

# Understanding vein disease

Chronic venous insufficiency (CVI) and varicose veins are more common than you may think, affecting more than 30 million people in the United States.<sup>1,2</sup>

<sup>1</sup> Gloviczki P, et al. *J Vasc Surg.* 2011;53:2S-48S.

<sup>2</sup> Lee A. U.S. Markets for Varicose Vein Treatment Devices 2011. RPUS11VR11. Toronto, Ontario. Millennium Research Group. June 2011.







Do you need to sit down during your workday because your legs ache and/or swell?

Do you miss out on doing the activities you love because your legs feel **heavy** or **painful**?



Do your burning or restless legs make it hard to sleep at night or affect your daily routine?

These are some of the often **misunderstood** and easily misdiagnosed signs and symptoms of **vein disease**.





# What is venous disease?

Vein disease – also called venous disease or chronic venous insufficiency (CVI) – is a **medical condition**.

It is recognized by Medicare, Medicaid, and private insurance carriers as a medical condition.



# How did I get it?

## Possible genetic risk factors<sup>1</sup>

- Gender: women are more likely to develop the disease
- Family history

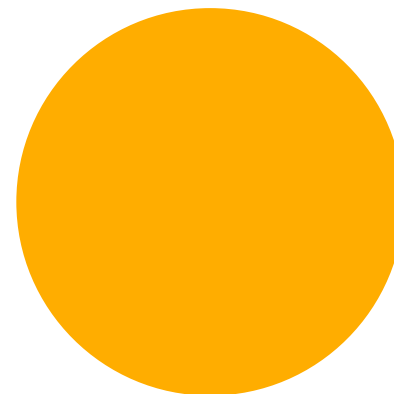
## Possible lifestyle risk factors

- 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)

<sup>1</sup>Chronic Venous Insufficiency. Johns Hopkins Medicine. Available at: <https://www.hopkinsmedicine.org/health/conditions-and-diseases/chronic-venous-insufficiency>. Accessed July 8, 2022.



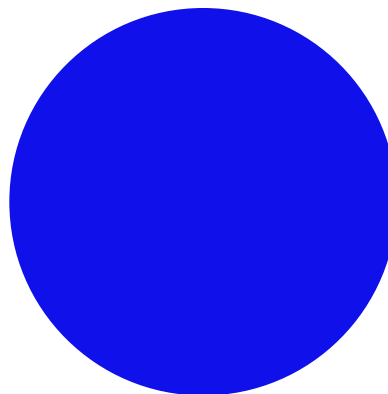




# What most people don't know

Varicose veins are not spider veins and they are not considered only cosmetic.

