Chronic Venous Disease Treatment Options for Your Patients

BD

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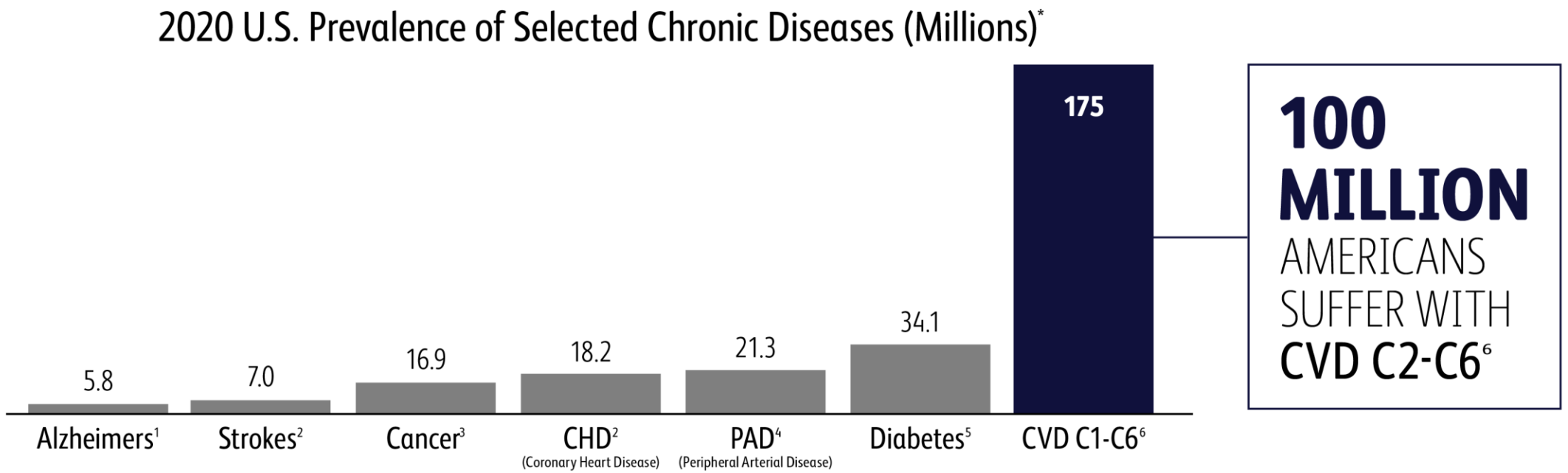
Understanding Chronic Venous Disease (CVD)

Venous Disease Affects Millions of Lives



CVD is a progressive disease. Without treatment, signs and symptoms may worsen.[7]

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

1 Alzheimer's Association. 2020 Alzheimer's Disease Facts and Figures. *Alzheimers Dement*. 2020;16(3) :391-460.
2 American Heart Association. Heart Disease and Stroke Statistics-2020 Update. *Circulation*. 2020;141:e139-e596.
3 American Cancer Society. *Cancer Facts and Figures 2020*. Atlanta: American Cancer Society; 2020.
4 Yost ML. *United States Critical Limb Ischemia by Rutherford Category Prevalence and Markets in Patients and Limbs*. Beaufort, SC: The Sage Group 2017.
5 Centers for Disease Control and Prevention. *National Diabetes Statistics Report, 2020*. Atlanta: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2020.
6 Yost ML. *Chronic Venous Disease (CVD): Epidemiology, costs, and consequences*. Beaufort, SC: The Sage Group 2016.
7 Eberhardt RT, Raffetto JD. Chronic venous insufficiency. *Circulation*. 2014;130(4):333-346.

Chronic Venous Disease Prevalence & Stats

- An estimated **175 million** Americans are affected by CVD in the U.S.[1]
- Risk of CVD **increases with age**, but can begin as early as adolescence[2]
- Visible venous disease is **far more** than a cosmetic problem[1,3]

The annual medical cost of venous disease is estimated at **$30-$90** Billion in the U.S.[1]

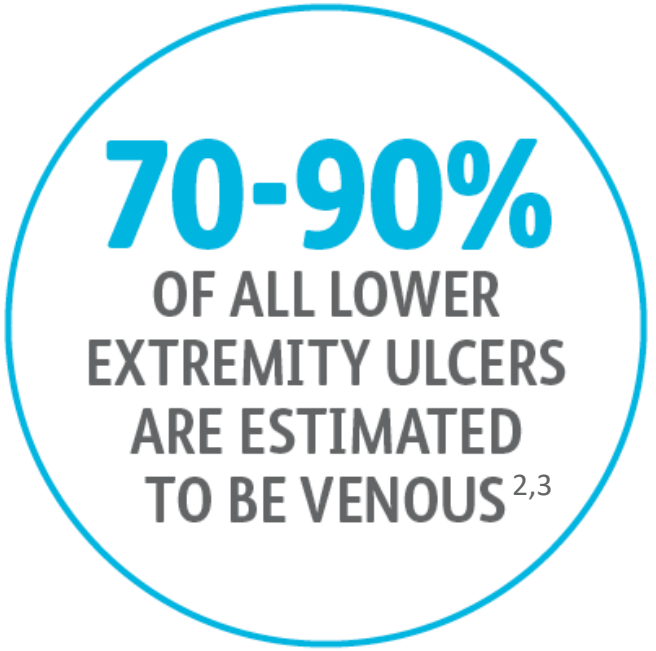
CVD represents a **significant and growing need** within our health care system.

1 Yost ML. *Chronic venous disease (CVD): Epidemiology, costs, and consequences*. Beaufort, SC: The Sage Group; 2016.
2 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
3 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.

Venous Ulcer Prevalence & Stats

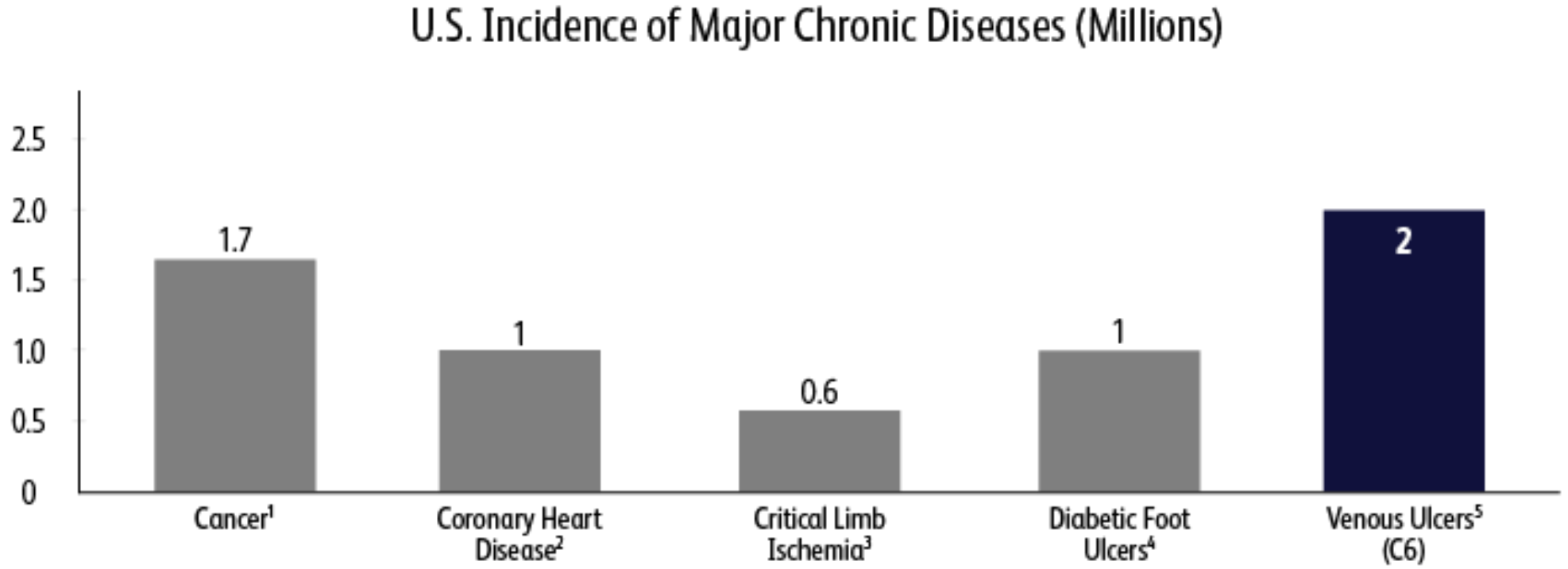
In the U.S., **4.8 million** people are estimated to suffer from venous ulcers with direct medical costs representing about **$38 billion** per year.[1]

