

UNDERSTANDING VEIN DISEASE



UC201706537 EN - For use in the U.S. only

Medtronic
Further, Together

Do you need to sit down during your work day 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 you have
burning or
restless legs
making it hard to
sleep at night and
affecting 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 Factors¹

- Age 40+
- Gender – women are more likely to develop the disease
- Family history



Possible Lifestyle Risk Factors¹

- Prolonged periods of sitting and/or standing
- Obesity or excessive weight
- Multiple pregnancies
- Heavy lifting
- Smoking

1. "Chronic Venous Insufficiency." Vascular Web. Society for Vascular Surgery, Jan. 2011. Web. <http://www.vascularweb.org/vascularhealth/Pages/chronic-venous-insufficiency.aspx>

WHAT MOST PEOPLE DON'T KNOW:

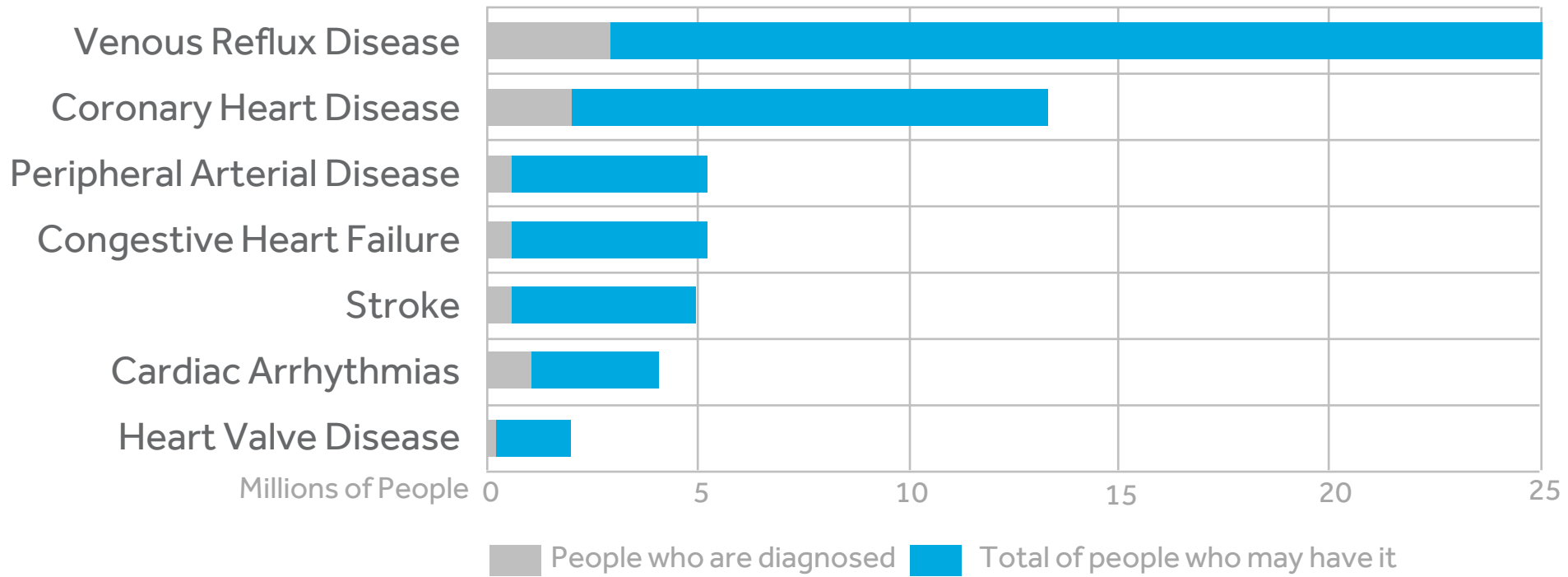
Varicose veins are **NOT** spider veins and they are **NOT** considered only cosmetic.¹



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

¹ Gordon P, Treat-Jacobson D, Sossoman L.B. Society for Vascular Nursing Position Statement on Inclusion of Vascular Disease into Nursing Education. Soc for Vascular Nursing. 2012;Sept:10