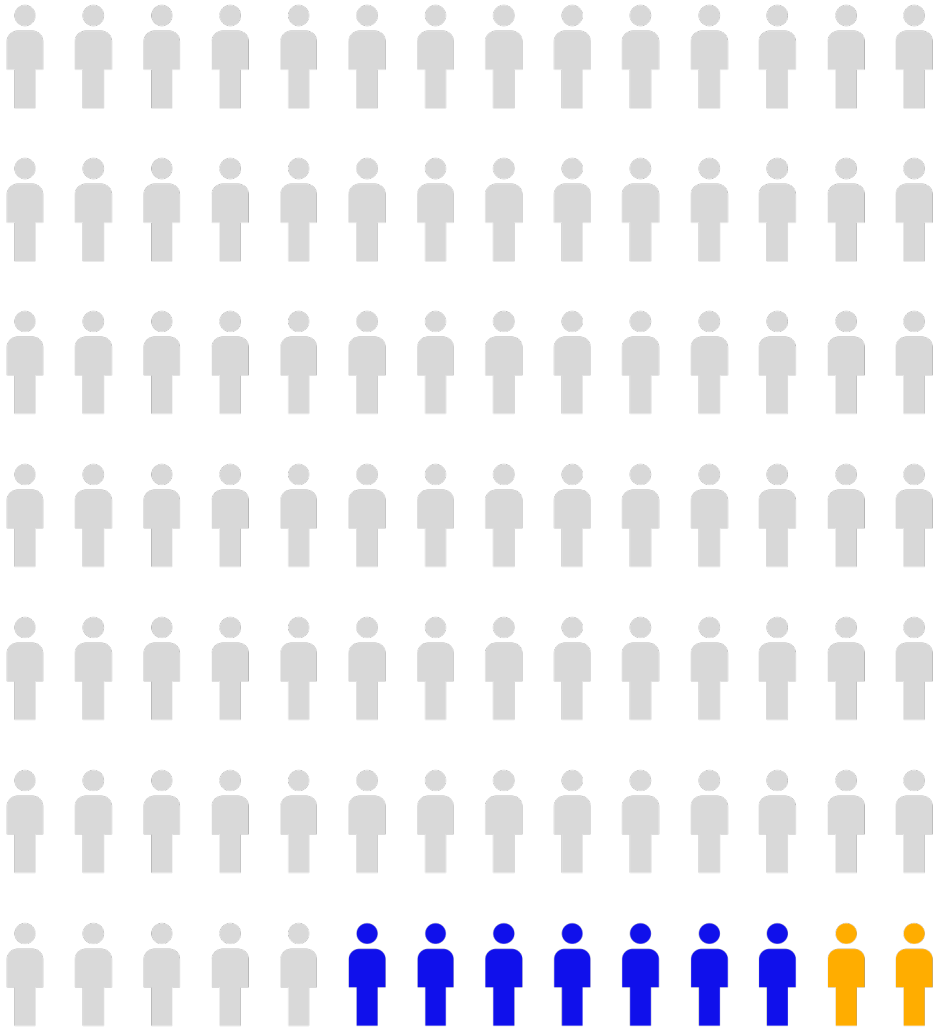
**Vein disease can affect all people, regardless of age, gender, or race.**





# Chronic venous insufficiency

## A clinical challenge



Of the  
> 30 million  
people in the United  
States with CVI and  
varicose veins ...<sup>†1</sup>

< 2 million  
seek treatment each year<sup>†1,2</sup>

< 500,000  
receive treatment each year<sup>†1,2</sup>

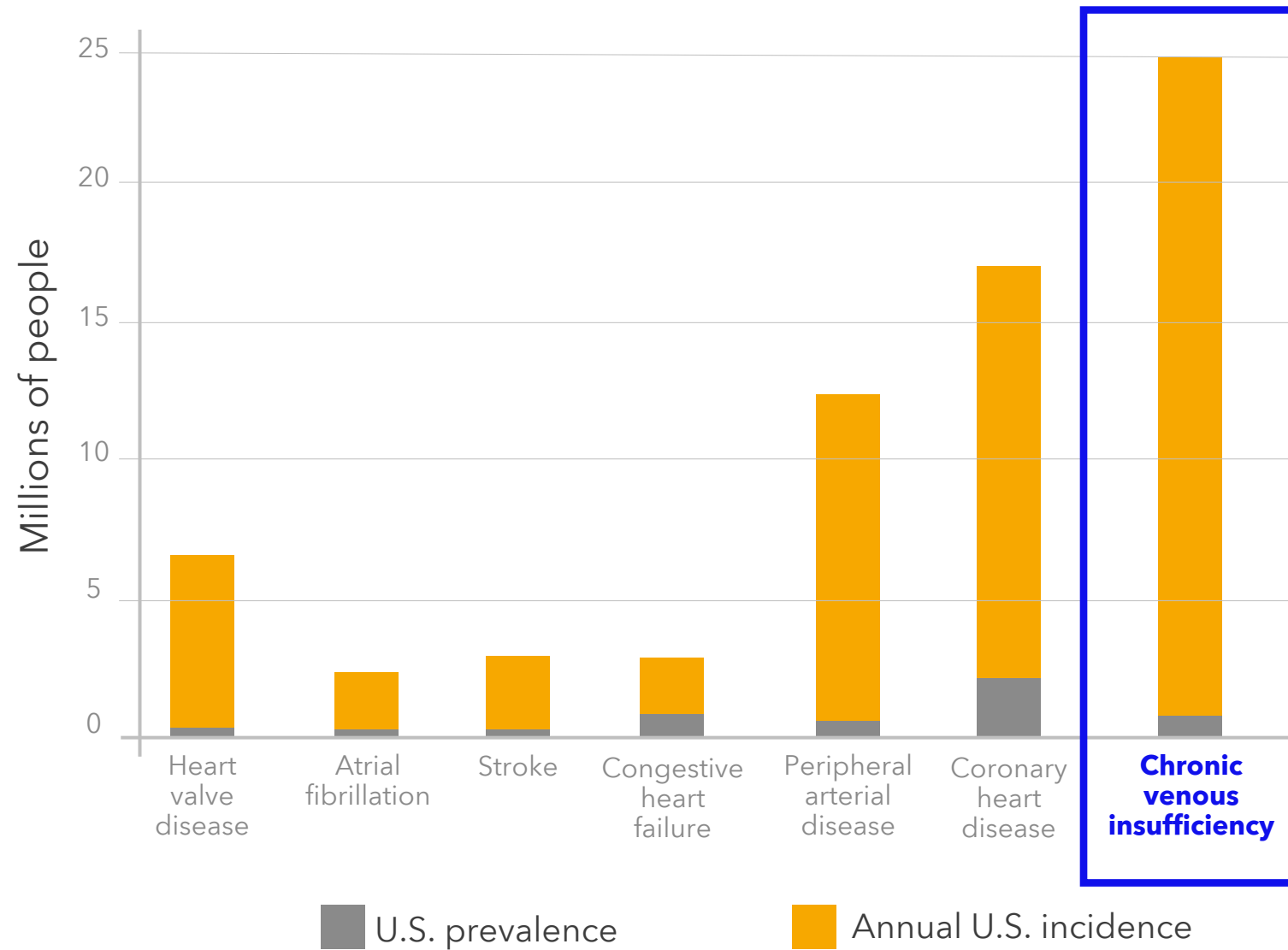
The vast majority of patients with CVI remain undiagnosed and untreated.