Venous leg ulcers are estimated to recur in **60%-70%** of patients[4]



1 Yost ML. *Chronic venous disease (CVD): Epidemiology, costs, and consequences*. Beaufort, SC: The Sage Group; 2016.
2 Rice J, Desai U, Cummings AKG, Birnbaum HG, Skornicki M, Parsons N. Burden of venous leg ulcers in the United States. *J Med Econ*. 2014;17(5):347-356.
3 O'Donnell TF, Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery(R) and the American Venous Forum. *J Vasc Surg*. 2014;60:3S-59S.
4 Parker CN, Finlayson KJ, Edwards HE. Predicting the likelihood of delayed venous leg ulcer healing and recurrence: development and reliability testing of risk assessment tools. *Ostomy Wound Manage*. 2017;63(10):16-33.

Incidence of New Venous Ulcer Cases



At **2.0 million** the annual number of new venous ulcer cases exceeds that of other chronic diseases including the 1.7 million new cases of all cancers combined and diabetic foot ulcers at 1.0 million new cases[5]

1 American Cancer Society. *Cancer Facts & Figures 2016*. Accessed September 2016, at http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016.
2 Mozaffarian D, Benjamin EJ, Go AS, et al. Heart Disease and Stroke Statistics-2016 Update: A Report From the American Heart Association. *Circulation.* 2016;133(4):e38-e360. doi: 10.1161/CIR.0000000000000350
3 Nehler MR, Duval S, Diao L, et al. Epidemiology of peripheral arterial disease and critical limb ischemia in an insured national population. *J Vasc Surg*. 2014;60(3):686-695.e2. doi: 10.1016/j.jvs.2014.03.290
4 American Diabetes Association. *Statistics about Diabetes*. Accessed September 2016, at http://www.diabetes.org/diabetes-basics/statistics.
5 Yost ML. *Chronic venous disease (CVD): Epidemiology, costs, and consequences*. Beaufort, SC: The Sage Group; 2016.

Chronic Venous Disease Risk Factors[1,2]

Age

Family History of Varicose Veins

DVT

History of Phlebitis

Obesity

Standing Occupation

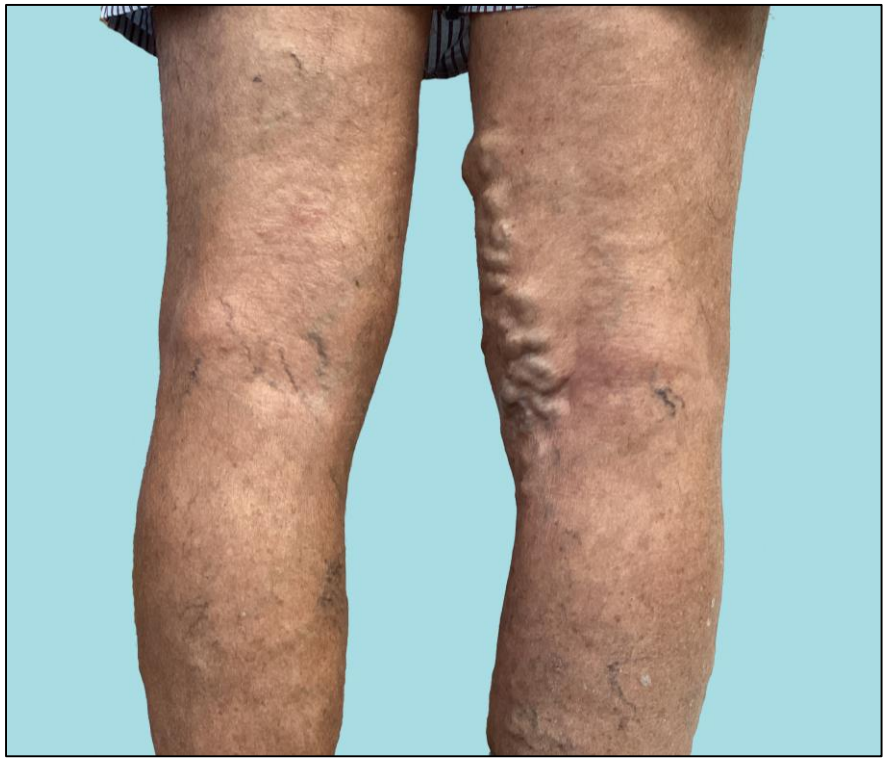
Multiple Pregnancies

Female Sex

1 Eberhardt RT, Raffetto JD. Chronic venous insufficiency. *Circulation*. July 22, 2014;130(4):333-346.
2 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

Signs and Symptoms of CVD[1]

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



Images courtesy of Matthew Wise, MD (Advanced Vein Center, Orange, CA)

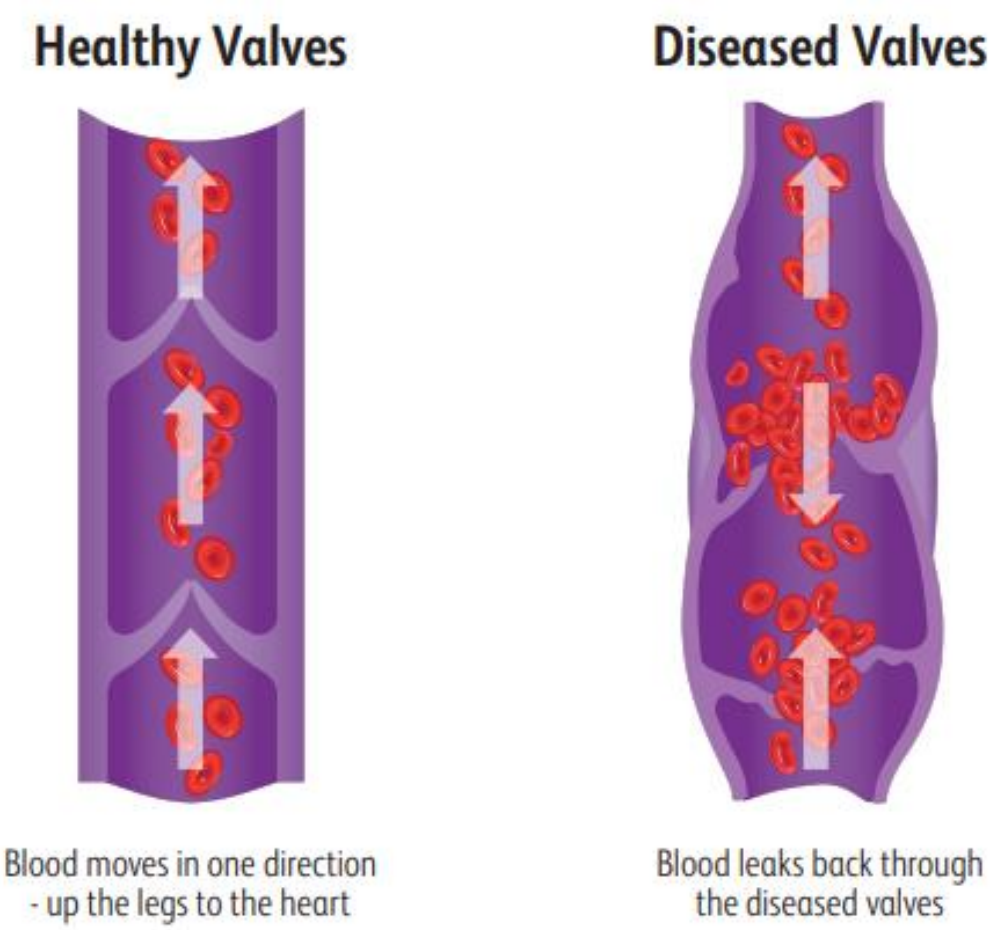
1 Gloviczki P, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg*. 2011 May;53(5 Suppl):2S-48S

