



Bluegrass Vascular Secures CE Mark Approval and Announces Successful Commercial Use of The Surfacer® Inside-Out® Access Catheter System

Novel system offers a minimally invasive Inside-Out solution to support the achievement of long-term arteriovenous access

SAN ANTONIO, Aug. 30, 2016 /PRNewswire/ -- [Bluegrass Vascular Technologies](#) (Bluegrass Vascular), a private medical technology company focused on innovating lifesaving devices and methods for vascular access procedures, announced that it has received CE Mark approval and is launching limited commercial sale of its Surfacer® Inside-Out® Access Catheter System. The Surfacer System is indicated for obtaining central venous access to facilitate catheter insertion into the central venous system via a novel Inside-Out approach.

"The launch of the Surfacer System in Europe brings a much-needed solution to a growing population of patients requiring vascular access for vital treatments and who currently have limited options due to obstructed upper body access," stated Gürkan Sengölge, M.D., Associate Professor of Medicine, Nephrology and Intensive Care Medicine at the Medical University of Vienna in Austria. "I was very pleased with my first commercial use of the Surfacer System. No other device offers such an innovative Inside-Out method for restoring access and preserving options in patients with chronically occluded veins. Based on my initial experience, I am confident that the Surfacer System will change the standard of care going forward."

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.

"Multiple central venous occlusions can cause significant long-term morbidity," explained John Gurley, M.D., Interventional Cardiologist, University of Kentucky Medical Center, Bluegrass Vascular founder and developer of the Inside-Out method. "The novel Inside-Out approach is an innovative and simple method that restores and preserves right-sided venous access despite chronic occlusion and retains the viability of other existing central veins."

"This is a major milestone both for our company and for patients with occlusive disease," stated Gabriele Niederauer, Ph.D., CEO and President of Bluegrass Vascular. "After successful use of our device in initial commercial cases and previously under Germany's Compassionate Use Program, we are eager to commercialize the system in Europe and meet the clinical demand from physicians treating patients with occluded central veins."

Bluegrass Vascular has launched the Surfacar System in limited markets, including the UK, Germany, Austria, Italy, and the Benelux. The company will also commence enrollment of the Surfacar System to Facilitate Access in Venous Occlusions (SAVE) Study, an observational, post-market registry for patients with limited or diminishing upper body venous access or pathology impeding standard access methods.

Bluegrass Vascular Announces Issuance of U.S. Patents

The United States Patent and Trademark Office (USPTO) recently issued two patents related to Bluegrass Vascular's technology for the Surfacar Inside-Out Access Catheter System. U.S. patent number 9,289,577 B2, "Occlusion Access System", covers a method for providing access to a central venous system of a patient. U.S. patent number 9,314,595 B2, "Central Venous Access System" covers a catheter system for use in accessing a patient's central venous system at a location near the neck.

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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