

# Help Restore Your Leg Health

Learn about Chronic Venous Disease,  
its symptoms, and treatment options.



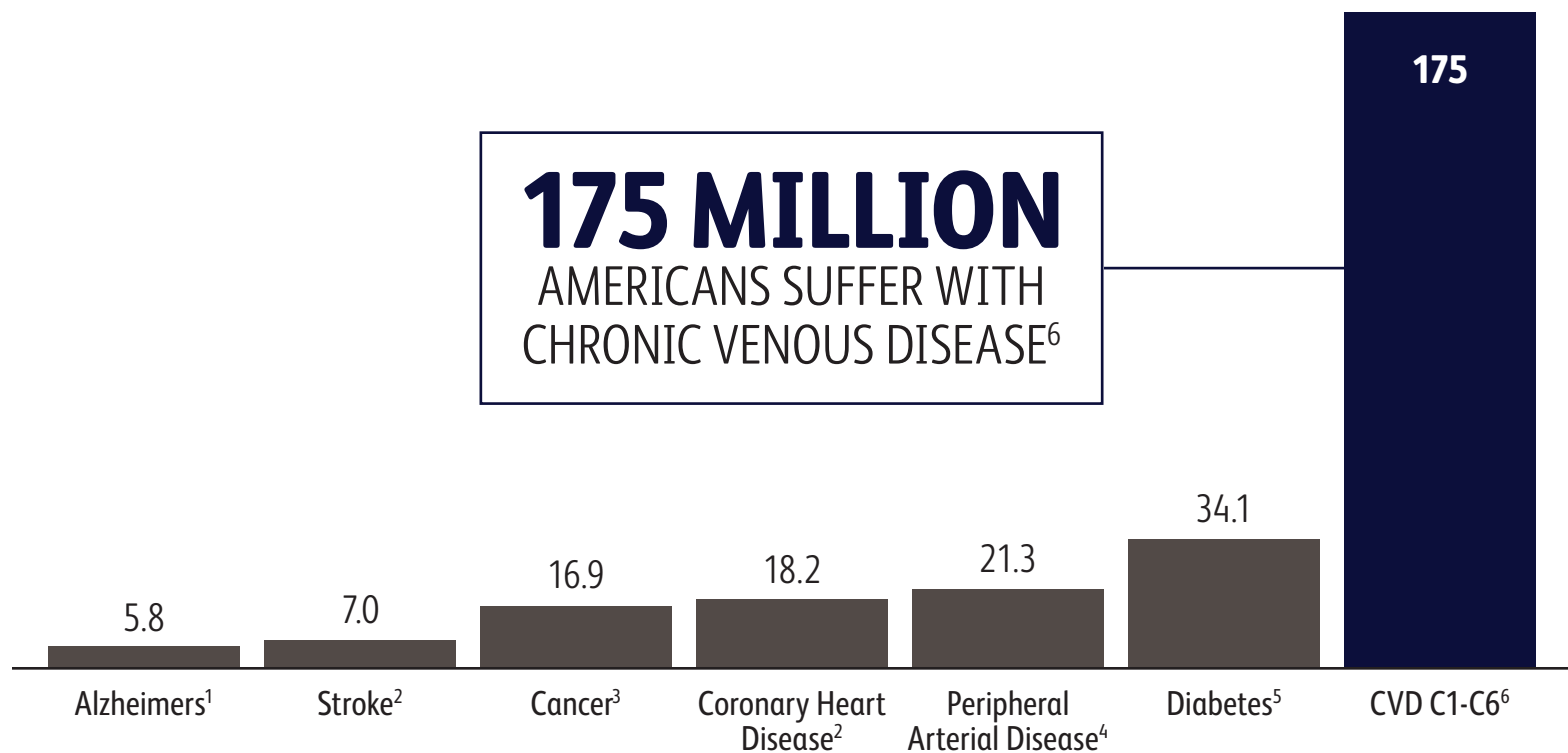


A close-up photograph of a person's lower legs and feet. The person is wearing dark blue shorts and is standing on a yellow exercise machine, possibly a step mill. Their feet are on the machine's pedals. The background is blurred, showing green grass and a white fence. A dark blue semi-circular overlay is positioned on the left side of the image, containing the text 'Understanding Venous Disease' in white.

