



# FIND RELIEF FROM VARICOSE VEINS

## UNDERSTAND

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

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. Superficial venous reflux disease may cause the following signs and symptoms in your legs:<sup>1</sup>

- Varicose veins
- Aching
- Swelling
- Cramping
- Heaviness or tiredness
- Itching
- Open skin sores
- Restlessness

## TREAT

**The goal when treating venous reflux disease is to reduce or stop the backward flow of blood.**

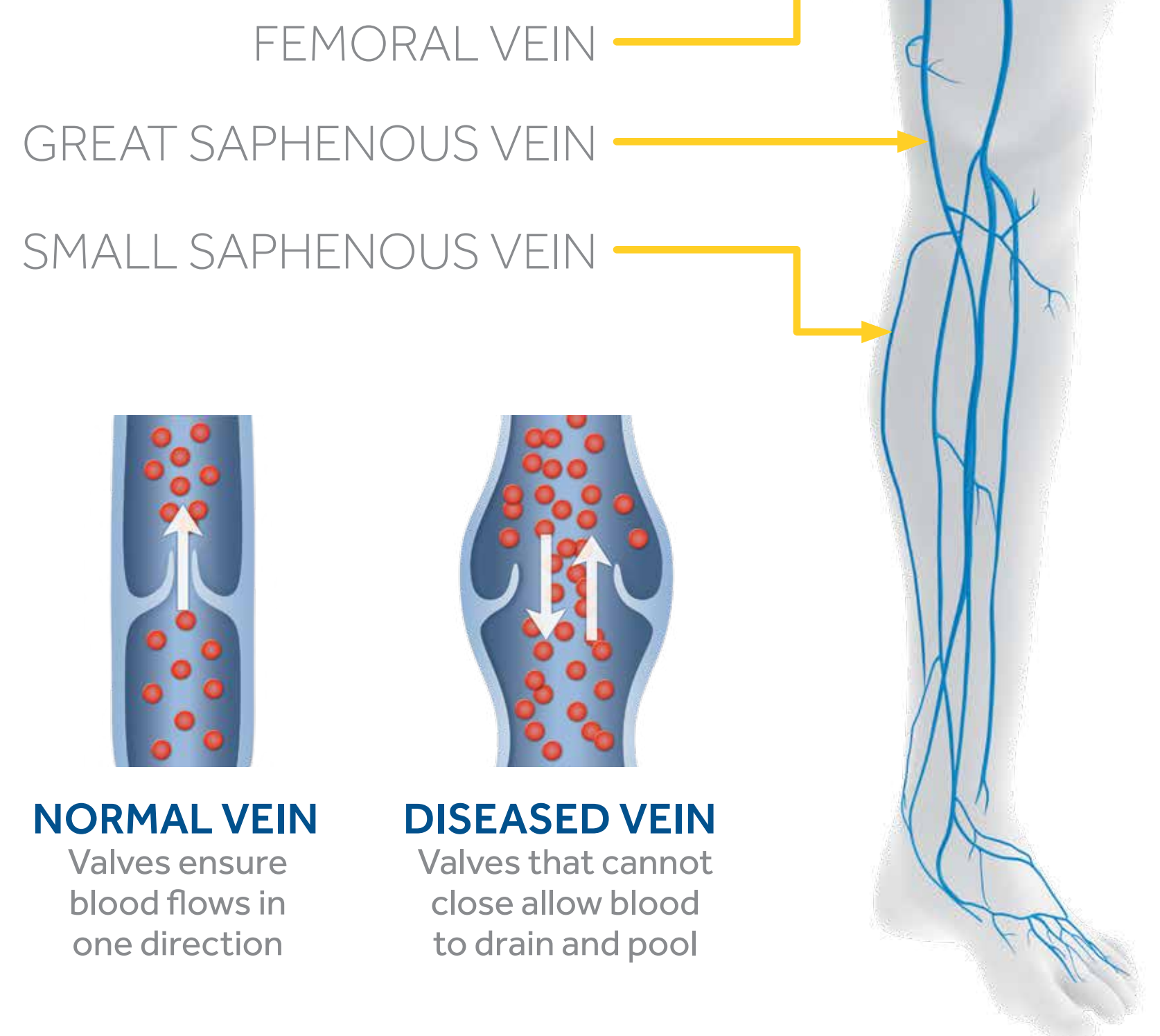
**The VenaSeal™ system improves blood flow by sealing—or closing—the diseased vein.**

The system delivers a small amount of a specially formulated medical adhesive to the diseased vein. The adhesive seals the vein and blood is rerouted through nearby healthy veins.



**VenaSeal™**  
Closure System

## VENOUS ANATOMY



## 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 bruising.<sup>2</sup>

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

**References:** 1 Ciqui, 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. 2 Morrison N. et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). *Journal of Vascular Surgery*. 2015.

**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.

**Warnings, precautions, and instructions for use can be found in the product labeling at <http://useifu.venaseal.com>.**

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

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