Venous Anatomy

Venous Pathophysiology

Venous reflux occurs when the valves stop working properly and allow blood to flow backward and pool in the lower leg veins.

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.[1]



1 Eberhardt RT, Raffetto JD. Chronic venous insufficiency. *Circulation*. 2014;130(4):333-346.

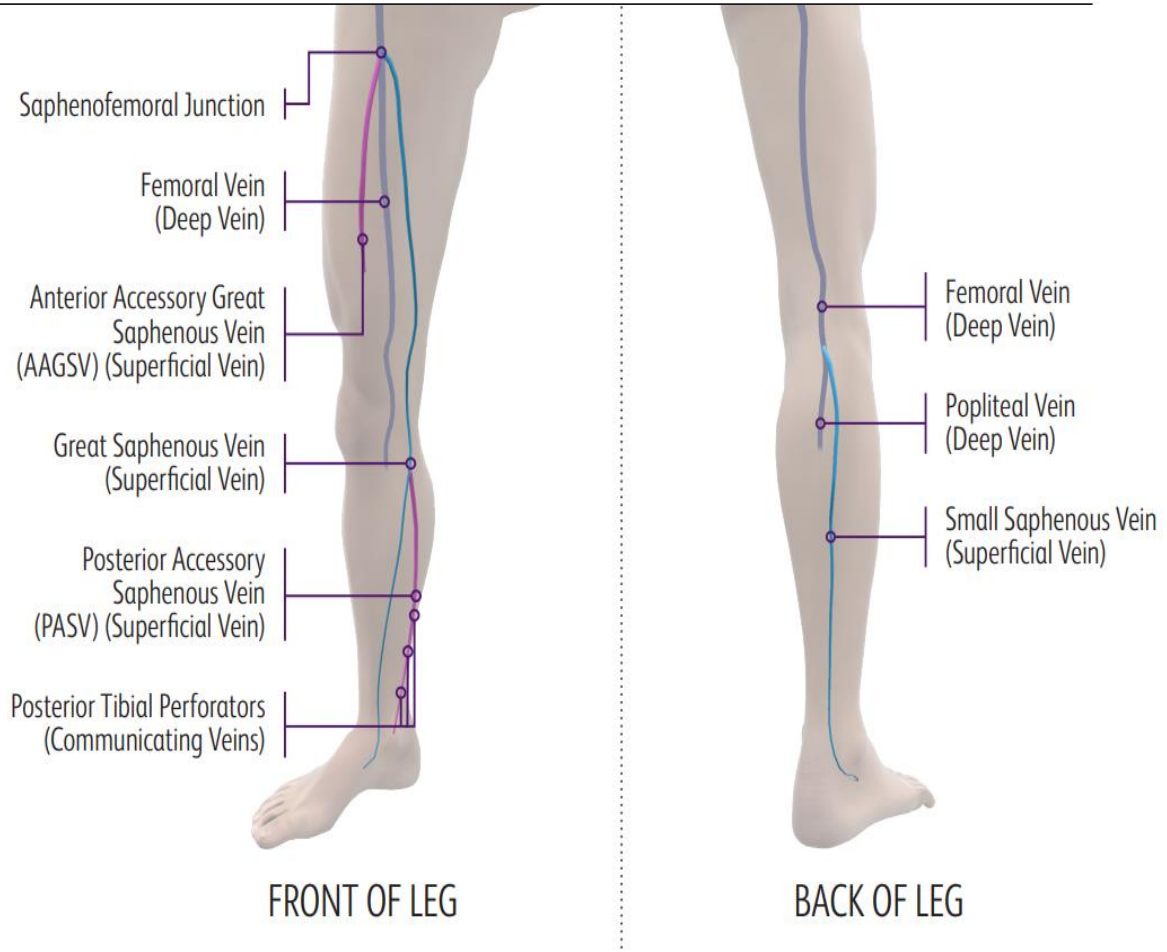
Great Saphenous and Small Saphenous Vein

GSV

- The longest vein in the body
- Typically runs a superficial subcutaneous course from mid thigh to knee
- Closely associated with saphenous nerve below mid-calf

SSV

- Begins posterior to the lateral malleolus
- Travels up calf between two heads of gastrocnemius muscle
- May have thigh extension
- Usually drains into the Sapheno-popliteal Junction (SPJ)