# Understanding Venous Disease

# Venous Disease Affects Millions of Lives

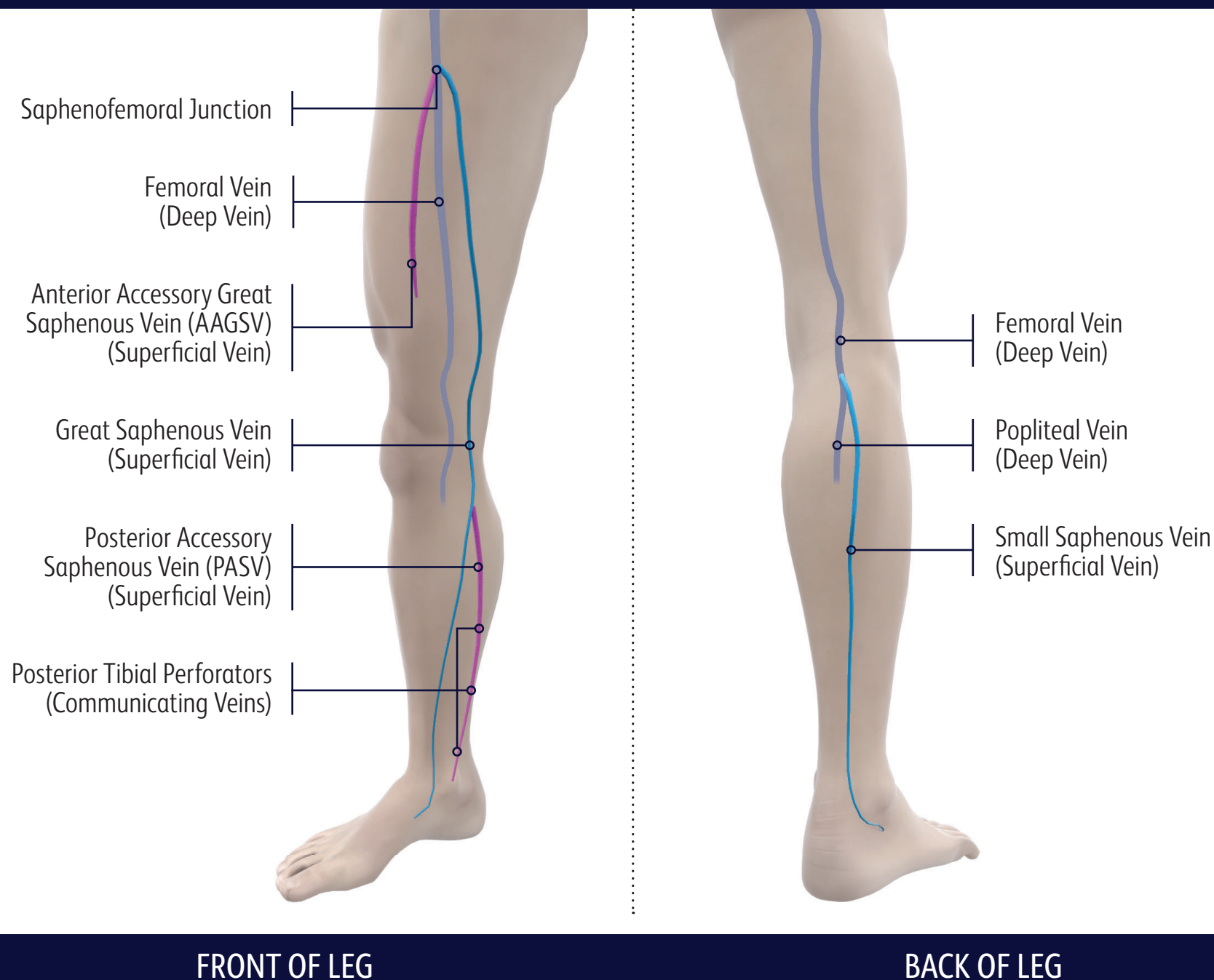
2020 U.S. Prevalence of Selected Chronic Diseases\* (Millions)



- Varicose Veins may be more than just a cosmetic issue.<sup>7</sup>
- CVD is a progressive disease. Without treatment, signs and symptoms may worsen.<sup>8</sup>
- At 2 million, the number of new venous ulcer cases exceeds that of other chronic diseases including the 1.7 million new cases of all cancers combined.<sup>6</sup>

\* Age ranges differ for prevalence population based on disease state, rates reported for years ranging from 2015 to 2020.

