Help Restore Your Leg Health

Learn about Chronic Venous Disease, its symptoms, and treatment options.
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.⁷
- CVD is a progressive disease. Without treatment, signs and symptoms may worsen.⁸
- 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.⁶

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

Saphenofemoral Junction

Femoral Vein (Deep Vein)

Anterior Accessory Great Saphenous Vein (AAGSV) (Superficial Vein)

Great Saphenous Vein (Superficial Vein)

Posterior Accessory Saphenous Vein (PASV) (Superficial Vein)

Posterior Tibial Perforators (Communicating Veins)

Femoral Vein (Deep Vein)

Popliteal Vein (Deep Vein)

Small Saphenous Vein (Superficial Vein)

FRONT OF LEG

BACK OF LEG
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.8

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.
Symptoms of Venous Disease

Common signs and symptoms in the lower legs include:

- 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.
Possible Risk Factors

- 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

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

1. Catheter delivers targeted heat along vein segments
2. Heat then causes the diseased vein to shrink
3. 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

Individual treatment results may vary. Images courtesy of Matthew Wise, MD, Advanced Vein Center, Orange, CA
Venclose Maven™ Perforator Catheter

The Veclose 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*

Individual treatment results may vary. Images courtesy of Nathan Tomita, DO, Pacific Vascular Institute, Kona, HI
Commonly Asked Questions
What can I expect from the Venclose™ Catheter procedure?

The Venclose™ RF Ablation Catheter and Venclose Maven™ 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.¹⁰
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. 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

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 physiologic 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 anesthesist 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; hematomas, 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 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 Generator 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.

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 EVSRF 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 2.5 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 1 cm to the heating element or a skin burn may occur. Do not administer more than three energy delivery cycles within any vein section. 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 2.5 cm heating element length and then pull back according to the 10 cm shaft markings; such a combination will likely trap blood between non-continuous treatments and may cause phlebitis. Do not treat with the heating element within the access sheath or closer than 2.5 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 physiologic 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 anesthesist is administered, or discomfort or injury may occur. Avoid contact of cords and cables with patient, lead, or other equipment.

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