

**Medtronic**

Relief from  
varicose veins  
is possible.

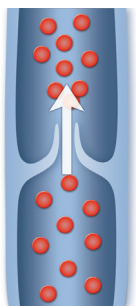
VenaSeal™  
procedure for  
vein disease



# Understanding the cause

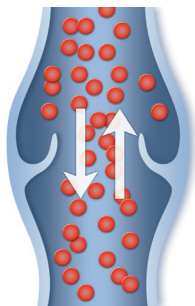
## About venous reflux

Healthy leg veins have valves that keep blood flowing to the heart.



**Normal vein**

Valves ensure blood flows in one direction



**Diseased vein**

Valves that cannot close allow blood to drain and pool

## Venous reflux

develops when valves stop working properly and allow blood to flow backward, or reflux, and pool in the lower leg veins.

Healthy leg veins have valves that keep blood flowing to the heart.

## Chronic venous insufficiency

If venous reflux is left untreated, it may worsen over time and develop into a more serious form of venous disease called chronic venous insufficiency (CVI).<sup>1</sup>

# CVI signs and symptoms in the legs or ankles<sup>2,3</sup>

- Varicose veins
- Aching or pain
- Swelling
- Cramping
- Heaviness or tiredness
- Itching
- Restlessness
- Skin changes and/or discoloration
- Open sores or ulcers



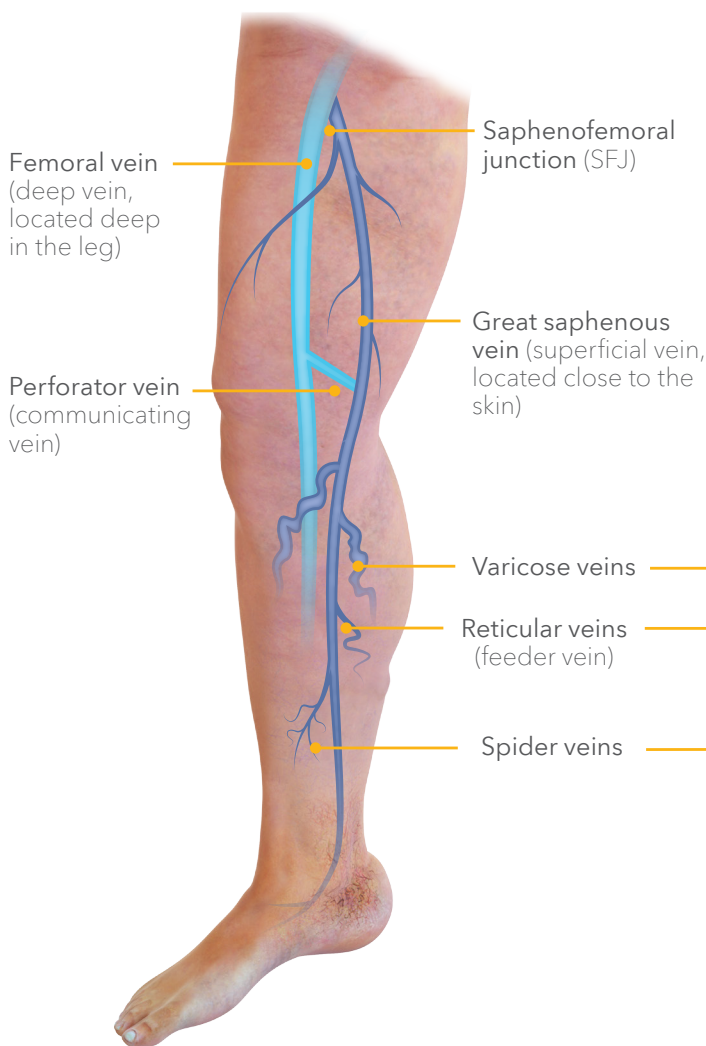
## CVI risk factors<sup>2</sup>

- Family history
- Lack of exercise
- Leg injury or trauma
- Prolonged sitting or standing
- Obesity or excess weight
- Current or previous pregnancies
- Smoking
- Blood clot (deep vein thrombosis)