# Venous Anatomy

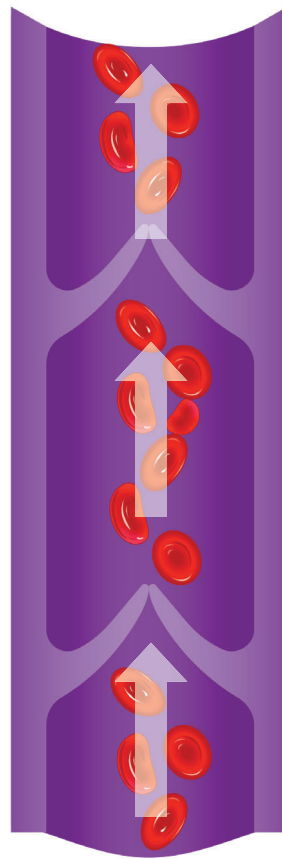




# Valve Function

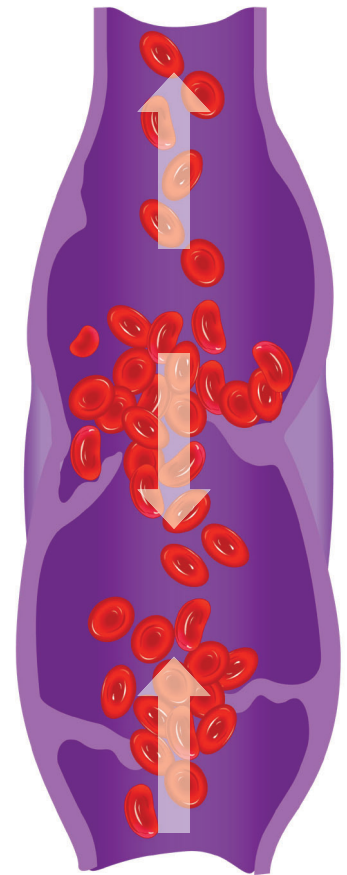
Healthy leg veins contain valves that open and close to assist the return of blood to the heart. Sometimes, the valves become damaged or diseased and can no longer close properly. As a result, blood can leak back through the valves and pool in the lower leg veins. This can lead to chronic venous disease.<sup>8</sup>

## Healthy Valves



Blood moves in one direction  
- up the legs to the heart

## Diseased Valves

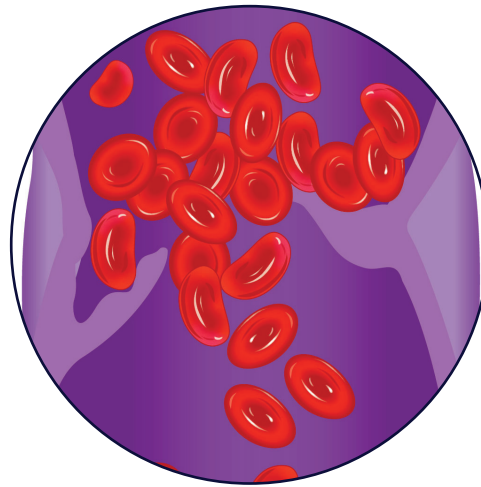


Blood leaks back through  
the diseased valves

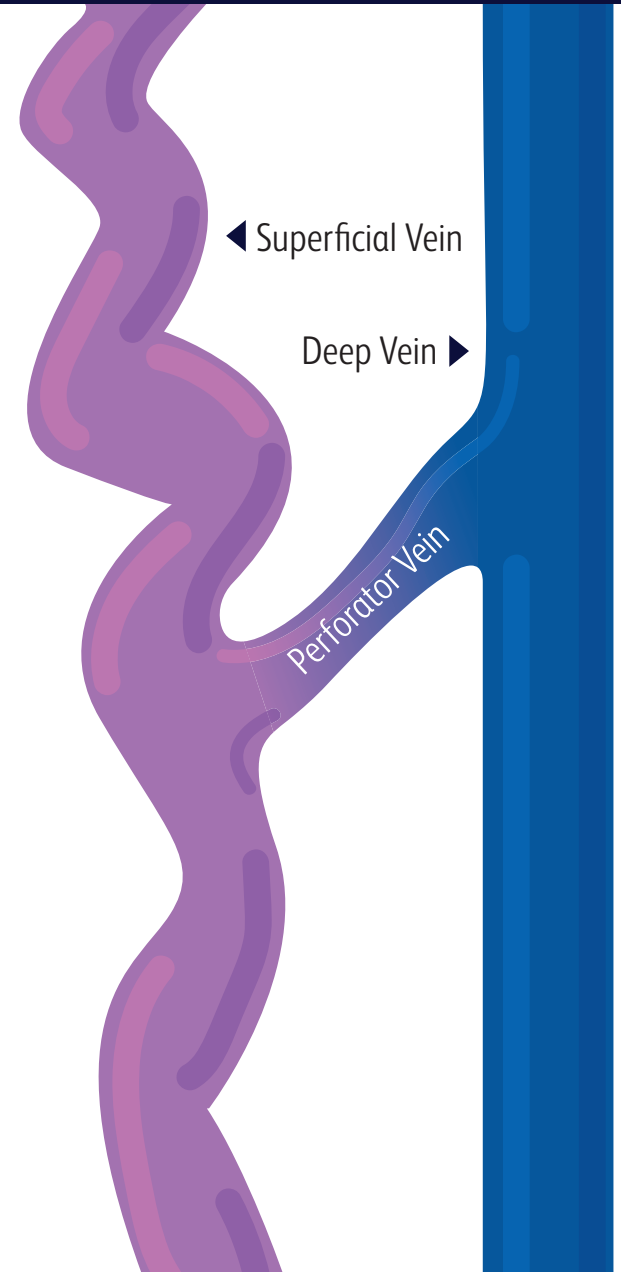
# Perforator Veins

Perforator veins connect the deep and superficial venous system, allowing passage of blood in between them.

Perforator vein insufficiency can result in pain, skin changes, and ulcers.



