Medtronic

VenaSeal™ Closure System

Introduce your patients to relief.

Non-thermal.
Non-tumescent.
Non-sclerosant.

The VenaSeal closure system offers relief for patients suffering from venous reflux disease by using a medical adhesive to permanently close the vein.

With no need for heat, the VenaSeal procedure delivers a comfortable patient experience[†1,2] and immediate vein closure,[1,2] with the results you have come to expect.

[†]No tumescent, no compression stockings.[‡]

Immediate closure[1,2]

How it works

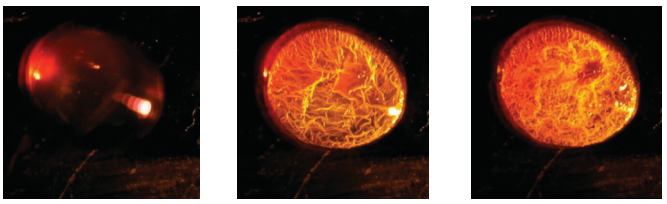
The VenaSeal closure system provides immediate vein closure, delivering consistent and reproducible results for your patients without the need for post-procedure compression stockings.[‡1,2]

Precision

The dispensing gun precisely controls the amount of adhesive, delivering 0.10 cc aliquots with each trigger pull.

Polymerization

Upon contact with blood, the adhesive begins to bond with the intima and compression is applied to close the vein. The adhesive was designed to remain permanently in the diseased vein and is encapsulated by chronic fibrosis.[3]



0 seconds | 24 seconds | 54 seconds

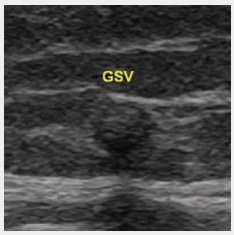
Viscosity

The viscosity of the adhesive is specifically designed to minimize migration and embolization outside the treatment area.

Flexibility

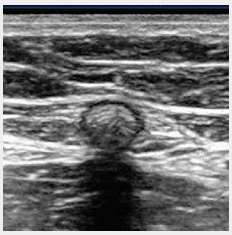
The adhesive is designed to be soft and flexible, and less likely to be felt by the patient.

VenaSeal adhesive over time



30 days
post-procedure

The ultrasound image shows chronic foreign body reaction, leading to fibrous occlusion in treated veins.



12 months
post-procedure

The VenaSeal adhesive is sonographically dense, as demonstrated by the shadowing in this ultrasound image.

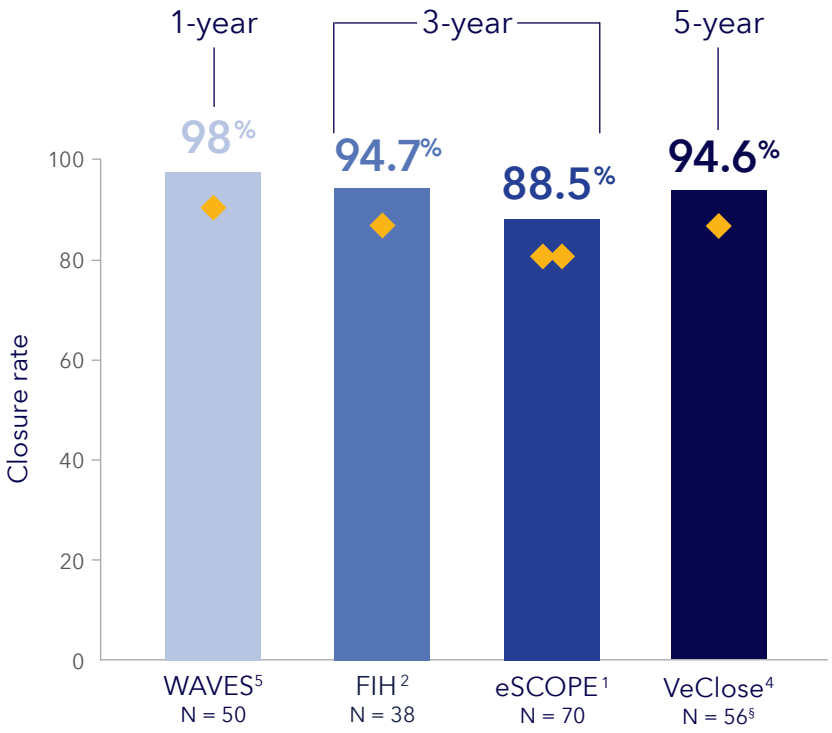
The results you have come to expect

VeClose 5-year Extension Study (IDE clinical trial)[4]

- One of the largest multicenter, randomized prospective comparisons of superficial venous ablation technologies
- **No DVT, PE, or adhesive-related allergies** were reported in the VenaSeal closure system study arm

94.6%
closure at
5 years[4]

VenaSeal system clinical study overview



[§]VenaSeal closure system includes nine roll-in patients.

