OCT 3, 2026

Medtronic announces new prospective, global clinical evidence from the Spectrum Program for VenaSeal™ closure system in advanced chronic venous disease

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Medtronic, a global leader in healthcare technology, announced new prospective findings from the VenaSeal™ Spectrum Program, further strengthening the evidence supporting the VenaSeal™ closure system across chronic venous disease. The findings were presented at the 2026 Venous Endovascular INterventional Strategies 2026 (VEINS) conference. This comes in addition to recent news that VenaSeal is now covered by all major commercial payers in the U.S., helping to expand access to treatment for patients.

Together, the growing body of clinical evidence and expanded payer coverage reflect significant progress in making VenaSeal more accessible to physicians and patients seeking treatment for chronic venous disease, from symptomatic venous insufficiency to advanced disease with active venous leg ulcers.

"At Medtronic, our goal is not only to advance innovation in venous disease treatment, but also to ensure patients can access therapies supported by strong clinical evidence," said David Moeller, sr. vice president and president, Medtronic Peripheral Vascular Health, which is part of the company's Cardiovascular portfolio. "The latest Spectrum data – combined with broad payer coverage – provide physicians and patients with greater confidence in VenaSeal as an effective treatment option for chronic venous disease."

The latest findings include 24-month results from the VenaSeal Spectrum Venous Leg Ulcer (VLU) Study. VenaSeal demonstrated durable outcomes, improvements in symptoms and quality of life,[1-3] and a strong safety[4] profile, relieving suffering in a frail population seeking relief from one of many comorbidities. VLUs can be extremely painful, interfering with patients' quality of life and requiring frequent dressing changes, visits to wound care centers, and complicated compression therapies. VenaSeal as a treatment eliminates the need for tumescent

anesthesia, reducing procedural trauma and discomfort, which are important considerations for patients with active ulcers and fragile tissue.[4] Unlike thermal ablation treatments, VenaSeal avoids risks such as nerve injury and skin burns, while minimizing the need for additional procedures.[5,6]

"These rigorous clinical results show that the VenaSeal system works in the most challenging subset of patients with severe disease — healing ulcers, relieving symptoms, treating the underlying venous disease, and achieving durable results," said Mr. Manjit Gohel, M.D., Principal Investigator for the VenaSeal Spectrum Program. "Based on these findings, it is evident that the VenaSeal system is an appropriate, safe, and effective treatment for venous leg ulcers, the most advanced phase of superficial venous disease."

The single-arm VenaSeal Spectrum VLU Study evaluated VenaSeal treatment in 125 participants, globally, with active venous leg ulcers and advanced chronic venous disease.

Key 24-month findings include:

- 88.1% ulcer healing rate through 24 months
- Median time to ulcer healing was 92 days
- 22.9% cumulative incidence of recurrence (77.1% freedom from ulcer recurrence) through 24 months after initial healing
- An average of 487 ulcer-free days following initial healing
- 78% anatomic closure through 24 months
- Symptoms and quality of life improved from baseline[1-3]
- Low reintervention rate through 24 months

The growing body of clinical evidence provides additional information to support treatment decisions and reinforces confidence in VenaSeal's safety,[7] effectiveness, durability, and patient impact, while expanded insurance coverage helps remove an important barrier to treatment access for patients and physicians.

More information on the VenaSeal Spectrum Program 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.

About the VenaSeal Spectrum VLU Study

The VenaSeal Spectrum VLU Study is one of three separate studies making up the VenaSeal Spectrum Program. It is a prospective, single-arm evaluation of the VenaSeal system in 125 participants with C6 disease. Twelve-month outcomes included time to ulcer healing and recurrence to ensure that particularly challenging symptoms were addressed, and anatomic closure to assess VenaSeal system's ability to treat the underlying chronic venous disease. In alignment with the high standards that Medtronic holds for patient safety and quality, safety events reported through 12-months post treatment underwent rigorous review by an independent committee and ulcer healing was confirmed by an independent wound core lab to ensure objective and representative assessment in this complex patient population.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading

global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow on LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

Contacts:
Shannon Dee
Public Relations
+1-763-232-7880

Ingrid Goldberg
Investor Relations
+1-763-505-2696

References

1. rVCSS = revised venous clinical severity score; ranges from 0 to 30, with lower scores indicating better health
2. mAVVQ = modified Aberdeen Varicose Vein Questionnaire; ranges from 0 to 100, with lower scores indicating better venous health.
3. EQ-5D-5L = EuroQoL 5-Dimensions, 5-Levels; ranges from 0 to 1, with higher scores indicating better health.
4. Proebstle TM, Alm BJ, Göckeritz O, et al. Five-year results from the prospective European multicentre cohort study on radiofrequency segmental thermal ablation for incompetent great saphenous veins. Br J Surg. February 2015;102(3):212–218.
5. Morrison N, Gibson K, McEnroe S, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). J Vasc Surg. April 2015;61(4):985–994.
6. Gibson K, Glorieux K. VenaSeal versus Ablation with Endothermal Laser or Radiofrequency for Saphenous Vein Incompetence: a Comparison of Utilization of Adjunctive Phlebectomy (VenaSeal Value). Presented at AVLS 2019.
7. Hypersensitivity reaction, granuloma, phlebitis, and ablation related thrombus extension and all serious adverse events (SAEs) were adjudicated by an independent CEC until 12M after treatment. No new related VenaSeal system specific AEs or SAEs between 6M and 24M.

https://news.medtronic.com/Medtronic-announces-new-prospective,-global-clinical-evidence-from-the-Spectrum-Program-for-VenaSeal-TM-closure-system-in-advanced-chronic-venous-disease