It is estimated that people live with CVI for up to 35 years before seeking treatment.<sup>3</sup>

<sup>†</sup>Statistics based on individuals over the age of 40.  
<sup>1</sup> Glociczki P, et al. *J Vasc Surg.* 2011;53:2S-48S.  
<sup>2</sup> Lee A. U.S. Markets for Varicose Vein Treatment Devices 2011. RPUS11VR11. Toronto, Ontario. Millennium Research Group. June 2011.  
<sup>3</sup> Dymedex Consulting, LLC. Strategic Market Assessment: Chronic Venous Insufficiency. November 2014.



# Prominent disease state comparison



## The impact of CVI

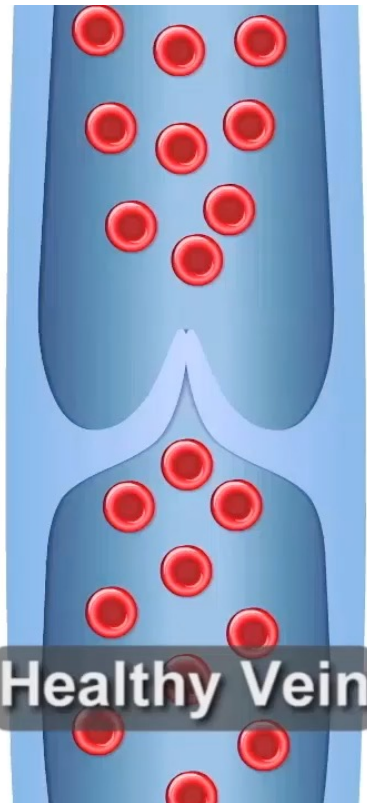
- 1.5x more prevalent than coronary heart disease (CHD)<sup>1,2</sup>
- 2x more prevalent than peripheral arterial disease (PAD)<sup>1,2</sup>
- 10x more prevalent than congestive heart failure<sup>2</sup>

<sup>1</sup>Yeldan I, et al. *J Tissue Viability*. 2021;30:310-316.