**Failed Valve**





# Symptoms of Venous Disease

## Common signs and symptoms in the lower legs include:<sup>9</sup>

- Varicose veins or spider veins
- Heaviness, aching, tightness or fatigue
- Discomfort, pain or swelling
- Restlessness or cramping
- Numbness or itching
- Skin texture or color changes
- Ulcer or wound



Without treatment, signs and symptoms may worsen. CVD can develop into a more serious form of vein disease called chronic venous insufficiency (CVI) that includes leg swelling, skin changes and, in severe cases, ulcerations.<sup>8</sup>

# Possible Risk Factors<sup>8</sup>



Family history of  
varicose veins



Age



Multiple pregnancies



Obesity



Long periods of  
standing or sitting



# How CVD Is Diagnosed



Current general health



Past medical history



Symptoms



Physician exam

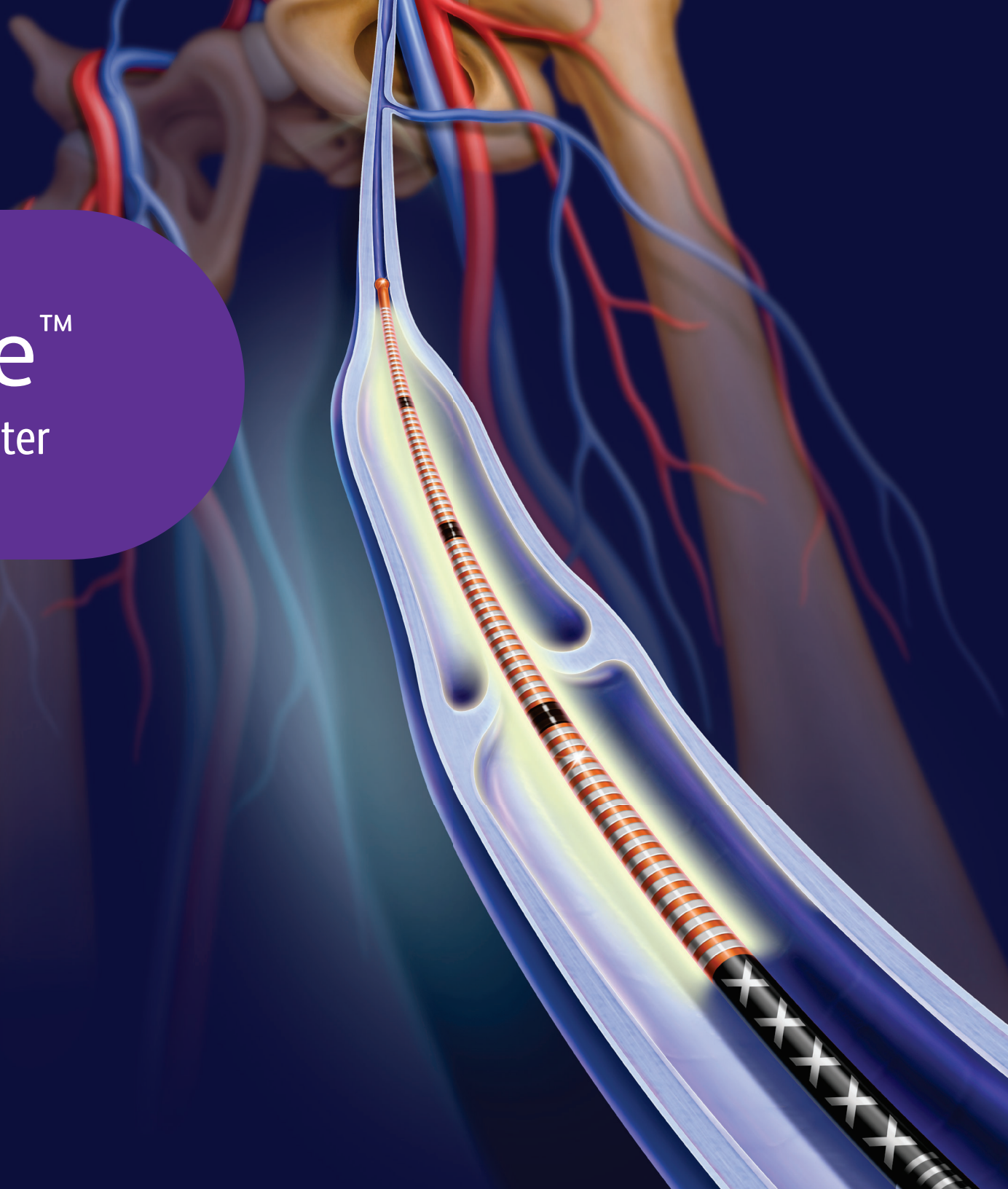


Ultrasound

# Venclose™

RF Ablation Catheter

Venclose™  
RF Ablation Catheter



