Surfacer system IDE study results published in Journal of Vascular Access

Bluegrass Vascular Technologies has announced the publication of the results of its prospective, multicentre SAVE-US (Surfacer system to facilitate access in venous occlusions—United States) study in the Journal of Vascular Access.

This US Food and Drug Administration (FDA) approved investigational device exemption (IDE) study was designed to evaluate the performance and safety of the Surfacer Inside-Out access catheter system (Surfacer system) when used to facilitate central venous access in patients with thoracic central venous obstructions. The results of this study led to the FDA recently granting de novo classification of the Surfacer system.

“The SAVE-US study met both its primary safety and effectiveness endpoints while demonstrating the ability to use the Surfacer system to gain central venous access in patients with upper body venous obstructions,” commented Mahmood Razavi, an interventional radiologist at St. Joseph Hospital in Orange, USA, was the principal investigator for the SAVE-US study and lead author for the publication reporting these results. “The Surfacer system provides a potentially life-saving approach for patients on haemodialysis and other therapies where placement of central venous catheters is required for treatment.”

“The publication of the results of the SAVE-US study further adds to the clinical evidence supporting the valuable role the Surfacer system can have in helping to establish central venous access in patients with venous obstructions,” stated Gabriele Niederauer, CEO and president of Bluegrass Vascular. “The findings of this study are consistent with previous reports associated with the use of Surfacer system, confirming the safety and efficacy associated with the use of the device.”

Launch of the Surfacer system in the USA is in progress and first commercial cases were successfully performed in May 2020.

Source: https://vascularnews.com/surfacer-system-ide-study-results-published/

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