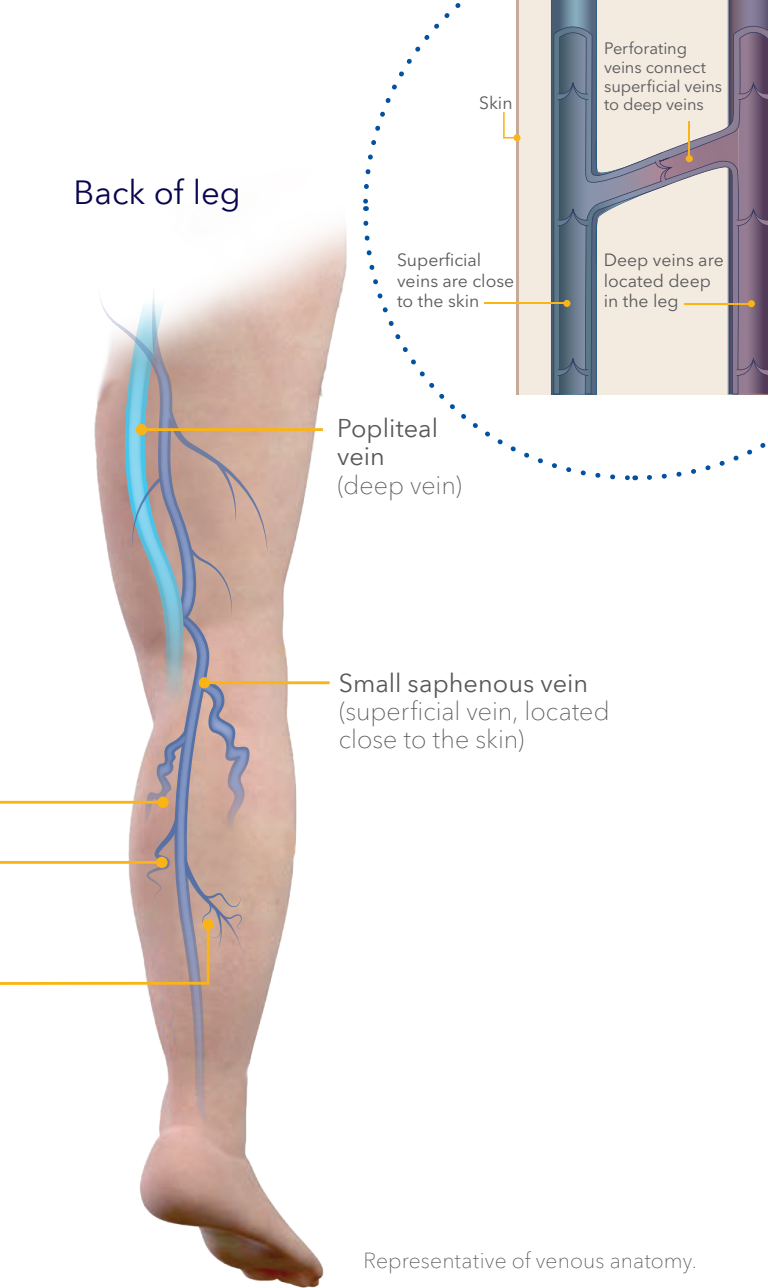
Using ultrasound to scan your leg(s), your physician will determine if you have venous reflux in your leg veins.

# Leg vein anatomy

## Front of leg



CVI and varicose veins are more common than you think. More than 30 million people in the United States are afflicted with venous reflux or the more serious disease, CVI.<sup>3</sup>



With proper treatment, your physician can help prevent the progressive symptoms of venous reflux.

Without treatment, venous reflux may progress and significantly impact your quality of life, and lead to venous leg ulcers.<sup>1</sup>

# Treatment

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 nonthermal treatment)

## Two treatment options

Thermal energy Traditional treatment option	VenaSeal closure system 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 procedure	No compression stockings after the procedure <sup>†</sup>

<sup>†</sup>Some patients may benefit from the use of compression stockings post-procedure.

## VenaSeal™ procedure nonthermal vein closure

### Demonstrated outcomes

The VenaSeal closure system is a safe and effective treatment, providing significant improvement in quality of life.<sup>4-8</sup>

In a U.S. study, the VenaSeal system and thermal radiofrequency ablation treatments had similar clinical results at five years: 94.6% closure for the VenaSeal system<sup>9</sup> and 91.9% for thermal energy.<sup>10</sup>

**The VenaSeal system** delivers a small amount of a specially formulated medical adhesive to close the diseased vein, rerouting blood to nearby healthy veins, which provides symptom relief.



**Before**

VenaSeal procedure



**Six weeks after**

VenaSeal procedure

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

## A more comfortable experience

- Simple, outpatient procedure
- No tumescent anesthesia
- Less pain and bruising than thermal ablation<sup>7,11</sup>
- Faster recovery time than thermal ablation<sup>7,11</sup>
- Compression stockings not needed after the procedure<sup>†11,12</sup>



**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.

- Adverse reactions to a foreign body (including, but not limited to, nonspecific mild inflammation of the cutaneous and subcutaneous tissue)
- 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)
- Hypersensitivity or allergic reaction to cyanoacrylates, such as urticaria, shortness of breath, and anaphylactic shock
- Infection at the access site
- 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), erythema (i.e., redness), or ulceration may occur at the injection site
- Vascular rupture and perforation
- Visible scarring





# What can I expect from the VenaSeal procedure?

## Answers to some common questions.

### **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. Here is a brief summary of what to expect: 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 (a small, hollow tube) into your leg. You may feel a 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 a 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.<sup>6</sup>

### Is there bruising after the VenaSeal procedure?

Most patients report little to no bruising after the VenaSeal procedure.<sup>6</sup>

### 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.



Relief is just the beginning.

#### **If you have more questions:**

- Talk to your doctor to learn more about the VenaSeal procedure
- **Find a doctor at:**  
[Medtronic.com/FindVeinDoctor](https://www.Medtronic.com/FindVeinDoctor)
- **Learn more at:**  
[Medtronic.com/VaricoseVeins](https://www.Medtronic.com/VaricoseVeins)



# Relief is just the beginning.

Learn more at:

[Medtronic.com/VaricoseVeins](https://www.Medtronic.com/VaricoseVeins)

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- <sup>5</sup> 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.
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- <sup>10</sup> 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.
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## 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.

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