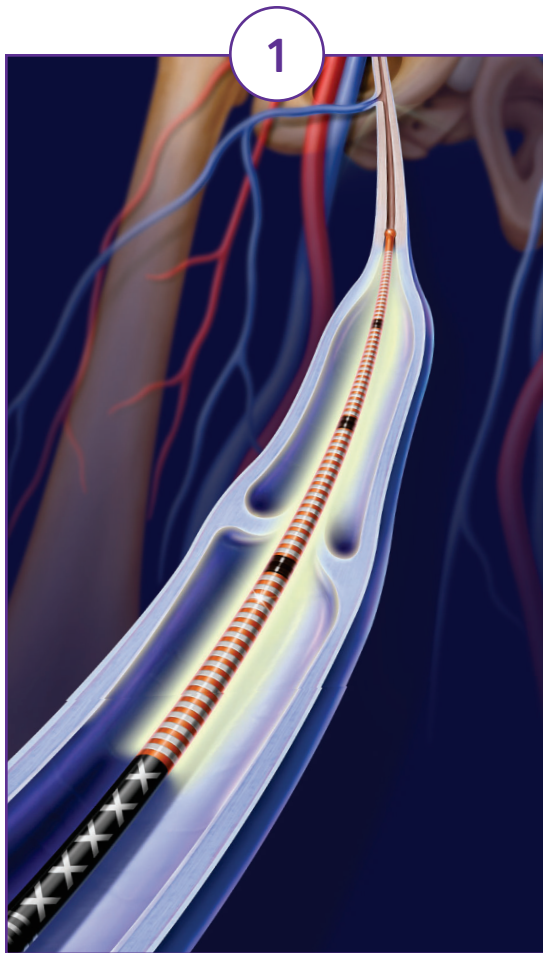


# Venclose™ RF Ablation Catheter

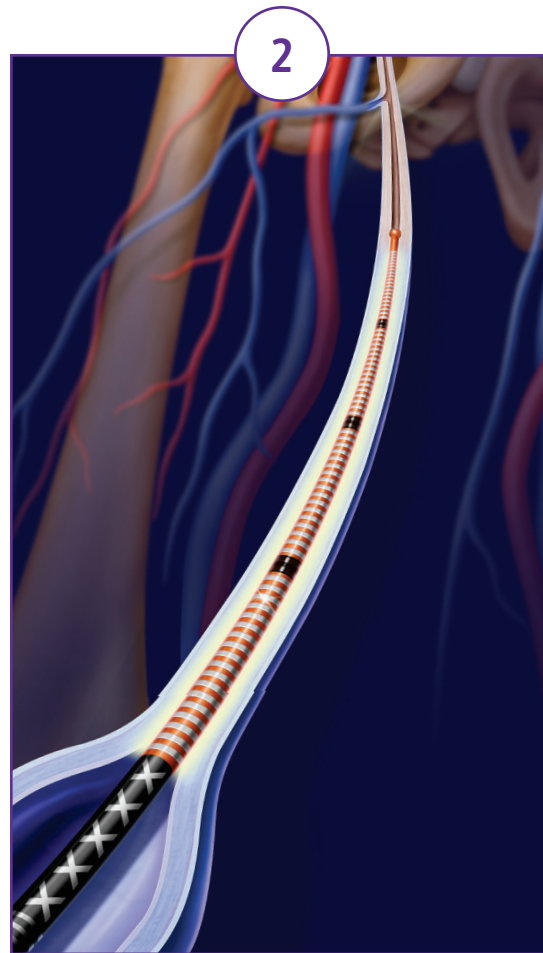
The Venclose™ RF Ablation Catheter is a minimally invasive treatment that uses radio frequency ablation (heat) to close down the diseased vein so blood is redirected to healthy veins.



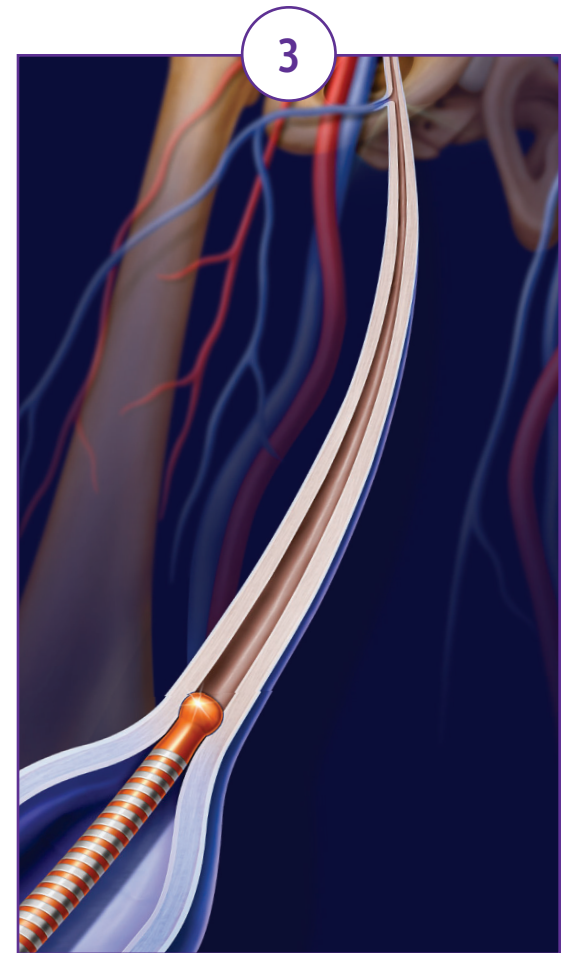
# Procedure Highlights



Catheter delivers targeted heat along vein segments



Heat then causes the diseased vein to shrink



Catheter is easily removed, blood flow is redirected to healthy veins



# Patient Results

## Before Treatment



## After Treatment



\* After treatment image is representative of patient typically 2 weeks post-op

# Venclose Maven™

Perforator Catheter



Venclose Maven™  
Perforator Catheter



# Venclose Maven™ Perforator Catheter

The Venclose Maven™ Perforator Catheter offers a minimally invasive endovascular treatment option that uses radiofrequency ablation (heat) to close incompetent perforator veins.



