

Bluegrass Vascular Announces Positive Results from Independent Study – Building on Growing Body of Evidence for Clinical Application of the Surfacer System

SAN ANTONIO, TX – October 27th, 2018 – <u>Bluegrass Vascular Technologies</u> (Bluegrass Vascular), a private medical technology company focused on innovating lifesaving devices and methods for vascular access procedures, announced today its Surfacer® Inside-Out® Access Catheter System has demonstrated positive commercial use, consistently achieving central venous access in patients with upper body occlusions. The study, presented today in a poster session at the 2018 <u>American Society of Nephrology (ASN) Annual Meeting</u> in San Diego, California, builds on positive results from the company's post-market international SAVE Registry announced earlier this month.

The results of the retrospective, independent study evaluating 32 cases with the Surfacer System demonstrated an impressive 97% success rate in all patients. In one patient access was not achieved due to significant scoliosis altering the anatomy. There were zero device-related complications reported, including bleeding, hematoma and catheter-related infection, and all patients displayed similar catheter function at three months.

"The clinical application of the Surfacer System, as shown in this study, proves to be extremely positive," stated Dr. Roman Reindel-Schwaighofer, Nephrology and Dialysis Fellow at the Medical University of Vienna in Austria and the lead author. "The Surfacer System provides a safe and effective solution that both preserves and restores vascular access for patients requiring hemodialysis who otherwise have very limited options."

The Surfacer System is a novel, CE-Marked device designed to reliably, safely and repeatedly gain central venous access for hemodialysis patients awaiting maturation of permanent vascular access. Failed venous access attempts may prevent permanent AV access, increasing patient morbidity and the overall cost of care.1

"Based on these results, I am very optimistic about the clinical impact of the Surfacer System and its ability to treat upper body vascular occlusions," stated Gürkan Sengölge, M.D., Associate Professor of Medicine, Nephrology and Intensive Care Medicine at the Medical University of Vienna and the study's senior author. "The ability to safely perform the procedure, in an outpatient setting, and have the option to repeat when necessary, has the potential to change the standard of care going forward."

"This is an exciting study that mirrors the commercial successes recently revealed in our international post-market SAVE Registry and similar positive trends observed in our SAVE-US IDE study," stated Gabriele Niederauer, Ph.D., CEO and President of Bluegrass Vascular. "I look forward to announcing additional data as it becomes available and as we near completion of our SAVE-US IDE trial."

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 <u>Merit Medical</u>, 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 <u>www.bluegrassvascular.com</u>.

Source: http://bluegrassvascular.com/asn-press-release/

October 27th 2018

