## Medtronic

# Look beyond your wound, find answers.

Treating your leg wound with compression may not be treating the cause – you may have chronic venous insufficiency.



### 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 the valves stop working properly and allow blood to flow backward (i.e., reflux) and pool in the lower leg veins.

# 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 symptoms and risk factors

### The link to venous leg ulcers

If CVI is not treated, legs can sometimes develop painful sores or wounds on the skin's surface, called **ulcers**. Ulcers may indicate a more severe and progressive state of the disease.<sup>1</sup>

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

- Varicose veins
- Aching or pain
- Swelling
- Cramping
- Heaviness or tiredness
- Itching
- Restlessness
- Skin changes
- Skin 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)

# You are not alone

# CVI and venous leg ulcers are more common than you think

More than **190 million people** around the world suffer from CVI.<sup>3</sup>

More than **1 million people** in the U.S. suffer from venous leg ulcers.<sup>4,5</sup>



### More than half

of venous ulcers treated are recurrent ulcerations.<sup>6</sup>

**70<sup>%</sup>-90<sup>%</sup>** of all ulcers below the knee are venous (caused by diseased veins).<sup>4,5</sup>



### Earlier treatment leads to better outcomes

## Don't wait to find treatment for your venous leg ulcers

A recent study showed that patients who received early vein closure treatment along with compression stocking therapy for venous leg ulcers experienced<sup>7</sup>:

- Significantly shorter time to healing
- Extended time free from ulcers

#### Ask your doctor about CVI screening. Or, visit medtronic.com/findveindoctor.



### Go beyond compression

Although compression stocking therapy improves leg ulcer healing, it does not treat the underlying causes of vein disease.

Our minimally invasive therapies can treat the cause of venous leg ulcers – and help you get back to living.

### Discover lasting relief

### VenaSeal™

Closure System

### Nonthermal vein closure

The VenaSeal closure 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.

#### A more comfortable experience

- Simple, outpatient procedure
- No tumescent anesthesia
- Less pain and bruising than thermal ablation<sup>8,9</sup>
- Faster recovery time than thermal ablation<sup>8,9</sup>
- $\bullet$  Compression stockings not needed after the procedure  $^{\rm t9,10}$

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.

#### **ClosureFast**<sup>™</sup>

Procedure

#### Thermal vein closure

The ClosureFast procedure uses radiofrequency energy or heat to close the diseased vein, which redirects blood flow to healthy veins, relieving symptoms.

#### The traditional treatment

- Minimally invasive outpatient procedure
- Local anesthesia along various points of the leg
- Less pain and bruising than laser treatment<sup>11</sup>
- Faster recovery time than laser treatment<sup>11</sup>
- Compression stockings needed for at least one week after procedure<sup>12</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.

#### Learn more at: medtronic.com/veindisease



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

#### References

- <sup>1</sup> Eberhardt RT, Raffetto JD. Chronic venous insufficiency. *Circulation*. July 22, 2014;130(4):333-346.
- <sup>2</sup> Chronic Venous Insufficiency. Johns Hopkins Medicine. Available at: https://www. hopkinsmedicine.org/health/conditions-and-diseases/chronic-venous-insufficiency. Accessed March 13, 2023.
- <sup>3</sup> Strategic Market Assessment: Chronic Venous Insufficiency. Dymedex Consulting, LLC. November 2014.
- <sup>4</sup> O'Donnell TF Jr., Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery<sup>\*</sup> and the American Venous Forum. J Vasc Surg. August 2014;60(2 Suppl):3S-59S.
- <sup>5</sup> Rice JB, Desai U, Cummings AK, et al. Burden of venous leg ulcers in the United States. J Med Econ. May 2014;17(5):347-356.
- Outpatient Wound Clinic Market Performance Report. Net Health Analytics. October 2013.
  Gohel MS, Heatley F, Liu X, et al. A Randomized Trial of Early Endovenous Ablation in
- Venous Ulceration. N Engl J Med. May 31, 2018;378(22)2105-2114. <sup>a</sup> Morrison N, Gibson K, McEnroe S, et al. Randomized Trial Comparing Cyanoacrylate
- Embolization and Radiofrequency Ablation for Incompetent Great Saphenous Veins (VeClose). J Vasc Surg. April 2015;61(4):985-994.
- <sup>9</sup> Proebstle, TM. The European Multicenter Study on Cyanoacrylate Embolization of Refluxing Great Saphenous Veins without Tumescent Anesthesia and without Compression Therapy. Results presented at: Charing Cross 2016; London, UK.
- <sup>10</sup> Almeida JI, Javier JJ, Mackay EG, et al. Thirty-sixth-month follow-up of first-in-human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. J Vasc Surg Venous Lymphat Disord. September 2017;5(5):658-666.
- <sup>11</sup> Almeida JI, Kaufman J, Göckeritz 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. June 2009;20(6):752-759.
- <sup>12</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.

#### VenaSeal<sup>™</sup> 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,

#### 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.

#### ClosureFast<sup>™</sup> Procedure Reference Statement

Indications for Use: The ClosureFast<sup>™</sup> 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. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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