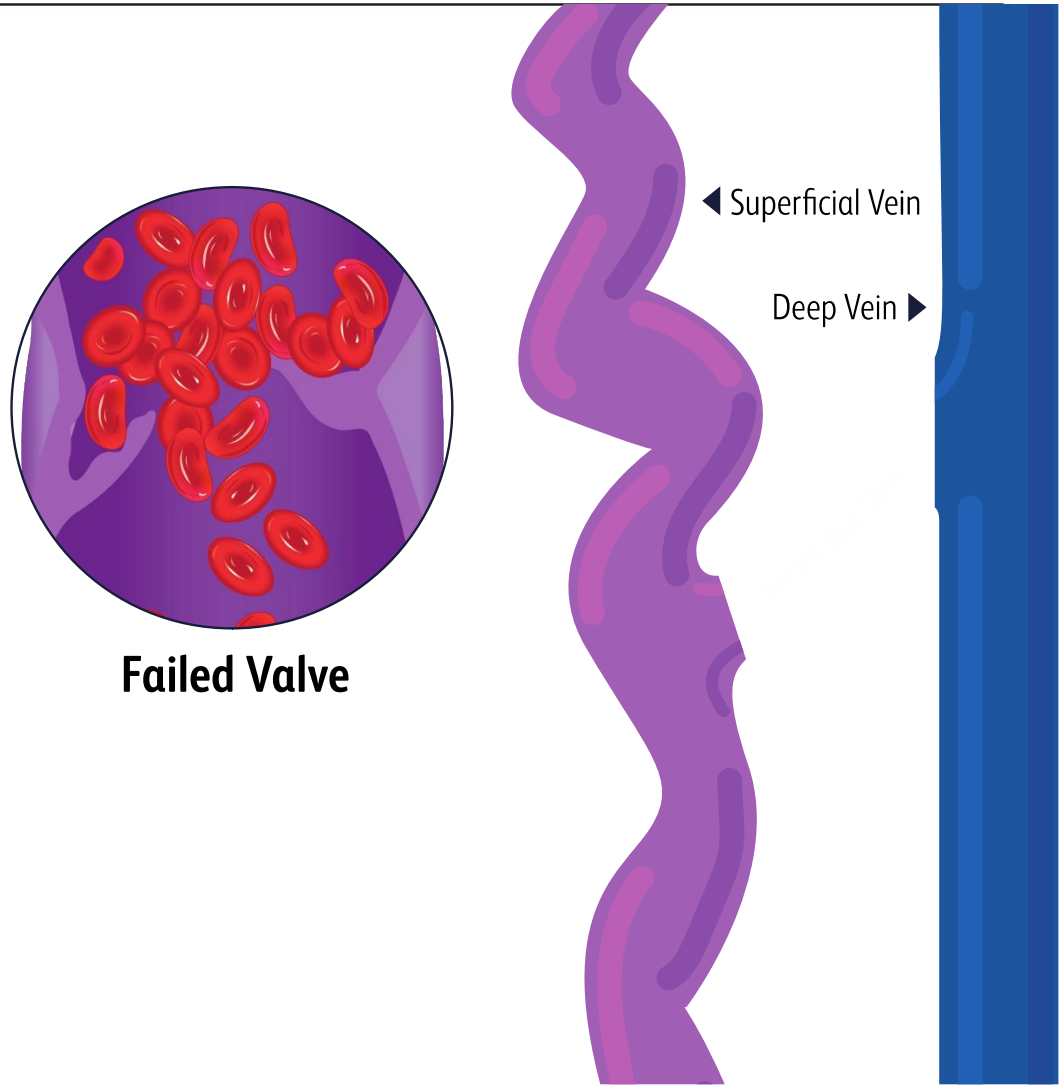


Perforator Veins

Presence of an active or healed ulcer is a potential indicator of incompetent perforator veins [1]

Society for Vascular Surgery/American Venous Forum (SVS/AVF) clinical practice guidelines for care of patients with chronic venous ulcer currently define a pathologic perforator as having a **"diameter of >3.5 mm and >500 milliseconds of retrograde flow"[1]**

These guidelines recommend ablation of pathologic perforator veins when located beneath or associated with potential ulcer beds in **lipodermatosclerosis (C4b), healed ulcers (C5), or active ulcers (C6)[1]**



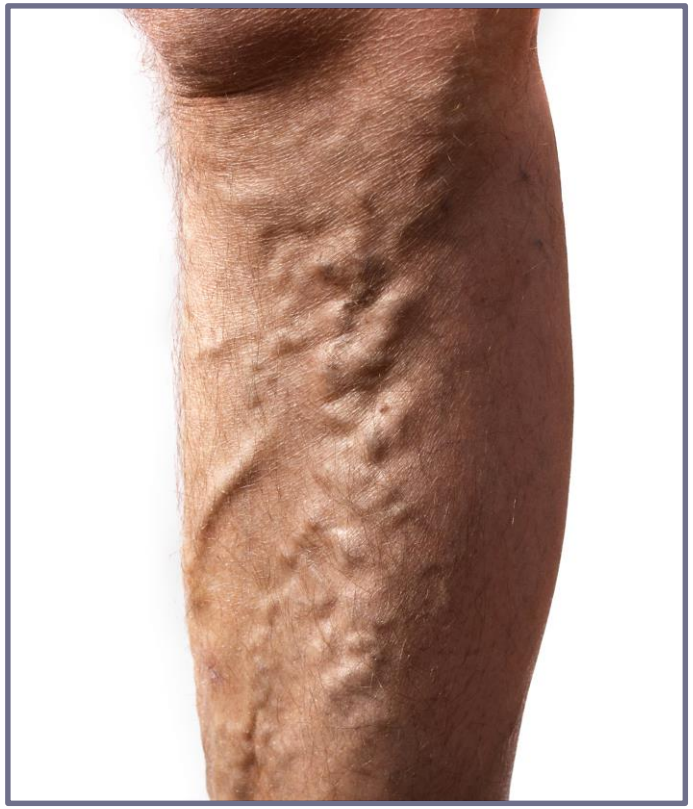
1 O'Donnell TF, Passman MA, Marston WA, et al. Management of venous leg ulcers: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg*. 2014;60:3S-59S.

Clinical Assessment

CEAP Classification for CVD

Clinical, Etiologic, Anatomic, Pathophysiologic[1]

- C0 No visible or palpable signs of venous disease
- C1 Telangiectasias or reticular veins
- C2 Varicose veins
  - C2r Recurrent varicose veins
- C3 Edema



1 Lurie F, Passman M, Meisner M, et al. The 2020 update of the CEAP classification system and reporting standards. *J Vasc Surg: Venous and Lym Dis*. 2020;8:342-352.

CEAP Classification for CVD

Clinical, Etiologic, Anatomic, Pathophysiologic[1]

- C4 Changes in skin & subcutaneous tissue secondary to CVD
  - C4a Pigmentation or eczema
  - C4b Lipodermatosclerosis or atrophie blanche
  - C4c Corona phlebectatica
- C5 Healed venous ulcer
- C6 Active venous ulcer
  - C6r Recurrent venous ulceration

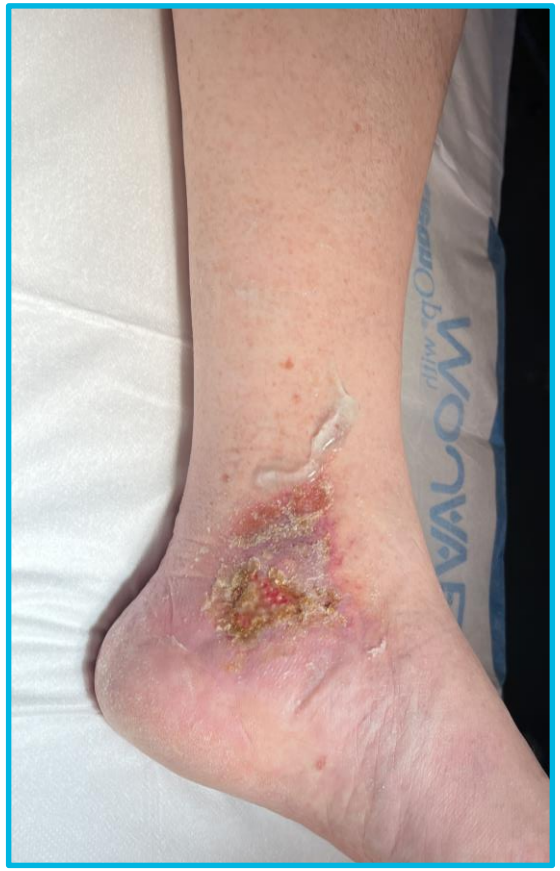
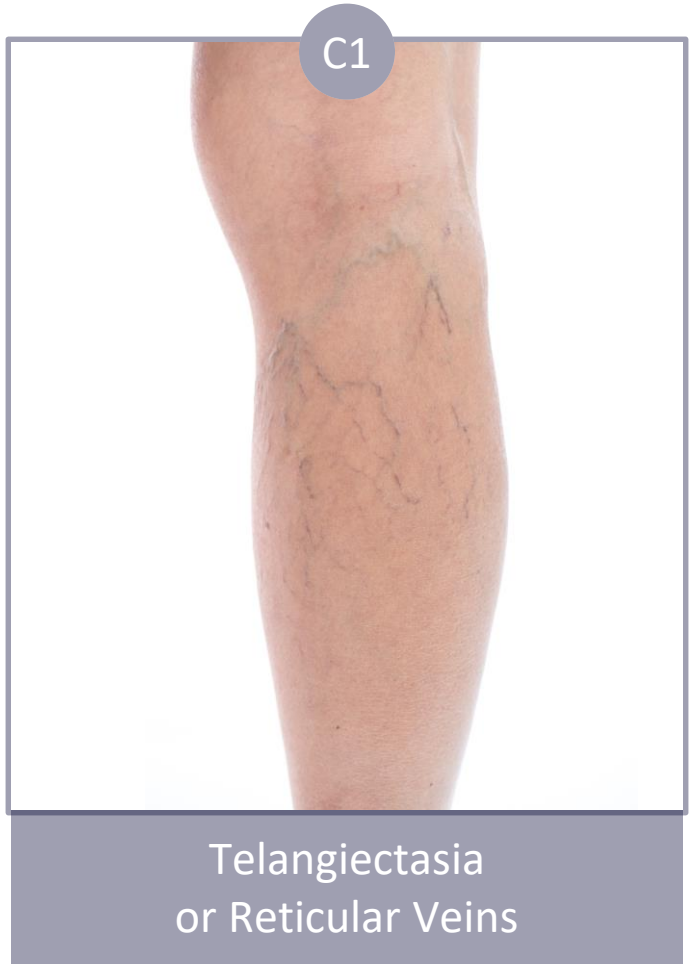
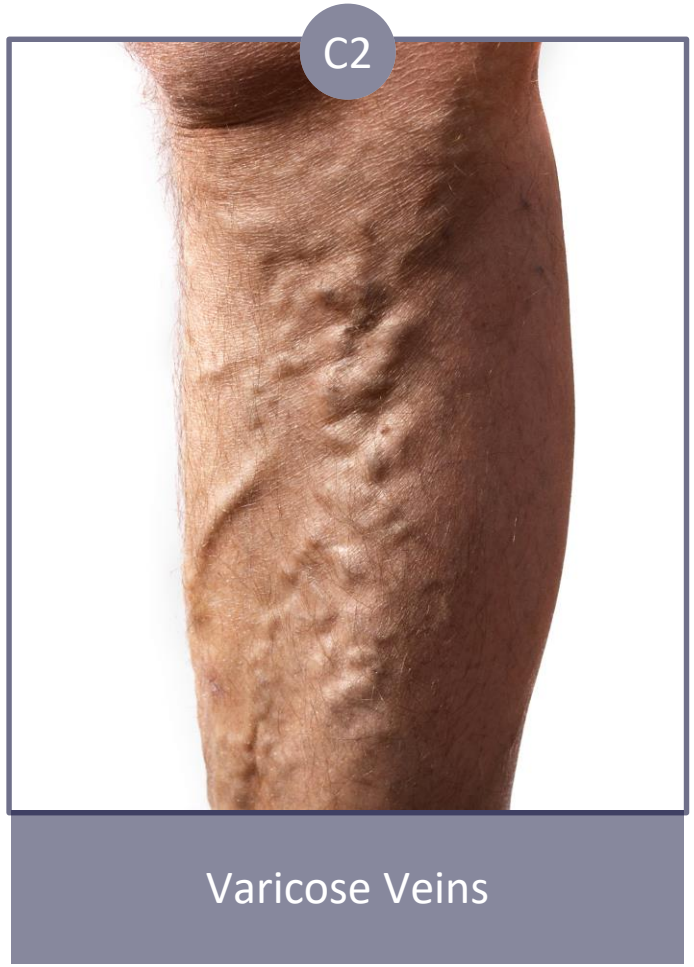