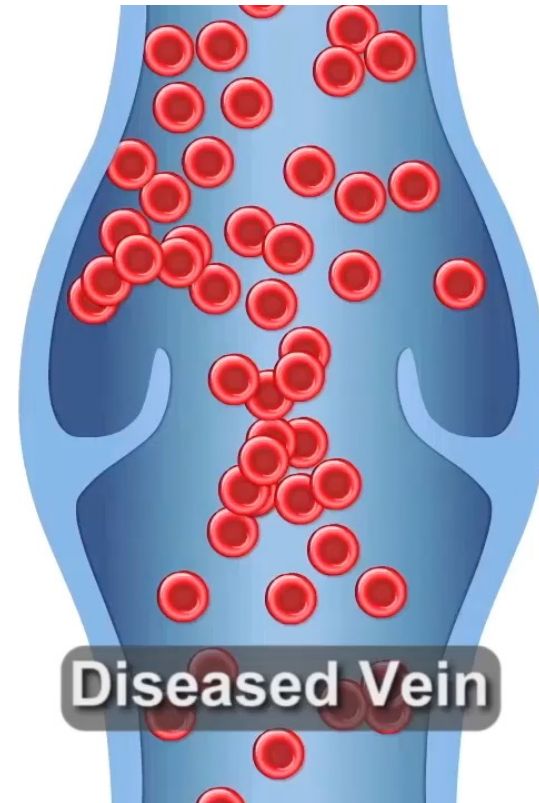
<sup>2</sup>Kim Y, et al. *Semin Vasc Surg*. 2021;34:59-64.



# Venous pathophysiology



Valves ensure blood flows in one direction.



Valves that cannot close allow blood to drain and pool.

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

Vein disease develops when the valves stop working properly and allow blood to flow backward and pool in the lower leg veins.<sup>1</sup>

<sup>1</sup> Gloviczki P, et al. *J Vasc Surg.* 2011;53:2S-48S.



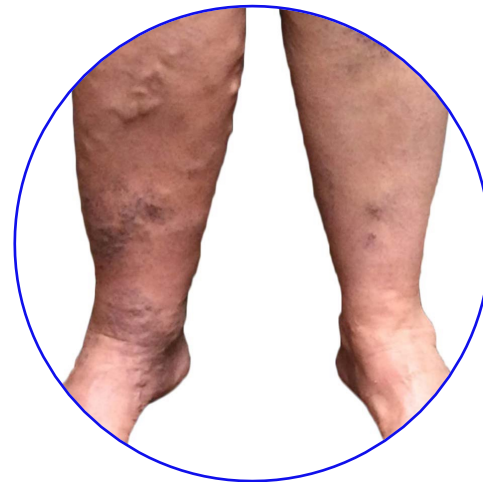
# It's more than just what you can see



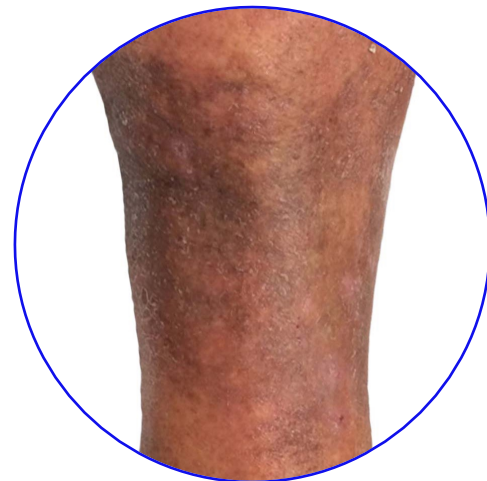
Spider veins



Varicose veins



Swelling



Skin color changes



Skin cracking/sores

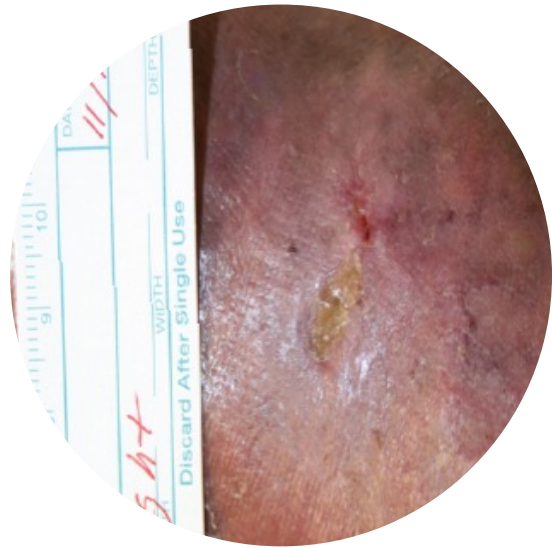
## Sometimes it's about how you feel:

- Heaviness
- Burning
- Aching
- Pain
- Fatigue
- Itching
- Cramping
- Restless leg

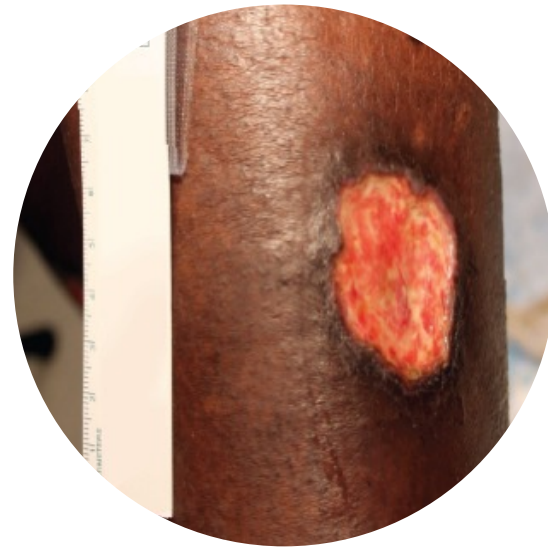
Images courtesy of Dr. Charles Dietzek.



# Advanced-stage disease



Healed venous ulcer



Active venous ulcer

**At this advanced stage, patients are typically in wound care centers undergoing radical wound treatments.**

**Vein disease is a chronic condition. Early detection and treatment of the disease are important.**



# Advanced-stage disease

70-90%

of lower leg ulcers  
are actually venous  
ulcers.<sup>1,2</sup>



**Take back your mobility!**

If you or your loved one has an open wound, ask your doctor if it could be a venous ulcer.

Proper diagnosis and treatment can dramatically improve the healing of a venous ulcer.

<sup>1</sup> O'Donnell TF, et al. *J Vasc Surg.* 2014;60:3S-59S.

<sup>2</sup> Rice JB, et al. *J Med Econ.* 2014;17:347-356.