IMPACT OF VEIN DISEASE COMPARED TO OTHER WELL KNOWN DISEASES



30 million Americans are affected^{2,3}

Only roughly **6.5%** of them seek treatment³

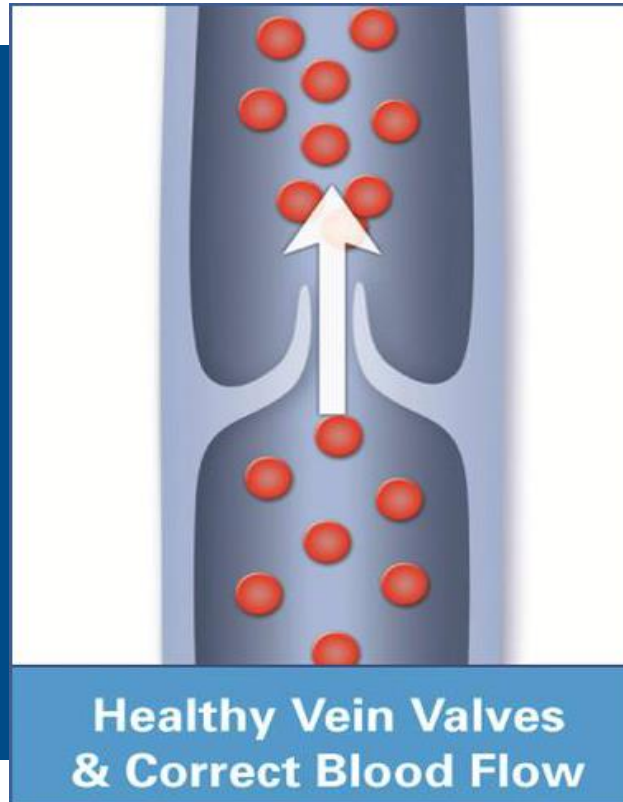
And **less than 1%** actually get treated!³

1 Chart courtesy of American Heart Association, SIR Brand et al. "The Epidemiology of Varicose Veins: The Framingham Study"
 2 Glociczki P, et al. The care of patients with varicose veins and associated chronic diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. JVS; May 2011
 3 Lee, A. US markets for varicose vein treatment devices 2011. Millennium Research Group, Inc. (A Decision Resource, Inc. Company), www.mrg.net, May 2011

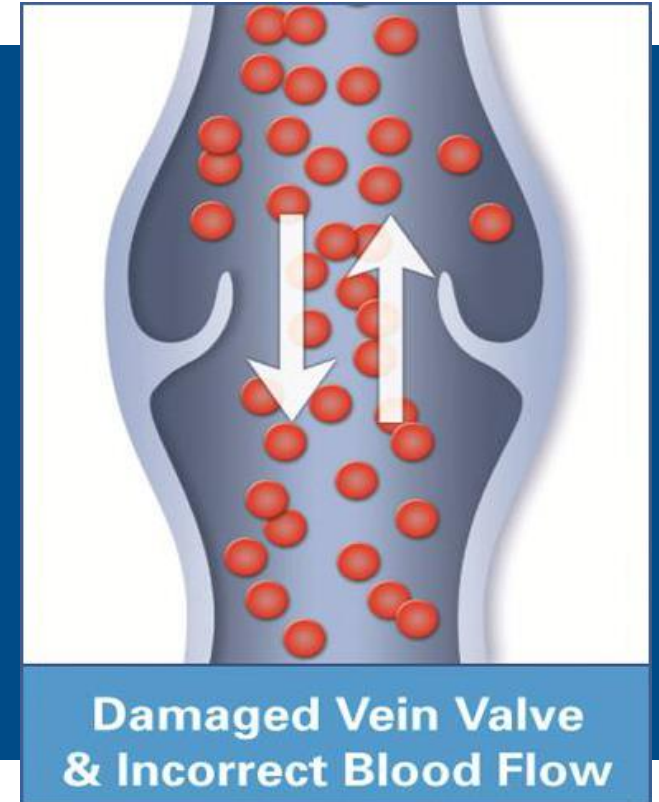
HEALTHY VS. DISEASED VEINS

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.¹

NORMAL VEIN



DISEASED VEIN



¹Gloviczki P, Comerota AJ, Dalsing MC, et al. The Care of Patients with Varicose Veins and Associated Chronic Diseases: Clinical Practice Guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg. 2011 May;53(5 Suppl):2S-48S.

IT'S MORE THAN JUST WHAT YOU CAN SEE

Spider Veins



Swelling



Skin Cracking/
Sores



Varicose Veins



Skin Color Changes



Sometimes it's about how you feel:

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

Images courtesy of Gordon Gibbs, M.D. and Jennifer Heller, M.D

ADVANCED-STAGE DISEASE

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



Healed
Venous Ulcer



Active
Venous Ulcer

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

Images courtesy of Gordon Gibbs, M.D. and Jennifer Heller, M.D

ADVANCED - STAGE DISEASE

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.

70-90%
of lower leg
ulcers are
actually
venous
ulcers.^{1,2}

¹ O'Donnell TF, Passman MA, Marston WA, et al.

