

**FIND
RELIEF**
FROM
VARICOSE
VEINS

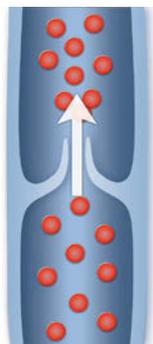
VenaSeal™
Closure System



Medtronic
Further, Together

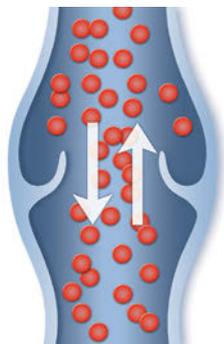
UNDERSTAND

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



NORMAL VEIN

Valves ensure blood flows in one direction



DISEASED VEIN

Valves that cannot close allow blood to drain and pool

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

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

Varicose veins

Aching

Swelling

Cramping

Heaviness or tiredness

Itching

Restlessness

Open skin sores

¹Criqui, 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.

VENOUS ANATOMY*

FEMORAL VEIN
(deep system)

SAPHENOFEMORAL
JUNCTION (SFJ)

GREAT SAPHENOUS
VEIN (GSV)

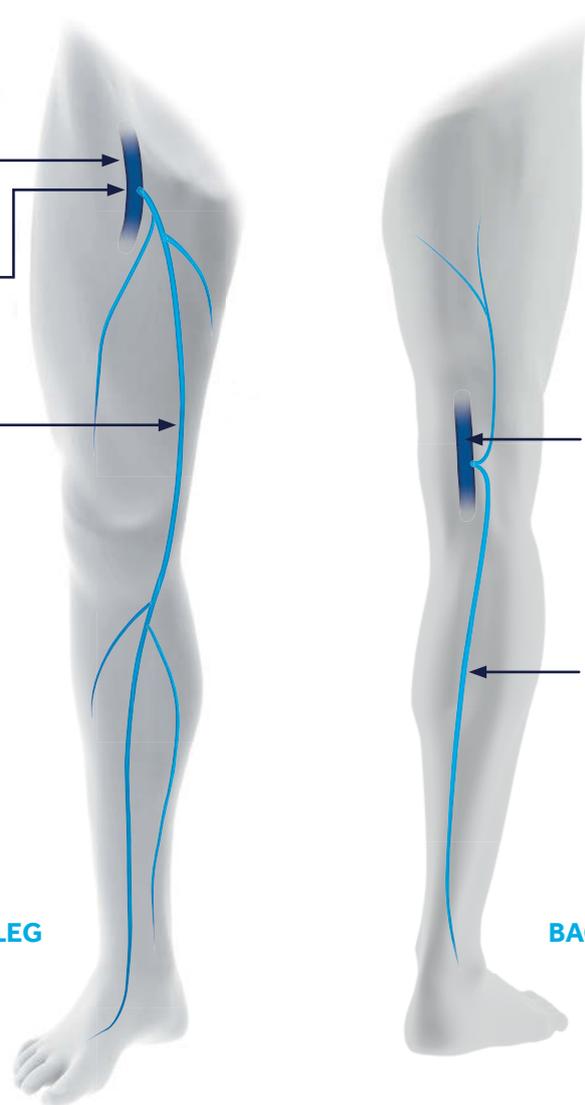
FRONT OF LEG

FEMORAL VEIN
(deep system)

SMALL SAPHENOUS VEIN
(SSV)

BACK OF LEG

*Representative of venous anatomy.



TREAT

Superficial venous reflux disease treatment aims to reduce or stop the backward flow of blood. The following may be prescribed to treat your superficial venous reflux disease. Your doctor can help you decide which treatment is best for you:

- Compression stockings
- Removing diseased vein
- Closing diseased vein (through thermal or non-thermal treatment)



VenaSeal™ Closure System

One non-thermal treatment option is the VenaSeal™ Closure System, which improves blood flow and relieves symptoms 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 permanently seals the vein and blood is rerouted through nearby healthy veins.

DEMONSTRATED OUTCOMES

The VenaSeal™ closure system is a safe and effective treatment, providing significant improvements in quality of life.^{1,2,3}

In a US study¹, the VenaSeal™ system and thermal radiofrequency ablation treatments had similar clinical results at 3 years; 94.4% closure for the VenaSeal™ system and 91.9% for thermal energy.

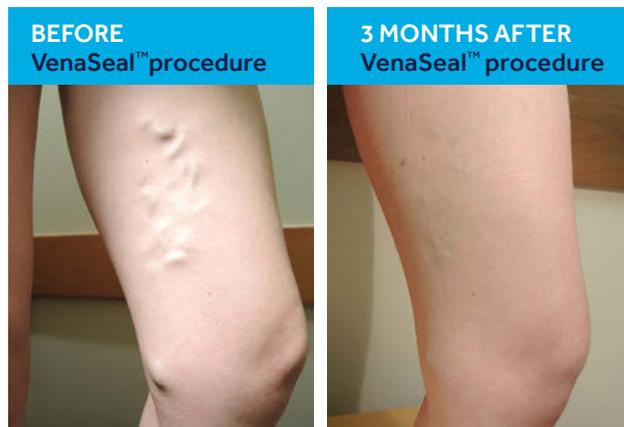
Side effects were minor and infrequent.

- The most common side effect was phlebitis (i.e., inflammation of a vein), and it typically occurred within the first 30 days after the procedure. Phlebitis is a commonly reported side effect in all vein treatments. Phlebitis occurred more frequently in VenaSeal™ system-treated subjects than in RFA-treated subjects, though the difference was not statistically significant.
- Please see the Potential risks 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



Individual results may vary.
Photos courtesy of Dr. Kathleen Gibson.

¹ The VeClose study, Medtronic Inc. Data on file.

² Proebstle TM. The European Multicenter Study on Cyanoacrylate Embolization of Refluxing Great Saphenous Veins without Tumescence Anesthesia and without Compression Therapy. Results presented at: Charing Cross; 2016; London, UK.

³ Almeida JI et al. Thirty-sixth-month follow-up of first-in-human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. *Journal of Vascular Surgery: Venous and Lymphatic Disorders*. Published Online: 2 June 2017.

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

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. Ultrasound will be used during the procedure to guide and position the catheter.
- After treatment, the catheter is removed and a small adhesive bandage placed over the puncture site.

After the Procedure:

- You will be taken to the recovery area to rest.
- Your doctor will recommend follow-up care as needed.

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 create scar tissue around the adhesive over time to keep the vessel permanently closed.

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.

¹ The VeClose Study, Medtronic, Inc. Data on file.

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
- Embolization (i.e., blockage of a vein or artery), including pulmonary embolism (i.e., blockage of an artery in the lungs)
- Hematoma (i.e., the collection of blood outside of a vessel)
- Hyperpigmentation (i.e., darkening of the skin)
- Infection at the access site
- 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)
- Superficial thrombophlebitis (i.e., inflammation of a vein caused by a blood clot)
- Urticaria (i.e., hives) or ulceration may occur at the site of injection
- Vascular rupture and perforation
- Visible scarring

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.medtronic.com/manuals.

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