# Procedure Highlights

1



Catheter is placed in the perforator vein

2



Heat is delivered to the incompetent perforator vein and causes the diseased vein to shrink

3



Catheter is easily removed and blood flow is redirected to healthy veins



# Patient Results

## Before Treatment




## After Treatment\*



\* After treatment image is representative of patient typically 2-3 months post-op





# Commonly Asked Questions

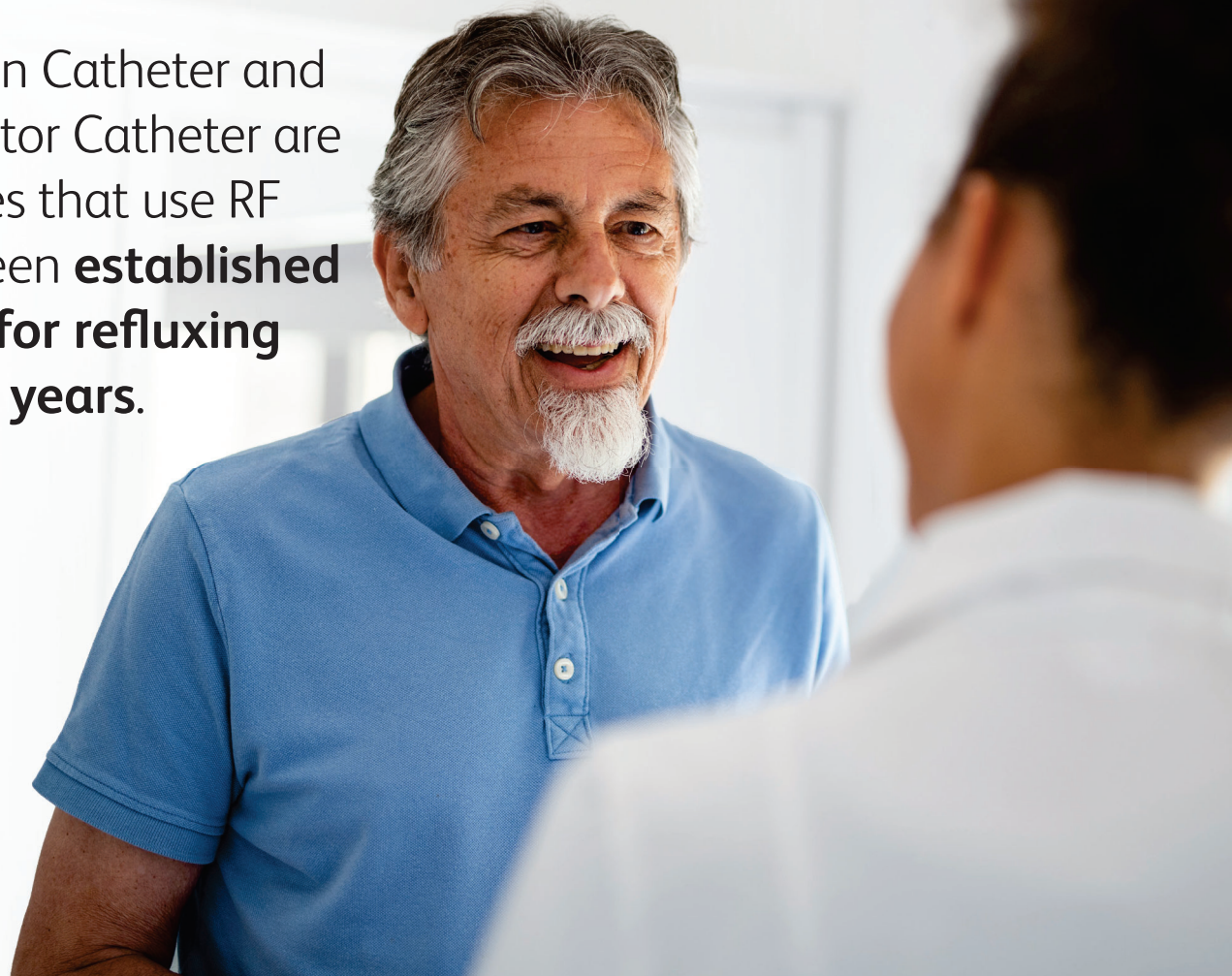
Commonly  
Asked Questions



# What can I expect from the Venclose<sup>TM</sup> Catheter procedure?

The Venclose<sup>TM</sup> RF Ablation Catheter and Venclose Maven<sup>TM</sup> Perforator Catheter are minimally invasive devices that use RF technology, which has been **established as a treatment option for refluxing veins for more than 20 years.**

RF ablation technology can potentially **reduce post-operative pain and bruising** in patients compared to vein stripping or laser therapy treatment.<sup>10</sup>



# How quickly can I resume normal activities?

While individual results may vary, patients can typically **resume normal activities within a few days** of an RF ablation procedure.<sup>11</sup>

Please consult with your physician prior to resuming normal activities.





