

SAVE-US pivotal trial completes enrollment and has positive clinical results

The SAVE-US (Surfacer system to facilitate access in venous occlusions—United States) pivotal trial has completed enrollment. The SAVE-US trial is evaluating the safety and efficacy of the [Surfacer Inside-Out access catheter system](#) (Bluegrass Vascular Technologies) in 30 patients across seven US centres, and demonstrated positive clinical results by meeting its primary and secondary endpoints.

According to a press release, the Surfacer system is a novel approach to achieving right-sided, upper body central venous access in patients with upper body venous occlusions or other conditions that preclude central venous access by conventional methods.

“I am quite encouraged by the highly positive results demonstrated by the Surfacer system,” states Mahmood Razavi, an interventional radiologist at St Joseph Hospital in Orange, USA, and lead investigator of the SAVE-US study. “I am eager for the system’s commercial approval, and look forward to offering a reliable and repeatable solution to patients with varying occlusion types, halting the devastating impact of central venous occlusive disease.”

Of the thirty patients enrolled in the US IDE SAVE-US trial, 90% met both the primary and secondary efficacy endpoints of facilitated central venous access by the Surfacer system. On average, central venous access was achieved in approximately 12 minutes despite a more complex patient population comprised largely of Type 3 and 4 occlusions (three or more occluded vessels).

“The Surfacer system passed the SAVE-US study with flying colours, confirming the system is a safe, viable option for achieving right-sided central venous access, preserving secondary central veins,” comments Ehab Sorial (Division of Vascular Surgery, Stanford, USA; Santa Clara Valley Medical Center, San Jose, USA), the study’s second highest enroller. Sorial first learned about the Surfacer system while working alongside John Gurley, the system’s inventor, for over a decade at the University of Kentucky, Lexington, USA. “This is a highly anticipated treatment that gives physicians a safe and effective alternative to other less efficacious treatments with higher complication rates. I am looking forward to its commercial approval and implementing it into my day-to-day practice.”

Bluegrass Vascular Technologies anticipate that the Surfacer system will be commercial available to physicians in 2020.

Source: <https://vascularnews.com/save-us-pivotal-trial/>

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