Image courtesy of Dr. Steven Elias

1 Lurie F, Passman M, Meisner M, et al. The 2020 update of the CEAP classification system and reporting standards. *J Vasc Surg: Venous and Lym Dis*. 2020;8:342-352.

CEAP Classification for CVD[1]





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CEAP Classification for CVD[1]

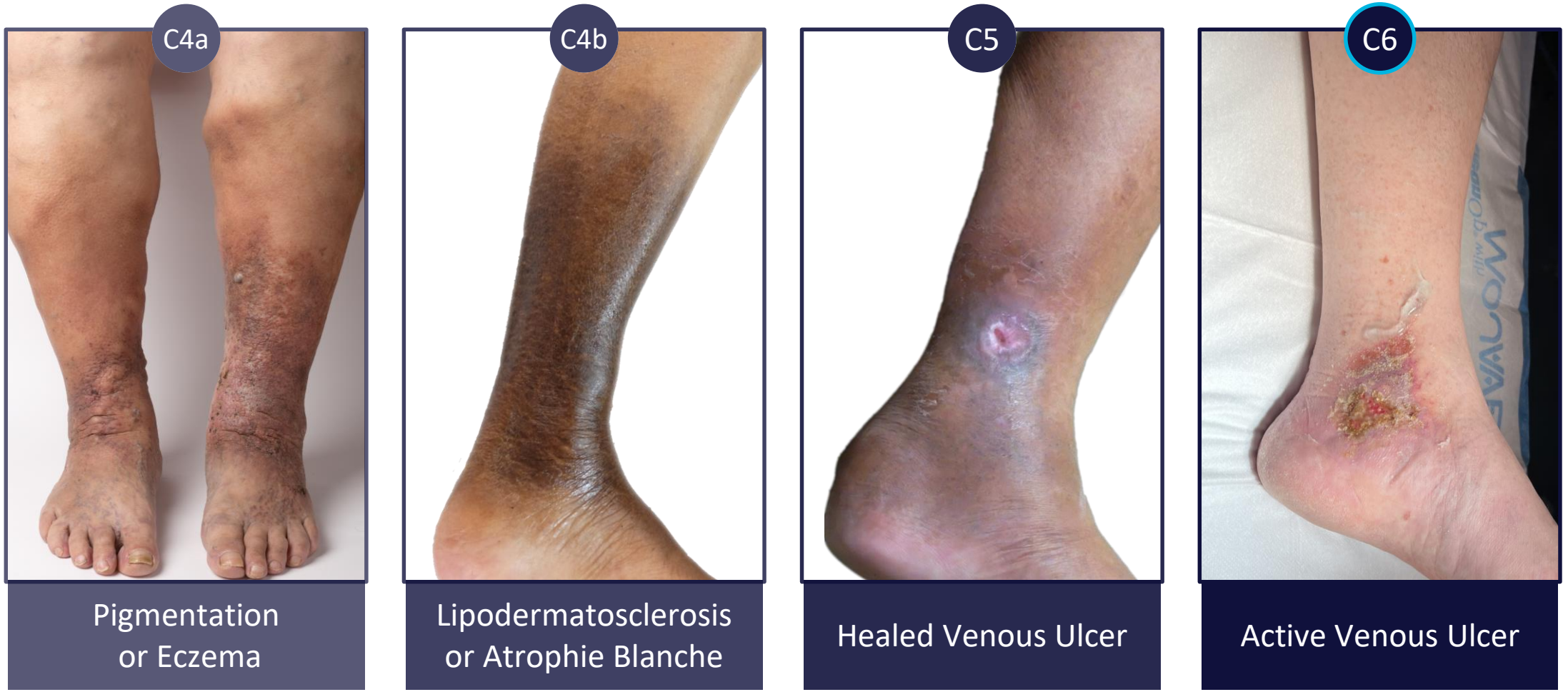


Image courtesy of Dr. Steven Elias

1 Lurie F, Passman M, Meisner M, et al. The 2020 update of the CEAP classification system and reporting standards. *J Vasc Surg: Venous and Lym Dis*. 2020;8:342-352.