# How is the Venclose™ Catheter procedure different from other vein procedures?

While some vein catheters can be reprocessed more than once and used on different patients, the **Venclose™ RF Ablation Catheter** and **Venclose Maven™ Perforator Catheter** are single-use devices. Additionally, both catheters are minimally invasive, thermal treatment options and not a permanent implant. Ask your physician about what treatment options might be best for you.



# Will my insurance cover the procedure?

Generally, **health insurers provide coverage for venous thermal ablation procedures.**

Insurance providers typically require certain preauthorization steps. It is important to review the requirements with your physician and insurance provider prior to treatment.



# References

- <sup>1</sup> Alzheimer's Association. 2020 Alzheimer's Disease Facts and Figures. *Alzheimers Dement*. 2020;16(3):391-460.
- <sup>2</sup> American Heart Association. Heart Disease and Stroke Statistics-2020 Update. *Circulation*. 2020;141:e139-e596.
- <sup>3</sup> American Cancer Society. *Cancer Facts and Figures 2020*. Atlanta: American Cancer Society; 2020.
- <sup>4</sup> Yost ML. *United States Critical Limb Ischemia by Rutherford Category Prevalence and Markets in Patients and Limbs*. Beaufort, SC: The Sage Group; 2017.
- <sup>5</sup> National Diabetes Statistics Report 2020. Estimates of Diabetes and Its Burden in the United States. U.S. Department of Health and Human Services. Center for Disease Control and Prevention.
- <sup>6</sup> Yost ML. *Chronic Venous Disease (CVD): Epidemiology, costs, and consequences*. Beaufort, SC: The Sage Group; 2016.
- <sup>7</sup> 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.
- <sup>8</sup> Eberhardt RT, Raffetto JD. Chronic venous insufficiency. *Circulation*. 2014;130(4):333-346.
- <sup>9</sup> 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):2S-48S.
- <sup>10</sup> Scovell S. Techniques for radiofrequency ablation for the treatment of lower extremity chronic venous disease. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. <https://www.uptodate.com/contents/techniques-for-radiofrequency-ablation-for-the-treatment-of-lower-extremity-chronic-venous-disease>. Accessed on October 27, 2022.
- <sup>11</sup> 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.



## Safety Information

**Indication for Use:** The Venclose Maven™ Catheter is intended to be used with the Venclose™ digiRF Generator as a system. The Venclose Maven™ Catheter is intended for endovascular coagulation of blood vessels in patients with perforator and tributary vein reflux.

**Contraindications:** The Venclose Maven™ Catheter is contraindicated in patients with thrombus in the vein segment to be treated.

**Warnings:** Potential impact to active implanted medical devices located nearby the intended treatment location in the lower limbs has not been evaluated. It is recommended not to coil the Venclose Maven™ connector cable directly above active implanted medical devices. The Venclose™ system is not intended to be used with magnetic resonance imaging. Thermal treatment of the vein may damage adjacent sensory or motor nerves. Risk of damage is greater near the calf or if no local anesthetic is used around the treated vein. Treatment of a vein located close to the skin surface may result in a skin burn. Ensure that the proximal end of the heating element is at least 0.5 cm from the skin. Do not treat within the deep venous system. Ensure that the distal tip of the catheter is greater than 0.5 cm from the deep venous system. Treatment of a vein located near the skin surface may result in a skin burn if the skin is not protected with fluid infiltration. Care should be taken to preserve adequate blood circulation, especially for patients with documented peripheral arterial disease. Catheter is for single patient use only. A contaminated catheter may lead to illness or death of the patient. Cleaning damage to the catheter may lead to ineffective treatment or injury. Venclose™ will not be responsible for any direct, indirect, incidental or consequential damages or expenses resulting from reuse of the catheter. Transcutaneous ultrasound imaging is recommended to confirm and maintain device tip and heating element position in the target vessel. Do not place heating element in a vein valve (for the purpose of restoring valve function) or in the deep venous system. If electromagnetic interference associated with stray energy from the digiRF System is encountered, reposition the imaging system and/or the digiRF generator to eliminate such interference. See the “Separations Distances” table in Section 12 in the digiRF Generator’s User Manual for further information. Nerve injury may occur from thermal damage to adjacent sensory nerves. Risk of nerve injury may be higher with treatment at or below the calf, or without perivenous fluid infiltration. Flammable agents for cleaning, disinfecting, or as solvents of adhesives shall be allowed to evaporate before using the Venclose™ system. Interference caused by use of the Venclose™ system may adversely influence operation of other electronic equipment.