Definition of occlusion

> 10 — No discrete segment of patency > 10 cm in the treated vein segment

> 5 — No discrete segment of patency > 5 cm in the treated vein segment

Study design

WAVES: Prospective, single-center, multi-investigator, post-market study

FIH: Prospective, single-center study

eSCOPE: Prospective, multicenter, post-market study

VeClose: Prospective, multicenter, randomized controlled trial

VenaSeal closure system

A comfortable patient experience

The VenaSeal closure system offers:

- Rapid return to normal activities after treatment[6,7]
- Minimized pain, tenderness and ecchymosis[7]
- Significant improvements in quality of life[8]

The VenaSeal closure system eliminates:[1,2]

- Tumescent anesthesia
- Thermal nerve injury
- Post-procedure compression stockings‡

Adverse events can include allergic reaction, inflammation, phlebitis, deep vein thrombosis and/or pulmonary embolism.

VenaSeal closure system is now reimbursed where covered under codes 36482 and 36483.Ω

‡Some patients may benefit from the use of compression stockings post-procedure.

ΩCPT codes for cyanoacrylate (VenaSeal system) do not guarantee payer coverage. Medtronic is actively pursuing coverage for VenaSeal system with Medicare, Medicaid, Commercial, and VA payers.

References

[1]Proebstle TM. The European Multicenter Study on Cyanoacrylate Embolization of Refluxing Great Saphenous Veins without Tumescent Anesthesia and without Compression Therapy. Results presented at Charing Cross 2016; London, UK.

[2]Almeida JI, Javier JJ, Mackay EG, Bautista C, Cher DJ, Proebstle TM. Thirty-sixth-month follow-up of first-in-human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. *J Vasc Surg Venous Lymphat Disord.* September 2017;5(5):658-666.

[3]Lui DM, et al. Cyanoacrylate Embolization for the Treatment of Saphenous Vein Reflux: Ultrasound Appearance and Correlative Findings of Comparative Model Histology. ACP 2014.

[4]Morrison N, Gibson K, Vasquez M, Weiss R, Jones A. Five-year extension study of patients from a randomized clinical trial (VeClose) comparing cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. *J Vasc Surg Venous Lymphat Disord.* November 2020;8(6):978-989.

[5]Gibson K. Cyanoacrylate Closure of Incompetent Great, Small and Accessory Saphenous Veins without the use of Post-Procedure Compression: A Post-Market Evaluation of the VenaSeal System (WAVES trial): 12 Month Data. Presented at Charing Cross 2016; London, UK.

[6]Gibson K, Ferris B. Cyanoacrylate closure of incompetent great, small and accessory saphenous veins without the use of post-procedure compression: Initial outcomes of a post-market evaluation of the VenaSeal System (the WAVES Study). *Vascular.* April 2017;25(2):149-156.

[7]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.

[8]Morrison N, Gibson K, Vasquez M, et al. VeClose trial 12-month outcomes of cyanoacrylate closure versus radiofrequency ablation for incompetent great saphenous veins. *J Vasc Surg Venous Lymphat Disord.* May 2017;5(3):321-330.

VenaSeal™ Closure System Brief Statement

Intended Use/Indications: The VenaSeal™ closure system (VenaSeal™ system) is indicated for use in the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV), through endovascular embolization with coaptation. The VenaSeal system is intended for use in adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound (DUS).

Contraindications: Separate use of the individual components of the VenaSeal closure system is contraindicated. These components must be used as a system. The use of the VenaSeal system is contraindicated when any of the following conditions exist: previous hypersensitivity reactions to the VenaSeal™ adhesive or cyanoacrylates, acute superficial thrombophlebitis, thrombophlebitis migrans, acute sepsis.

Potential Adverse Effects of the Device on Health: The potential adverse effects (e.g., complications) associated with the use of the VenaSeal system include, but are not limited to, adverse reactions to a foreign body (including, but not limited to, nonspecific mild inflammation of the cutaneous and subcutaneous tissue), arteriovenous fistula, bleeding from the access site, deep vein thrombosis (DVT), edema in the treated leg, embolization, including pulmonary embolism (PE), hematoma, hyperpigmentation, hypersensitivity or allergic reactions to cyanoacrylates, such as urticaria, shortness of breath, and anaphylactic shock, infection at the access site, pain, paresthesia, phlebitis, superficial thrombophlebitis, urticaria, erythema, or ulceration may occur at the injection site, vascular rupture and perforation, visible scarring.

Warnings, precautions, and instructions for use can be found in the product labeling at http://manuals.medtronic.com.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Learn more at
medtronic.com/VenaSeal

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