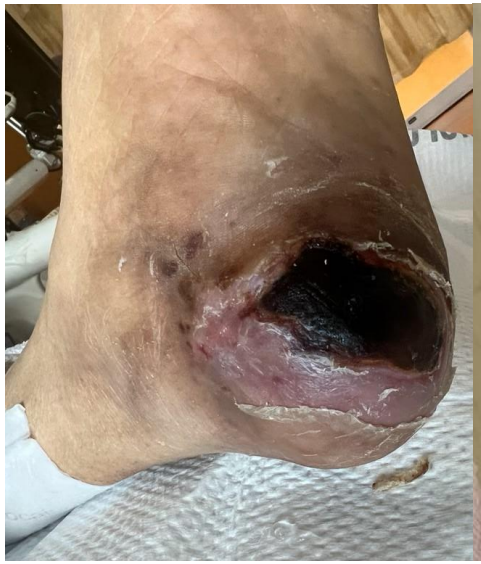
Arterial Ulcers vs. Venous Ulcers

	Arterial[1]	Venous[1]
Cause	Insufficient blood supply to area, causing ischemia (tissue death)	Pooling of blood causing increased pressure in the veins
Risk Factors	Vascular insufficiency, uncontrolled blood sugars in people with diabetes melitus. limited joint mobility or mobility problems, improper footwear	Varicose veins, deep vein thrombosis, incompetent valves, muscle weakness in the legs, immobility, pregnancy
Skin Changes	Shiny, thin, flaky, hair loss, rubor (pinkish red)	Hyperpigmented (hemosiderosis—purple, dark reddish brown), telangiectasias, thickening (lipodermatosclerosis), peri-wound maceration, scaling/crusting
Location	Foot more often than leg	Lower leg, almost never foot
Laterality of Leg	Usually lateral	Usually medial
Wound Edges	Well defined	Irregular, poorly defined
Wound Bed	Pale or necrotic	Dark red, fibrinous slough
Odor	If infected (gangrene)	Usually none
Pain (in ulcer)	Uncommon unless infected or acute ischemia	Uncommon unless infected
Edema	No	Yes

1 Star A. Differentiating lower extremity wounds: arterial, venous, neurotrophic. *Semin Intervent Radiol*. 2018:35:399-405.

Arterial vs. Venous Ulcer Differences

Arterial



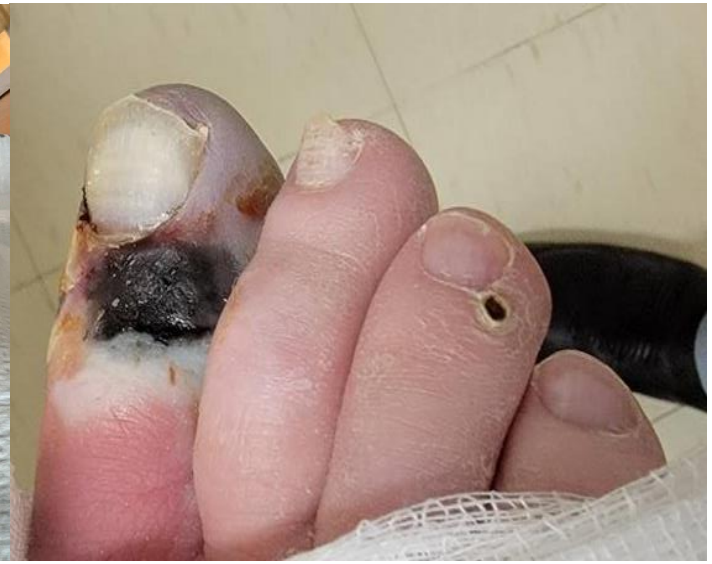
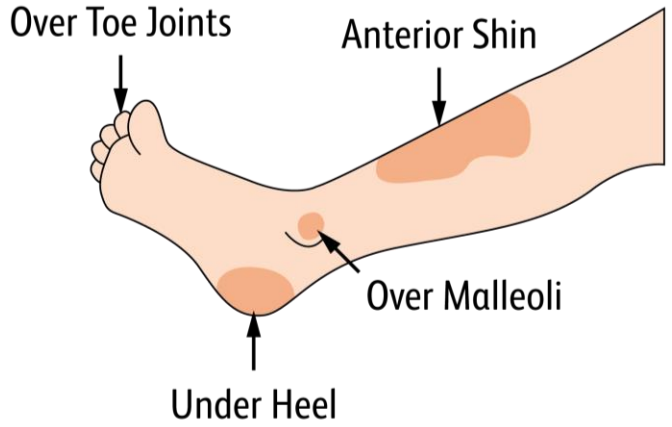
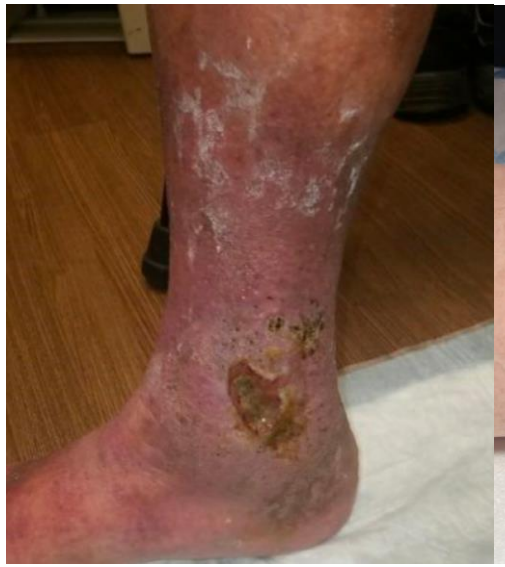


Image courtesy of Dr. Miguel Montero-Baker

Image courtesy of Dr. Eric Secemsky



Venous



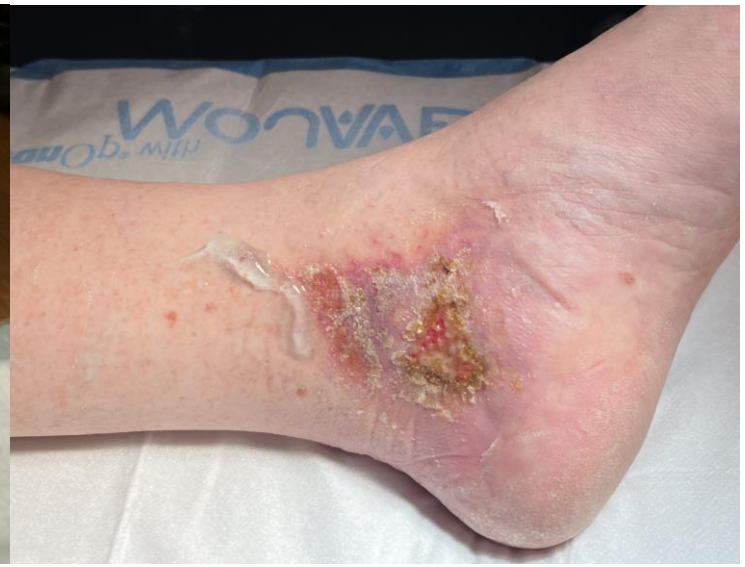
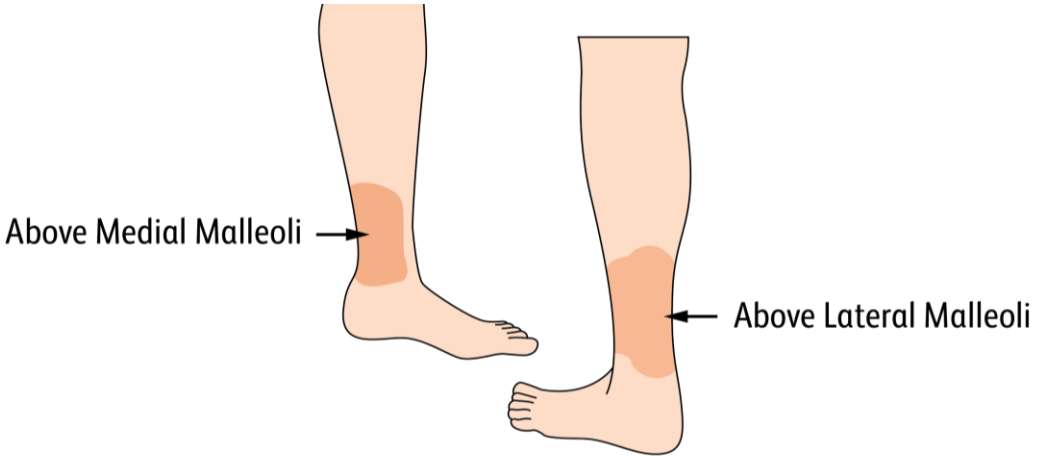


Image courtesy of Dr. Erin Murphy

Image courtesy of Dr. Steven Elias



Patient Assessment & Diagnosis

If a patient has suspected or clinically evident chronic venous disease, they should be referred to a physician experienced in treating venous reflux disease for proper evaluation, testing and diagnosis.[1]

- Current general health condition
- Past medical history
- Symptoms
- Physical exam

- Ultrasound study accurately diagnoses venous reflux disease[1]
- Evaluate for venous occlusion or thrombus[1]
- Map the course of the incompetent superficial veins[1]

1 De Maeseneer M, Pichot, O, Cavezzi A, et al. Duplex ultrasound investigation of the veins of the lower limbs after treatment for varicose veins - UIP consensus document. *Eur J Vasc Endovasc Surg*. 2011;42:90-102.

