

Chronic Venous Disease (CVD)

CVD impacts 175 million people in the United States.¹

With CVD affecting so many individuals, there is a significant and growing need within the health care system.

Healthy leg veins contain valves that open and close to assist the return of blood to the heart. Sometimes, the valves become damaged or diseased and can no longer close properly.²

While risk of CVD increases with age, it can begin as early as adolescence.³ It's important to know that visible vein disease may be more than just a cosmetic problem.^{1,4}

Risk factors that contribute to CVD include: family history of varicose veins; being over the age of 50; female sex; deep vein

thrombosis (DVT); history of blood clots; multiple pregnancies; obesity; smoking; and lifestyles that include long periods of standing or sitting.^{2,5} CVD is a progressive disease, and without treatment signs and symptoms may worsen. CVD can develop into a more serious form of vein disease called chronic venous insufficiency (CVI).²

Small connecting veins, called perforating veins, can have valves that don't work. When blood begins to reflux (flow backwards) or the valve doesn't work, pressure can build within the vein walls. This can lead to nonhealing ulcers and could also cause skin or tissue changes.^{6,7}

Venclose Maven™ Perforator Catheter

Product Overview

The Venclose Maven™ Perforator Catheter is a minimally invasive device that is intended for the closing of blood vessels in patients with perforator and tributary vein reflux.

The Venclose Maven™ Catheter uses radiofrequency (RF) technology, which has been a venous reflux treatment option for more than 20 years. While various treatments are available for venous reflux, RF ablation has wide acceptance and is the most common approach used in the U.S.⁸ RF ablation applies heat to a refluxing vein, causing it to shrink and close. Once treatment is successfully completed, blood flow will naturally re-route towards the nearby deeper and healthier veins to return to the heart.

The Venclose Maven™ Catheter can be used to treat late-stage venous disease for patients with more advanced stages of CVD, such as pain, discomfort, leg swelling, skin changes and, in severe cases, venous ulcers.²

Patient Procedure Benefits

Because the Venclose Maven™ Catheter Procedure is minimally invasive, it can usually be performed in a vein specialist's office in an outpatient setting.

While individual results may vary, patients can typically resume normal activities within a few days of an RF ablation procedure.⁹ Please consult with your physician prior to resuming normal activities.

While some vein catheters can be cleaned and used again on different patients, the Venclose Maven™ Catheter is a single-use device that is only used on one patient.

In addition to improving current symptoms, treating refluxing perforator veins may also help heal long-standing wounds (ulcers) and prevent them from coming back.¹⁰

References:

1. Yost ML. Chronic Venous Disease (CVD): Epidemiology, costs, and consequences. Beaufort, SC: *The Sage Group*; 2016.
2. Eberhardt RT, Raffetto JD. Chronic venous insufficiency. *Circulation*. 2014;130(4):333-346.
3. Schultz-Ehrenburg U, Reich-Schupke S, Robak-Pawelczyk B, et al. Prospective epidemiological study on the beginning of varicose veins. *Phlebologi*. 2009;38(01):17-25. doi: 10.1055/s-0037-1622252
4. Criqui MH, Denenberg JO, Langer RD, Kaplan RM, Fronek A. Epidemiology of chronic peripheral venous disease. In Bergan J, ed. *The Vein Book*, 1st ed. Academic Press; 2006.
5. Gloviczki P, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg*. 2011 May;53(5 Suppl):25-48S.
6. Vandy F, Wakefield TW. Varicose veins: evaluating modern treatments, with emphasis on powered phlebectomy for branch varicosities. *Interv Cardiol*. 2012;4(5):527.
7. Whiddon LL. The treatment of venous ulcers of the lower extremities. *Proc (Bayl Univ Med Cent)*. 2007;20(4):363-366.
8. Decision Resources Group. Varicose Vein Treatment Devices: Medtech 360: Market Analysis: US: 2019. Canada: *Millennium Research Group, Inc.*; 2018.
9. Rasmussen LH, Lawaetz M, Bjoern L, Vennits B, Blemings A, Eklof B. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. *Br J Surg*. 2011;98(8):1079-1087.
10. 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;60:35-59S.

The Venclose Maven™ Catheter is intended for endovascular coagulation of blood vessels in patients with perforator and tributary vein reflux. The Venclose Maven™ Catheter is contraindicated in patients with thrombus in the vein segment to be treated. Potential adverse events include, but are not limited to the following: vessel perforation; skin discoloration; nerve injury; temporary sensation of tingling or prickling; blood clots; blood clots in the deep veins; infection of the veins; bruise with swelling; infection; skin burn; blood clot in lung artery; and pain. **Please consult product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions.**