

RELIEF IS JUST THE BEGINNING

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. **IMPORTANT:** Please reference the Instructions For Use (IFU) for a complete listing of indications, contraindications, warnings and precautions, adverse effects and suggested procedure. An electronic IFU can be accessed at www.useifu.venaseal.com.

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**FIND
RELIEF**
FROM
VARICOSE
VEINS

VenaSeal™
Closure System

Medtronic
Further, Together

UNDERSTAND

Varicose veins may be a sign of something more severe—**venous reflux disease**

Your doctor can help you understand if you have this condition.

Healthy leg veins have valves that keep blood flowing to the heart. Venous reflux disease develops when the valves stop working properly and allow blood to flow backward (i.e., reflux) and pool in the lower leg veins. If venous reflux disease is left untreated, symptoms can worsen over time.

Superficial **venous reflux disease** may cause the following signs and symptoms in your legs:¹

Varicose veins

Aching

Swelling

Cramping

Heaviness or tiredness

Itching

Open skin sores

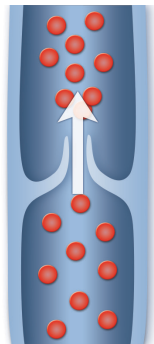
Restlessness

VENOUS ANATOMY

FEMORAL VEIN

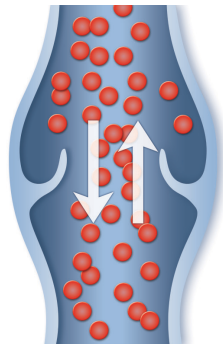
GREAT SAPHENOUS VEIN

SMALL SAPHENOUS VEIN



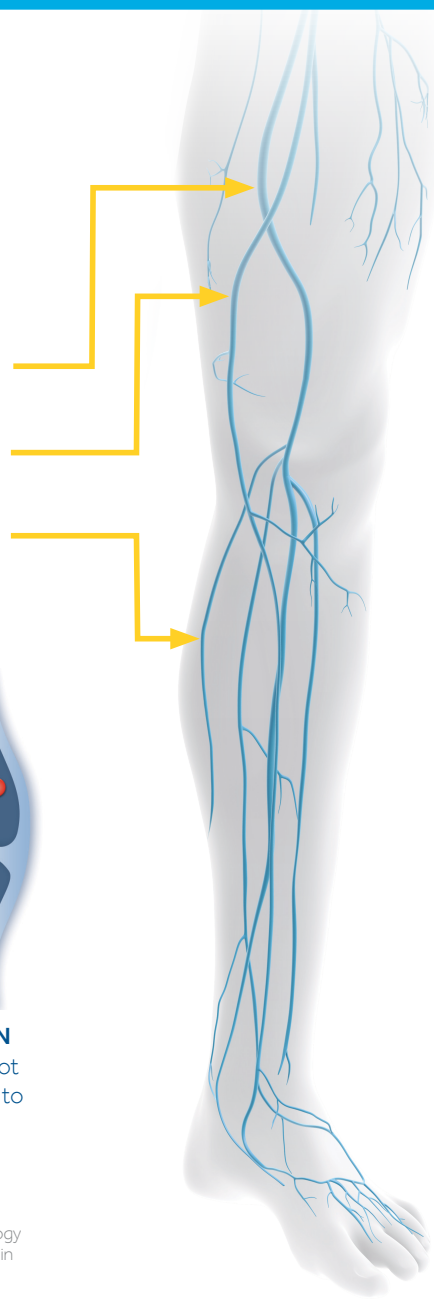
NORMAL VEIN

Valves ensure blood flows in one direction



DISEASED VEIN

Valves that cannot close allow blood to drain and pool



¹ Criqui, M. H., Denenberg, J. O., Langer, R. D., Kaplan, R. M., & Fronek, A. (2013). Epidemiology of Chronic Peripheral Venous Disease. In J. J. Bergan & N. Bunke-Paquette (Eds.), *The Vein Book* (pp. 27-36). New York, NY: Oxford University Press.

TREAT

Superficial venous reflux disease treatment aims to reduce or stop the backward flow of blood. Treating the diseased vein improves overall blood flow and relieves symptoms. For some patients, compression stockings alone may improve blood flow. For other patients, closing or removing the diseased vein may be necessary to improve blood flow. Closing or removing the diseased vein directs blood to nearby healthy veins. Your doctor can help you decide which treatment option is best for you.



VENASEAL™ CLOSURE SYSTEM

The VenaSeal system improves blood flow by sealing—or closing—the diseased vein. The system delivers a small amount of a specially formulated medical adhesive to the diseased vein. The adhesive seals the vein and blood is rerouted through nearby healthy veins.

CLINICAL TRIAL EXPERIENCE

Three clinical studies demonstrate results that support the clinical safety and effectiveness of the VenaSeal system.^{1,2,3}

The treated superficial veins close immediately and stay closed. Blood flows through nearby healthy veins and symptoms improve. *In the US study,*

- The VenaSeal system and thermal energy (radiofrequency ablation; RFA) treatments have similar clinical results (at 3 months, 99% closure for the VenaSeal system and 95.4% closure for thermal energy).^{1*}
- 96.8% of veins remained closed at 12 months after treatment with the VenaSeal system or RFA.¹

Side effects are minor and infrequent.