Treatment Modalities

Current Treatment Modalities

Conservative Therapies[1]

- Exercise
- Leg elevation
- Compression stockings
- Unna boot
- Venoactive drugs

Thermal Ablation[1]

- Radiofrequency (RF) ablation
- Laser ablation

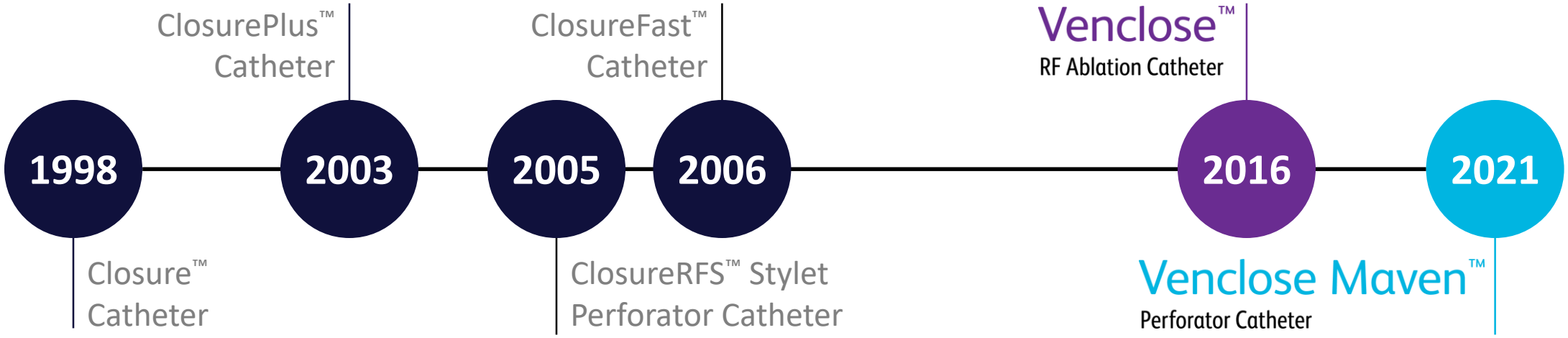
Surgical Stripping[1]

Non-thermal, Non-tumescent[1]

- Mechanochemical
- Sclerotherapy
- Cyanoacrylate adhesive

1 De Maeseneer MG, Kakkos SK, Aherne T, et al. European Society for Vascular Surgery (ESVS) 2022 clinical practice guidelines on the management of chronic venous disease of the lower limbs. *Eur J Vasc Endovasc Surg*. 2022;63:184-267.

First CVD RF Innovation In Over a Decade



Non-surgical, catheter-based thermal ablation → Fibrotic seal → Vein occlusion

RF Venous Solutions

Venclose™
RF Ablation Catheter

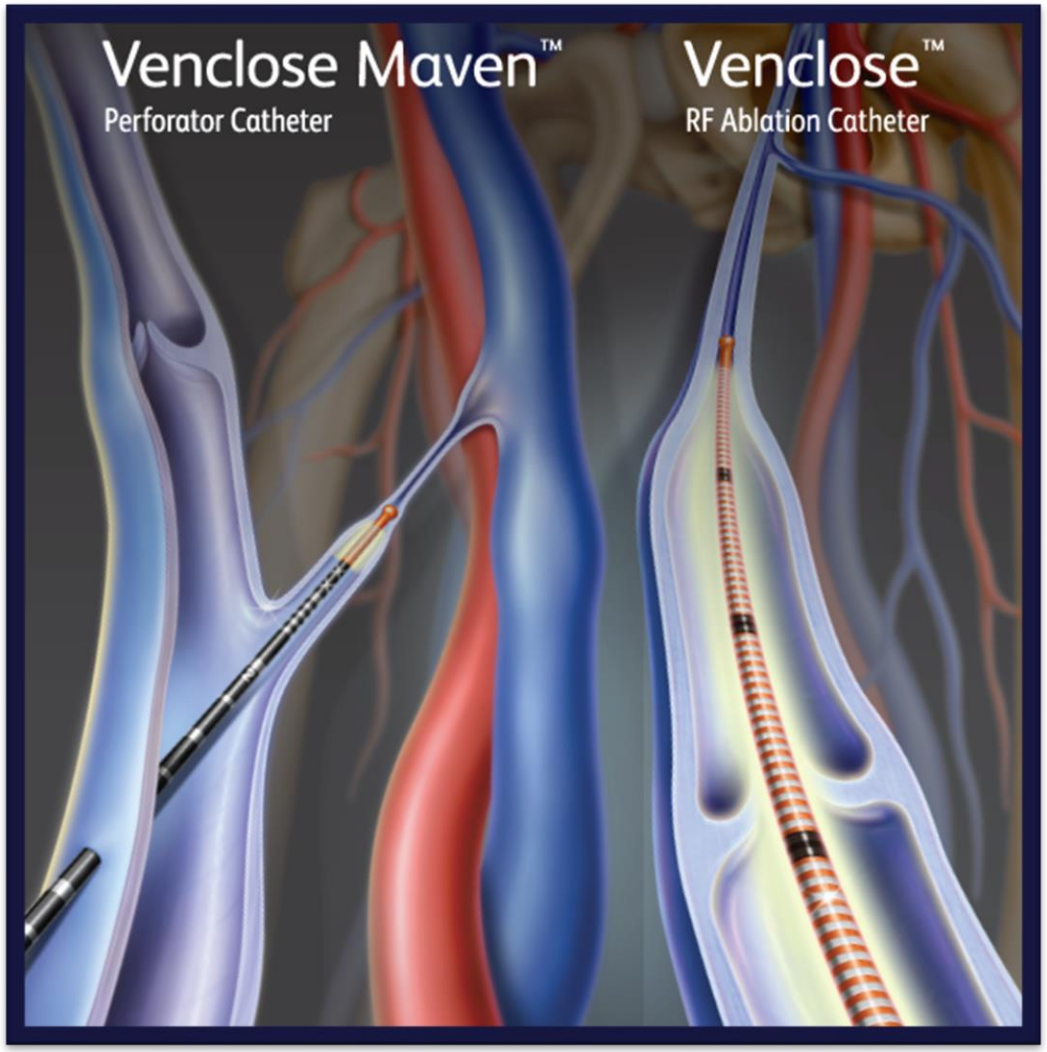
Venclose Maven™
Perforator Catheter

BD

BD Venclose™ RF Ablation System

Treating the spectrum of superficial venous reflux disease with the latest RF technology on the market.*

RF technology has been established as a treatment option for refluxing veins for more than **20 years**.



