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Spectrum Venous Leg Ulcer study demonstrates clinical support for use of VenaSeal™ in advanced superficial venous disease

Results from study indicate strong healing rate of chronic venous ulcers when VenaSeal™ is used in patients with advanced superficial venous disease

Medtronic, the global leader in health care technology, today announced the primary and secondary outcomes of the VenaSeal Spectrum Venous Leg Ulcer (VLU) Study in a podium-first presentation at the 2025 Charing Cross International Symposium.

This single-arm study prospectively assessed time to ulcer healing following VenaSeal™ treatment in patients with an active venous leg ulcer (classified as C6), as the primary endpoint, and a secondary endpoint of vein closure through 12 months. Results from the Spectrum VLU Study provide essential evidence that VenaSeal effectively heals venous leg ulcers, the most advanced stage of superficial venous insufficiency (SVI), by treating patients at the source of their disease.

“This rigorous clinical data demonstrates that VenaSeal delivers outstanding ulcer healing rates in a challenging subset of patients with advanced superficial venous disease,” said Prof. Manj Gohel, principal investigator of the VenaSeal Spectrum Program, consultant vascular surgeon and honorary senior lecturer, Cambridge University Hospitals, Imperial College (Cambridge, U.K.). “The evidence should give physicians confidence that VenaSeal is an effective, safe, and appropriate treatment for a range of patients experiencing SVI.”

The Spectrum VLU data directly addresses SVI treatment in an understudied, complex patient population. Several factors make C6 patients more complex to treat, including being of advanced chronological age and having high rates of serious comorbidities. This new data builds on the known efficacy of endovenous interventions for less severe superficial venous disease (C2-C5)¹, by demonstrating the value proposition for VenaSeal in the most complex VLU cases.

Healing potential

VenaSeal delivered strong healing rates, rapid closure, and freedom from ulcer recurrence.

- 81.3% ulcer healing rate (1 yr)

- 82.7% anatomic closure rate (1 yr)
- 83.0% freedom from ulcer recurrence (1 yr, after healing has occurred)

The median ulcer age in the study was 169 days, with a maximum ulcer age of 6,816 days (18 years and 8 months), demonstrating that VenaSeal can heal even the most chronic and long-standing ulcers.

Safety and effectiveness endpoints

Safety events underwent rigorous review by an independent committee to ensure objective and representative assessment. The following rates were observed:

- VenaSeal system-specific safety events were consistent with prospective literature. Events included: hypersensitivity to VenaSeal (0.8%), phlebitis (8.8%), granuloma (1.6%), Ablation-related thrombus extension (ARTE) (2.4%)
- No deaths related to device or procedure
- Eight serious adverse events (SAEs) related to the device or procedure: infections (4), superficial vein thrombosis (3), granuloma (1)
- Low hypersensitivity rate of 0.8%

“This new data from the Spectrum Program expands the body of knowledge showing that VenaSeal is an effective treatment across the full range of superficial venous disease severity,” said David Moeller, senior vice president and president, Peripheral Vascular Health, which is part of the Cardiovascular portfolio at Medtronic. “It demonstrates that VenaSeal is appropriate and reliable for complex SVI cases, building on the breadth of published data on treatment earlier in the course of the disease.”

The [VenaSeal Spectrum Program](#) is one of the largest and most innovative clinical programs in the treatment of venous disease. More information is available at medtronic.com/spectrum. The VenaSeal closure system is commercially available in 70 countries, including the U.S. and all EU member countries.

1. Cai PL, Hitchman LH, Mohamed AH, Smith GE, Chetter I, Carradice D. Endovenous ablation for venous leg ulcers. *Cochrane Database Syst Rev*. 2023;7(7):CD009494. Published 2023 Jul 27. doi:10.1002/14651858.CD009494.pub3

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