- The most common side effect was phlebitis (i.e., inflammation of a vein). Phlebitis occurred more frequently in VenaSeal-treated subjects compared to RFA-treated subjects. Phlebitis is a commonly reported side effect in all vein treatments, including the VenaSeal system and RFA, and they typically occurred within the first 30 days after the procedure.¹
- Please see the Potential Risk section for more information.

REDUCES DISCOMFORT AND RECOVERY TIME

THERMAL ENERGY: THE TRADITIONAL TREATMENT OPTION	VENASEAL™ CLOSURE SYSTEM: AN INNOVATIVE TREATMENT OPTION
Heat closes the vein	Adhesive seals the vein
Multiple needle sticks of numbing medicine	Only one needle stick of numbing medicine
Compression stockings required after the procedure	No compression stockings after the procedure**

In comparison, patients treated with the VenaSeal system experience less pain and bruising.¹

*VeClose study. Covidien Inc. Data on file.

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

¹ Morrison N. et al, Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). *Journal of Vascular Surgery*. 2015.

² Proebstle TM et al, The European multicenter cohort study on cyanoacrylate embolization of refluxing great saphenous veins. *Journal of Vascular Surgery*. 2014.

³ Amleida JI et al, Two-year follow-up of first human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. *Phlebology*: published online 30 March 2014.



FAQ

What can I expect of the VenaSeal™ procedure?

Before the Procedure:

You will have an ultrasound imaging exam of the leg that is to be treated. This exam is important for assessing the diseased superficial vein and planning the procedure.

During the Procedure:

Your doctor can discuss the procedure with you. A brief summary of what to expect is below:

- You may feel some minor pain or stinging with a needle stick to numb the site where the doctor will access your vein.
- Once the area is numb, your doctor will insert the catheter (i.e., a small hollow tube) into your leg. You may feel some pressure from the placement of the catheter.
- The catheter will be placed in specific areas along the diseased vein to deliver small amounts of the medical adhesive. You may feel some mild sensation of pulling or tugging. Ultrasound will be used during the procedure to guide and position the catheter.
- After treatment, the catheter is removed and a bandage placed over the puncture site.

After the Procedure:

You will be taken to the recovery area to rest. Your doctor will discuss with you what observations will be performed following treatment.

When will my symptoms improve?

Symptoms are caused by the diseased superficial vein. Thus, symptoms may improve as soon as the diseased vein is closed.

When can I return to normal activity?

The VenaSeal procedure is designed to reduce recovery time. Many patients return to normal activity immediately after the procedure. Your doctor can help you determine when you can return to normal activity.

Is the VenaSeal procedure painful?

Most patients feel little, if any, pain during the outpatient procedure.¹

Is there bruising after the VenaSeal procedure?

Most patients report little-to-no bruising after the VenaSeal procedure.¹

What happens to the VenaSeal™ adhesive?

Only a very small amount of VenaSeal adhesive is used to close the vein. Your body will naturally absorb the adhesive over time.

How does the VenaSeal procedure differ from thermal energy procedures?

The VenaSeal procedure uses an adhesive to close the superficial vein. Thermal energy procedures use heat to close the vein. The intense heat requires a large volume of numbing medicine, which is injected through many needle sticks. The injections may cause pain and bruising after the procedure.

Is the VenaSeal procedure covered by insurance?

As with any procedure, insurance coverage may vary. For more information, please contact your insurance provider.



The VenaSeal™ Procedure may not be right for everyone

Your doctor can help you decide if the VenaSeal procedure is right for you. The VenaSeal procedure is contraindicated for individuals with any of the following conditions:

- Thrombophlebitis migrans (i.e., inflammation of a vein caused by a slow moving blood clot)
- Acute superficial thrombophlebitis (i.e., inflammation of a vein caused by a blood clot)
- Previous hypersensitivity reactions to the VenaSeal adhesive or cyanoacrylates
- Acute sepsis (i.e., whole-body inflammation caused by an immune response to an infection)

Potential risks

The VenaSeal procedure is minimally invasive and catheter-based. As such, it may involve the following risks. Your doctor can help you understand these risks.

- Allergic reaction to the VenaSeal adhesive
- Arteriovenous fistula (i.e., an abnormal connection between an artery and a vein)
- Bleeding from the access site
- Deep vein thrombosis (i.e., blood clot in the deep vein system)
- Edema (i.e., swelling) in the treated leg
- Hematoma (i.e., the collection of blood outside of a vessel)
- Hyperpigmentation (i.e., darkening of the skin)
- Infection at the access site
- Neurological deficits including stroke and death
- Non-specific mild inflammation of the cutaneous and subcutaneous tissue
- Pain
- Paresthesia (i.e., a feeling of tingling, pricking, numbness or burning)
- Phlebitis (i.e., inflammation of a vein)
- Pulmonary embolism (i.e., blockage of an artery in the lungs)
- Urticaria (i.e., hives) or ulceration may occur at the site of injection
- Vascular rupture and perforation
- Visible scarring

¹ Morrison N. et al, Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). *Journal of Vascular Surgery*. 2015.