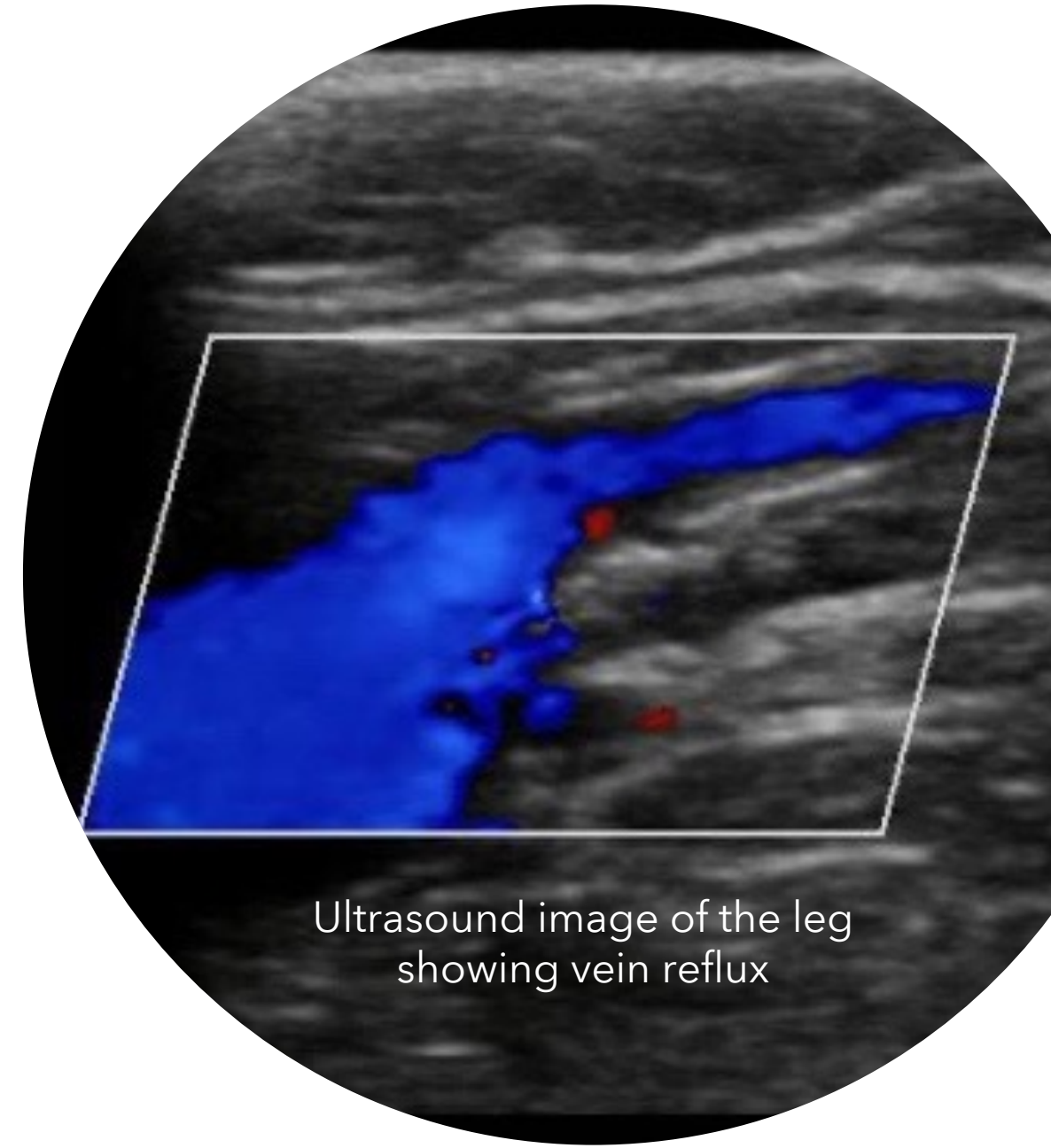
# How to learn if you have vein disease

An ultrasound scan is the only definitive way to diagnose vein disease.

A technician uses this test to get an image of the inside of your leg veins. A doctor will review the test results to determine if the valves inside the veins are working properly.

Although insurance coverage varies by individual plan and the severity of disease, MOST insurance carriers, including Medicare, will cover necessary clinical tests (like an ultrasound test) that are done to help your doctor diagnose or rule out a suspected illness or condition.<sup>1</sup>

(Consult your insurance carrier for specific coverage rules.)



Ultrasound image of the leg showing vein reflux

<sup>1</sup> Medicare coverage for diagnostic laboratory tests. Medicare.gov. Available at: <https://www.medicare.gov/coverage/diagnostic-tests.html>. Accessed July 8, 2022.



What can I do about it?

This disease is  
common –  
and treatable!

Your doctor will put together your  
treatment plan based on:

- Ultrasound test results
- A history and physical that focuses  
on your symptoms, family history,  
and lifestyle factors





# Treatment options

Conservative therapies are required by insurance carriers. They can require up to three months of conservative therapies that show limited to no improvement to symptoms or quality of life before giving approval for additional/other treatment options.

Examples: Exercise, leg elevation, compression stockings, over-the-counter anti-inflammatory medication, or Unna boot (for ulcers).

**Conservative measures may only offer temporary relief of symptoms.**

**Compression stockings will not cure varicose veins, although they are effective in relieving symptoms caused by the condition and may reduce the risk of blood clots.<sup>1</sup>**

<sup>1</sup>How Do Compression Socks Work? Veindirectory.org. Available at: <https://www.veindirectory.org/article/prevention-management/compression-sockings-how-can-they-help>. Accessed July 8, 2022.

# Treatment options for vein disease

## Thermal energy treatment options

### Laser ablation

Numbing agent is given by multiple needle sticks down the leg, and heat is used to close the vein.

### ClosureFast™ radiofrequency ablation procedure

Numbing agent is given by multiple needle sticks down the leg, and heat is used to close the vein.



[See how it works](#)

## Non-thermal treatment options

### Mechanochemical ablation and foam sclerotherapy

No multiple needle sticks to give numbing agent down the leg, and heat is not used. Mechanical device is used to deliver the closure therapy to the vein.

### VenaSeal™ closure system

No heat, no multiple needle sticks to deliver numbing agent down the leg. Specially formulated medical adhesive is used to close the vein.