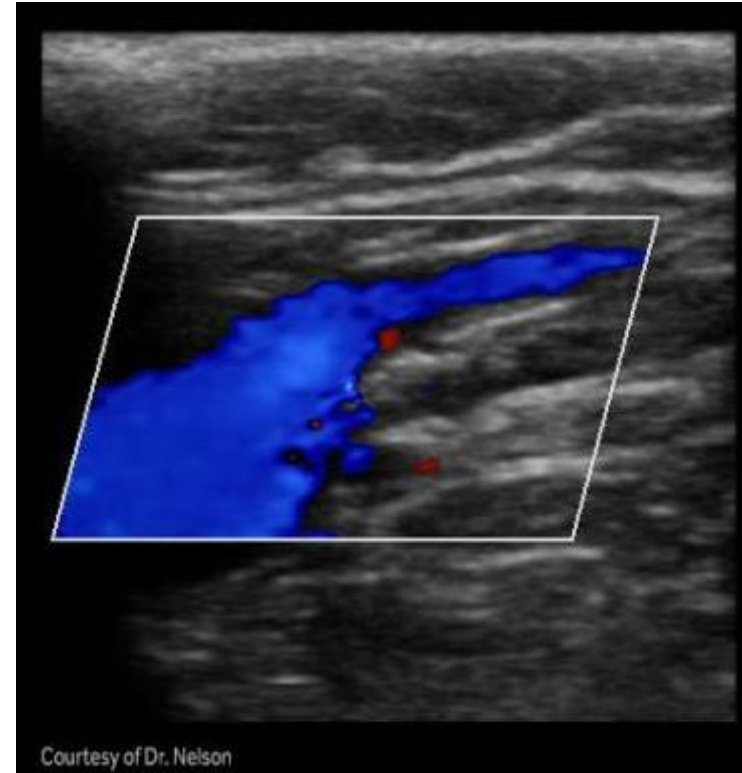
Management of venous leg ulcers: Clinical Practice Guidelines of the Society for Vascular Surgery® and the American Venous Forum. J Vasc. Surg. 2014; 60; 35-595

² Rice JB, Desai U, Cummings AK, et al. Burden of venous leg ulcers in the United States. 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 it.

The technician uses this test to look inside the veins of your leg to determine if the valves 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 done to help your doctor diagnose or rule out a suspected illness or condition.¹

(Consult your insurance carrier for specific coverage rules.)

1. <https://www.medicare.gov/coverage/diagnostic-tests.html> The Official U.S. Government Site for Medicare

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 & 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 daily life before giving approval for treatment.

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

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.¹

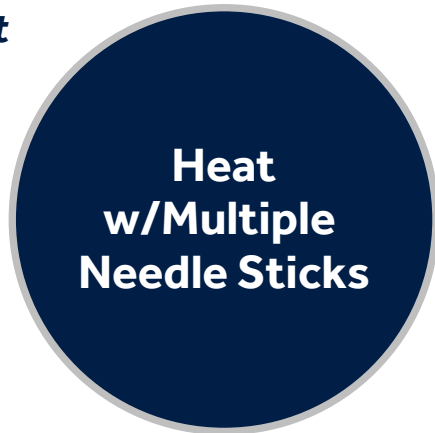
Conservative measures **MAY** only offer **TEMPORARY** relief of symptoms

1. Vein Articles (2015, July). What You Need to Know About Compression Stockings. *The Vein Directory*. Retrieved from <http://veindirectory.org>

CURRENT TREATMENT OPTIONS

Treatment Options for Vein Disease

Most common treatment option



**Heat
w/Multiple
Needle Sticks**

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

**EVLT™*system
(laser)**

**ClosureFast™
catheter**



**No Heat
No Multiple
Needle Sticks**

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.