**Precautions:** Store in a dry, cool place. Do not bend catheter shaft into a tight radius; kinking of the shaft may render the catheter inoperable. To prevent damage to the guidewire, ensure that the guidewire does not protrude from the catheter tip when inserting catheter into vein. If fluid contacts the Venclose Maven™ cable connector, wipe it clean and dry before inserting into the generator. Do not leave the guidewire within the catheter lumen at the heating element location during treatment as it will cause the guidewire to become stuck within the catheter lumen. Do not advance the catheter against resistance, or vein perforation may occur. Uneven blood pooling or flow along the heating element may result in inconsistent effectiveness and/or may damage the catheter. Do not begin treatment without verifying that the length of heating element that will actively heat remains inserted a length of at least 0.5 cm from the vein access point. The portion of the catheter shaft within 2.0 cm of the heating element may exceed 41°C during treatment. Testing of this region has shown that a maximum temperature of 42°C can be reached. If the generator stops treatment due to improper heating, remove the catheter and inspect. Replace the catheter if damage is found. Failure to respond to advisory indicators can result in damage to the catheter. If using direct external compression, do not compress the skin closer than 0.5 cm to the heating element or a skin burn may occur. Do not re-advance the catheter and re-treat an acutely treated vein section or it may increase risk of embolism. Do not treat with the heating element within the access sheath or closer than 0.5 cm to the point of skin access or a skin burn, catheter damage or sheath damage may result. The vein wall may be thinner in an aneurysmal segment. To effectively occlude a vein with an aneurysmal segment, additional compression may be needed over the aneurysmal segment, and the treatment of the vein should include segments proximal and distal to the aneurysmal segment. Use of a flush through the catheter while the heating element is active will interfere with treatment and heat the fluid exiting the end of the catheter. Avoid fluid delivery through the catheter when tip of catheter is near an area that should not be thermally coagulated. Failure to evenly compress the vein over the full length of the heating element may result in inconsistent effectiveness and/or possible catheter damage. Place monitoring electrodes as far as possible from the Venclose™ catheter when the digiRF generator and physiological monitoring equipment are used simultaneously on the same patient. Do not use needle monitoring electrodes. Use monitoring systems incorporating high frequency current-limiting devices. There is a risk of pooling of flammable solutions under the patient, or in body depressions such as the umbilicus, and in body cavities such as the vagina. These fluids should be mopped up before using the Venclose™ system. Endogenous gases (e.g., cotton and gauze saturated with oxygen) may be ignited by sparks produced within the generator during normal use of the Venclose™ system. The Venclose™ system is for use without a neutral electrode. The patient should not come into contact with grounded conductive components or conductive components with appreciable capacitance to earth, such as metallic operating table supports. Do not begin energy delivery (by pressing the catheter handle button or a connected foot switch) before the catheter is properly positioned within the intended treatment vessel and anesthesia is administered, or discomfort or injury may occur. Avoid contact of cords and cables with patient, lead, or other equipment.

**Potential Complications and Adverse Events:** Potential adverse events include, but are not limited to the following: vessel perforation; skin discoloration; nerve injury; temporary paresthesia; thrombosis; deep vein thrombosis; phlebitis; hematoma; infection; skin burn; pulmonary embolism; pain.

**Indication for Use:** The Venclose™ EVSRF Catheter is intended to be used with the Venclose™ digiRF Generator as a system. The Venclose™ EVSRF catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

**Contraindications:** The Venclose™ EVSRF catheter is contraindicated in patients with thrombus in the vein segment to be treated.

**Warnings:** Potential impact to active implanted medical devices located nearby the intended treatment location in the lower limbs has not been evaluated. It is recommended not to coil the EVSRF connector cable directly above active implanted medical devices. The Venclose™ system is not intended to be used with magnetic resonance imaging. Thermal treatment of the vein may damage adjacent sensory or motor nerves. Risk of damage is greater near the calf or if no local anesthetic is used around the treated vein. Treatment of a vein section closer than 1 cm to the skin may result in a skin burn. Direct external compression may reduce the distance between the vein and skin. Treatment of a vein located near the skin surface may result in a skin burn if the skin is not protected with fluid infiltration. Care should be taken to preserve adequate blood circulation, especially for patients with documented peripheral arterial disease. Catheter is for single patient use only. A contaminated catheter may lead to illness or death of the patient. Cleaning damage to the catheter may lead to ineffective treatment or injury. Venclose™ will not be responsible for any direct, indirect, incidental or consequential damages or expenses resulting from reuse of the catheter. Transcutaneous ultrasound imaging is recommended to confirm and maintain device tip and heating element position in the target superficial vessel. Do not place heating element in a vein valve (for the purpose of restoring valve function), a perforating or non-superficial communicating vein, or in the deep venous system. If electromagnetic interference associated with stray energy from the digiRF System is encountered, reposition the imaging system and/or the digiRF generator to eliminate such interference. See the “Separations Distances” table in Section 12 in the digiRF System User’s Manual for further information. Nerve injury may occur from thermal damage to adjacent sensory nerves. Risk of nerve injury may be higher with treatment at or below the calf, or without perivenous fluid infiltration. Flammable agents for cleaning, disinfecting, or as solvents of adhesives shall be allowed to evaporate before using the Venclose™ system. Interference caused by use of the Venclose™ system may adversely influence operation of other electronic equipment.

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# Venclose Maven™

## Perforator Catheter

# Venclose™

## RF Ablation Catheter

