



American Journal of Kidney Diseases Publishes Positive Clinical Results in First Independent, Multicenter Study of the Surfacer® Inside-Out® Access Catheter System

SAN ANTONIO, Dec. 19, 2019 /PRNewswire/ -- [Bluegrass Vascular Technologies](#) (Bluegrass Vascular), a private medical technology company focused on innovating lifesaving devices and methods for vascular access procedures, announced today the [publication](#) of positive results associated with a clinical study involving the use of the Surfacer® Inside-Out® Access Catheter System in the peer-reviewed American Journal of Kidney Diseases.

The publication highlights the first-ever independent, multicenter study investigating the applicability of the Surfacer System, a novel approach to achieving right-sided, upper body central venous access in patients with obstructions or other conditions that preclude central venous access by conventional methods. The study was directed by lead investigator and the publication's senior author, Gürkan Sengölge, M.D., Associate Professor of Medicine, Nephrology and Intensive Care Medicine at the Medical University of Vienna. Dr. Sengölge is a long-time supporter of the Surfacer System, approaching 50 cases successfully completed to-date.

The present study enrolled 32 patients, the majority (83%) of which had either Type 3 or 4 complex obstructions (3 or more occluded vessels). Of those enrolled, 97% met both the primary and secondary efficacy endpoints of achieving central venous access through the use of the Surfacer System and catheter patency at 3 months. No procedure-related complications were observed and no catheter-related infections occurred within the first week after catheter placement.

"Thoracic central venous occlusion is a significant issue, which can impact long-term morbidity, particularly in hemodialysis patients who depend on central venous catheters for dialysis therapy," explained Roman Reindl-Schwaighofer, M.D., from the Division of Nephrology at Medical University Vienna, and first author on the study. "This study demonstrates that the Surfacer System is a reliable and safe means of repeatedly establishing vascular access, currently a challenge with alternative surgical options or sharp recanalization techniques."

"The erosion of subclavian and left-sided vascular access routes are of great concern to this patient population due to their higher rates of central stenosis and catheter dysfunction," stated Vladimir Matoussevitch, M.D., Vascular Surgeon and Head of the Vascular Access Unit at the University Hospital of Cologne in Germany.

Mr. James Gilbert, Transplant and Access Surgeon from University Oxford Hospitals NHS Trust, further emphasized the clinical importance of the system, pointing out: "the Surfacer System supports the recommended 'always right, never subclavian' approach to preserving vascular real estate in a challenging patient population."

"This study adds to the growing body of evidence highlighting the need for standardized treatment of central venous occlusions and demonstrating the positive clinical impact of the Surfacor System," stated Gabriele Niederauer, Ph.D., CEO and President of Bluegrass Vascular. "We look forward to broadening our clinical partnerships in Europe and the U.S. to best support this effort."

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.

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