**ClariVein™*
catheter**

**Varithena™*
foam**



**No Heat
No Multiple
Needle Sticks**

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



**VenaSeal™
system**

*New technology**

Least common treatment option

Surgical Vein Stripping

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

**US only*

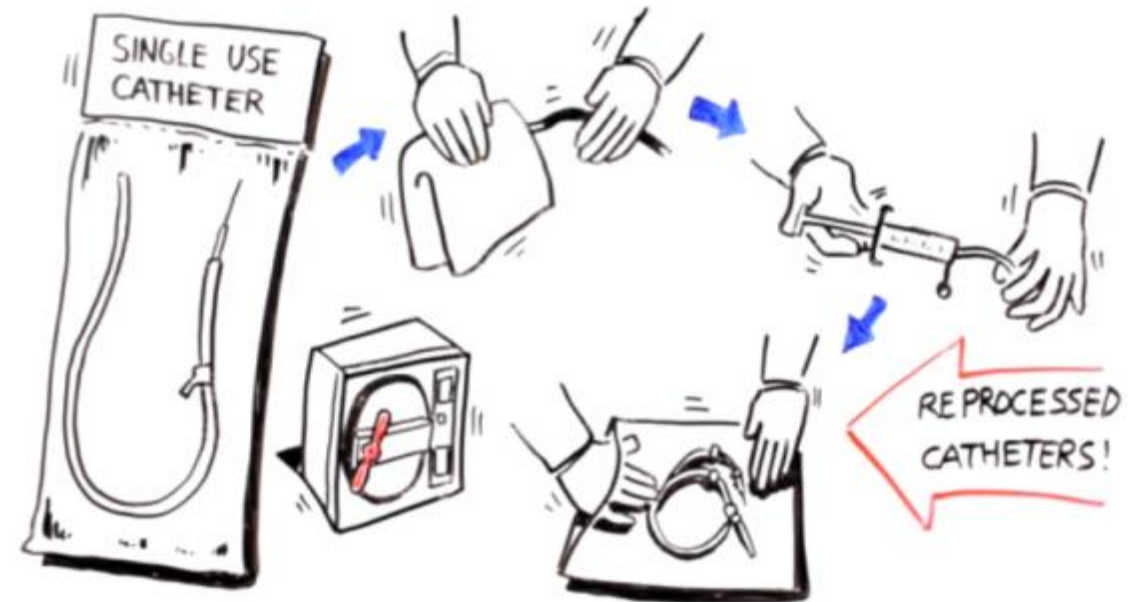
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REPROCESSING – WHAT YOU NEED TO KNOW

What is reprocessing in the medical device space?

“Resterilized” or “reprocessed” medical devices are used in the medical field with surgical tools and instruments that are autoclaved/sterilized at high heat and pressure after each patient use.



What does it mean when catheters are reprocessed?

There are companies that collect used ClosureFast catheters, re-sterilize them, and then sell them back to doctors to be used in other patients.¹



To learn more, view the video:

<http://medtronicendovascular.com/patients/6-0-find-a-doctor/>

REFERENCES

¹ Northeast Scientific, INC Reprocessed Varicose Vein RF Catheter Aug 2009. K090661. https://www.accessdata.fda.gov/cdrh_docs/pdf9/K090661.pdf

SUMMARY - WHAT HAVE YOU LEARNED?

TREATMENT IS EASY

Most procedures are done in office without sedation



TREATMENTS ARE MINIMALLY INVASIVE

Quickly able to resume normal activities, including work!



NEW TECHNOLOGY

Eliminates multiple needle sticks and the need for compression stockings¹.



IT'S NOT JUST COSMETIC

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

FIND RELIEF FROM SYMPTOMS!

Most patients report a noticeable improvement in their symptoms within one week to two weeks following the ClosureFast™ procedure.²

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

2. Almeida JI, Kaufman J, Gockeritz O, et al. Radiofrequency Endovenous ClosureFAST Versus Laser Ablation for the Treatment of Great Saphenous Reflux: A Multicenter, Single-blinded, Randomized Study (Recovery Study). J Vasc Interv Radiol. 2009 Jun;20(6):752-759.



**FIND RELIEF FROM
VARICOSE VEINS**



**MINIMALLY INVASIVE
TREATMENTS
AVAILABLE**



**RAPID RETURN TO
NORMAL ACTIVITY**

STATEMENTS

This content was developed for Medtronic training purposes. Do not copy or distribute.

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 exists.

Potential Adverse Effects of the Device on Health: Below is a list of the potential adverse effects (e.g., complications) associated with the use of the VenaSeal system. The adverse events associated with the device are similar to those with traditional endovenous thermal ablation procedures. In addition, there are several risks unique to the VenaSeal system due to its material and product design as an implant. These potential adverse events include, but are not limited to, allergic reactions to cyanoacrylates, such as hives, asthma, hay fever and anaphylactic shock, arteriovenous fistula, bleeding from the site of access, deep vein thrombosis (DVT), edema in the treated leg, embolization, including pulmonary embolism (PE), hematoma, hyperpigmentation, infection at the access site, non-specific mild inflammation of the cutaneous and subcutaneous tissue, pain, paresthesia, phlebitis, superficial thrombophlebitis, urticaria or ulceration may occur at the site of injection, vascular rupture and perforation, visible scarring.

Warning, precautions, and instructions for use can be found in the product labeling. For VenaSeal, this labeling can be found at <http://useifu.venaseal.com>

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

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