stated Maurizio Gallieni, MD, Director of the Nephrology and Dialysis Unit at San Carlo Borromeo Hospital in Milan, Italy and one of the investigators of the SAVE study. “It offers a proven and important means of gaining reliable and repeatable central venous access in patients who otherwise have very limited options.”

Of patients enrolled in the international SAVE registry, central venous catheters were placed according to labeled indications in 29 of 30 patients with a 100% success in achieving patency and access. Absence of adverse events in data reported for all treated patients with a single conversion in one patient (3%) with a significant vascular anomaly preventing access. All primary safety and performance endpoints were met in 29 of 30 patients. Patients presented with a variety of occlusion types, including 16 patients (30.2%) with bilateral internal jugular (BIJ) and subclavian (SC) occlusion, 17 patients (32.1%) with brachiocephalic (BC) occlusion, 12 patients with (22.6%) superior vena cava (SVC) occlusion above the azygos and 8 patients (15.1%) with total occlusion of the SVC.

The expanded enrollment in the U.S. IDE to six sites in its 30-patient SAVE-US pivotal trial will continue to evaluate the safety and efficacy of the Surfacer System as demonstrated in the international SAVE registry.

“Central venous occlusion is a major clinical problem for dialysis patients,” stated Dr. Eric Peden, MD, Vascular Surgeon at Houston Methodist Hospital in Houston, Texas and one of the first enrolling SAVE-US IDE investigators. “Early results of the Surfacer System are very encouraging. I look forward to supporting the study to its completion.”

“These are major milestones for our company and for patients with occlusive disease. I am extremely pleased by the early positive results of the international SAVE registry and similar positive trends observed in the SAVE-US IDE study,” stated Gabriele Niederauer, Ph.D., CEO and President of Bluegrass Vascular. “As we near FDA approval, we look forward to supporting our clinical efforts in the U.S. and building on the commercial momentum in Europe.”

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 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 prominent 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: <http://bluegrassvascular.com/registry-enrollment/>

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