[See how it works](#)

## Surgical vein stripping (least common)

The original method of removing the vein. This procedure is rarely done in the United States as it involves surgery under sedation, scarring, and long recovery periods.



# Summary: what have you learned about the most common treatment options?

Old treatments like vein stripping are used less often. Today, there are minimally invasive, more innovative treatment options.



## Vein stripping

Is not a common treatment now.



## Treatment is easy

Most procedures are done in-office without sedation.



## Treatments are minimally invasive

Quickly able to resume normal activities, including work!



## Innovative technology

Eliminates multiple needle sticks and the need for compression stockings.†

- Because vein disease is a medical condition, most insurance plans cover its treatment. (Speak with your insurance provider prior to seeking treatment.)

- Most patients report a noticeable improvement in their symptoms within one week to two weeks following the ClosureFast™ procedure.<sup>1</sup>

Possible complications of the ClosureFast procedure may include nerve injury, hematoma, phlebitis, thrombosis, and/or pulmonary embolism. Talk to your doctor about the risks and benefits.

- The VenaSeal™ procedure allows patients to return to their normal activities immediately after the procedure.<sup>2,3</sup>

Possible complications of the VenaSeal procedure may include allergic reaction, inflammation, phlebitis, deep vein thrombosis, and/or pulmonary embolism. Talk to your doctor about the risks and benefits.

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

<sup>1</sup> Almeida JJ, et al. *J Vasc Interv Radiol.* 2009;20:752-759.

<sup>2</sup> Morrison N, et al. *J Vasc Surg.* 2015;61:985-994.

<sup>3</sup> Gibson K, et al. *Vascular.* 2017;25:149-156.



Learn more at  
[Medtronic.com/breakfree](https://www.Medtronic.com/breakfree)

Minimally invasive treatments are available – like the ClosureFast™ and VenaSeal™ procedures – making relief from varicose veins possible.

See and feel a difference in your legs!





# Brief statement

## VenaSeal™ closure system

**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>.

## ClosureFast™ Endovenous Radiofrequency (RFA) Ablation Catheter

### Reference Statement:

**Indications for Use:** The ClosureFast™ endovenous radiofrequency ablation (RFA) catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

**Contraindications:** The ClosureFast catheter is contraindicated for use in patients with thrombus in the target vein segment.

**Potential Adverse Effects of the Device on Health:** The potential complications include, but are not limited to, the following: adjacent nerve injury, hematoma, pulmonary embolism, thrombosis, infection, phlebitis, skin burn or discoloration, and vessel perforation.

**Important:** Please reference the Instructions For Use (IFU) for a complete listing of indications, contraindications, warnings and precautions, adverse effects, and suggested procedure.

## ClosureRFS™ Endovenous Radiofrequency Stylet

### Reference Statement:

**Indications for Use:** The ClosureRFS™ stylet is intended for use in vessel and tissue coagulation, including treatment of incompetent (i.e., refluxing) perforator and tributary veins.

**Contraindications:** The ClosureRFS stylet is contraindicated for use in patients with thrombus in the vein segment to be treated.

**Potential Adverse Effects of the Device on Health:** The potential complications include, but are not limited to, the following: arteriovenous fistula, infection, phlebitis, skin burns, hematoma, nerve damage, pulmonary embolism, and thrombosis.

**Important:** Please reference the Instructions For Use (IFU) for a complete listing of indications, contraindications, warnings and precautions, adverse effects, and suggested procedure.

## ClosureRFG™ Radiofrequency Generator

### Reference Statement:

**Indications for Use:** The ClosureRFG generator is used with radiofrequency catheters intended for vessel and tissue coagulation.

**Contraindications:** Refer to the applicable radiofrequency catheter instructions for use for a list of contraindications related to a ClosureFast system procedure.

**Potential Adverse Effects of the Device on Health:** Refer to the applicable radiofrequency catheter instructions for use for a list of potential complications related to a ClosureFast system procedure.

**Important:** Please reference the Operation Manual for a complete listing of indications, warnings, precautions safety notices, and operational information.

**CAUTION:** Federal (USA) law restricts these devices to sale by or on the order of a physician.

[medtronic.com/breakfree](http://medtronic.com/breakfree)

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