 * As of April 2023

Venclose™ RF Ablation System Advantages

- While various treatments are available for CVD, RF ablation has wide acceptance and is the predominant approach used for the treatment of refluxing veins in the U.S.[1]
- RF ablation technology can potentially reduce postoperative pain and bruising in patients compared to vein stripping or laser therapy treatment.[2]
- The Venclose™ RF Ablation System is a single-use device. It is not a reprocessed catheter or a permanent implant.

1 Decision Resources Group. *Varicose Vein Treatment Devices: Medtech 360: Market Analysis: US: 2019*. Canada: Millennium Research Group, Inc.; 2018.
2 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-forradiofrequency-ablation-for-the-treatment-of-lower-extremity-chronic-venous-disease. Accessed on October 27, 2022

Venclose™ RF Ablation Catheter

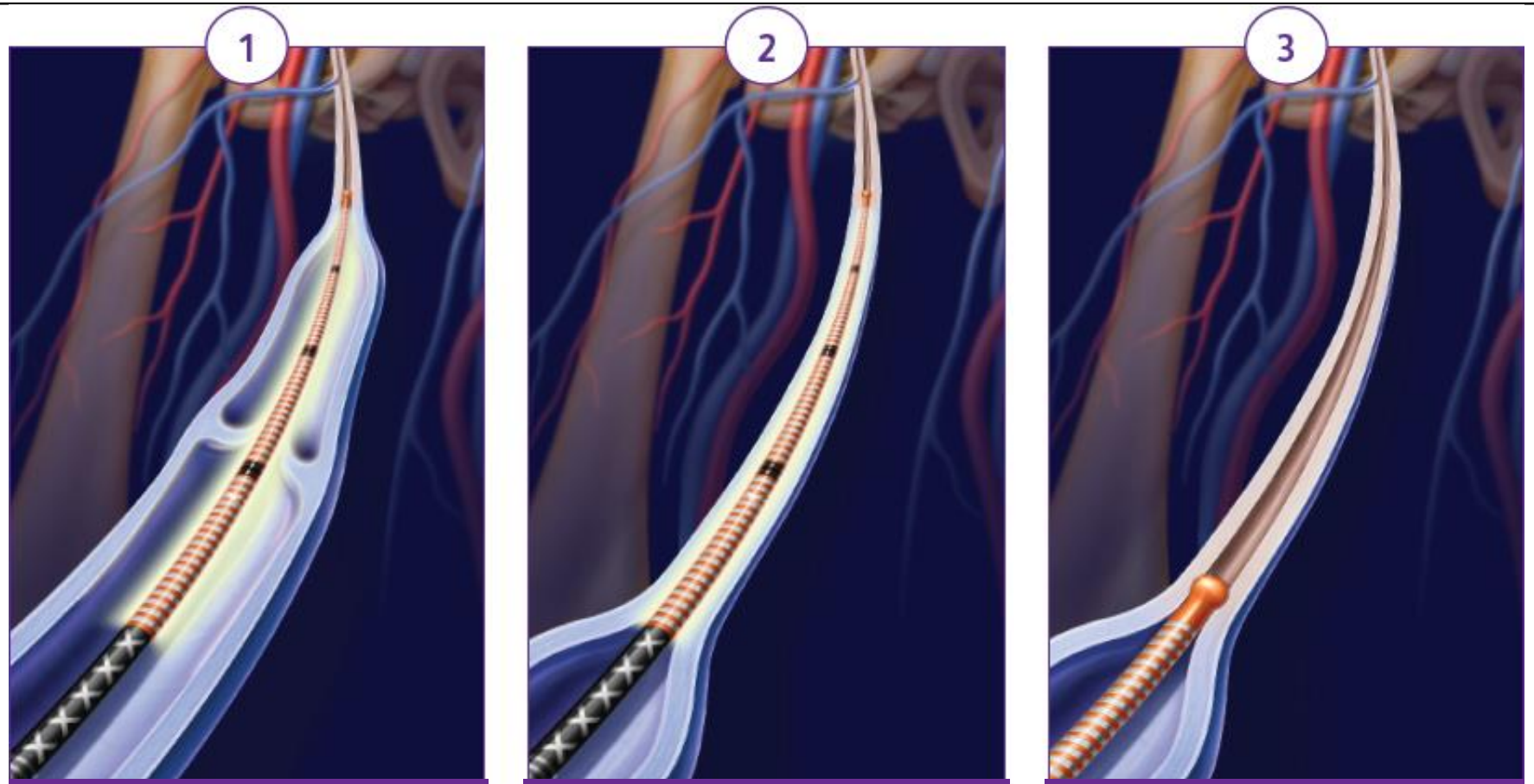
42% MORE
HEATING LENGTH
USING A SINGLE
RF CATHETER*

Venclose™ RF Ablation Catheter is a minimally invasive treatment solution for patients with superficial vein reflux.

Venclose™ RF Ablation Catheter is the **only** RF device with dual heating lengths to treat long and short refluxing segments with one catheter.[1]

*Compared to ClosureFast™
[1]As of April 2023

Radiofrequency Energy Delivered by the Venclose™ RF Ablation Catheter

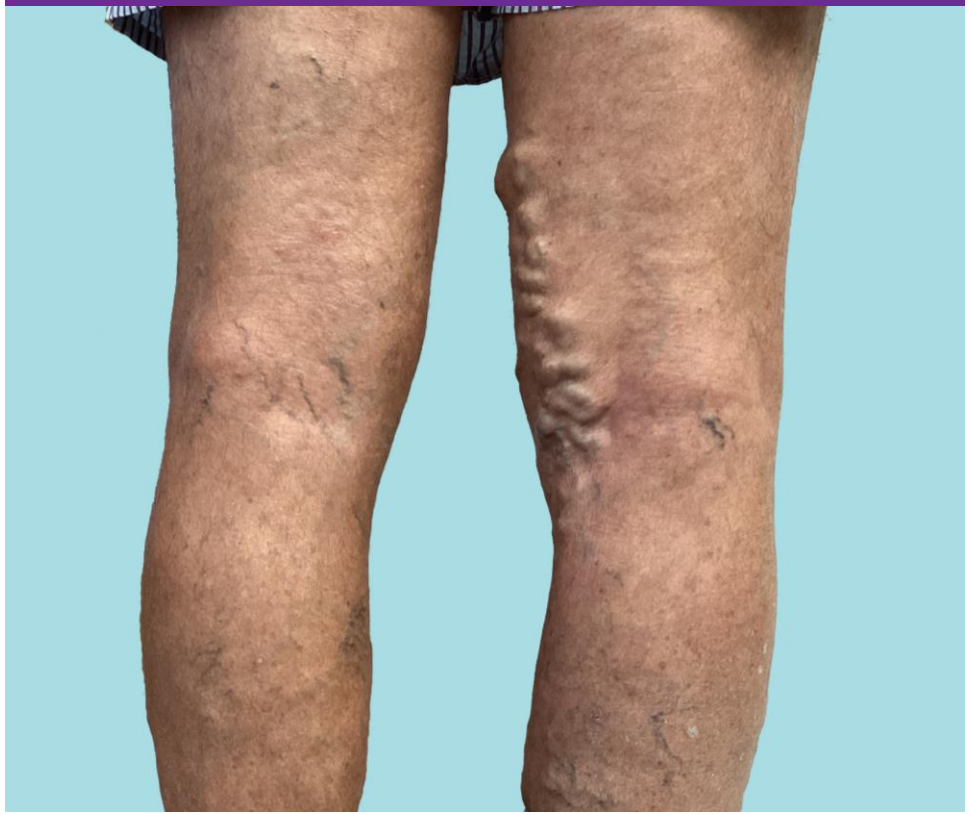


1	2	3
Catheter delivers targeted heat along vein segments	Heat then causes the diseased vein to shrink	Catheter is easily removed, blood flow is redirected to healthy veins

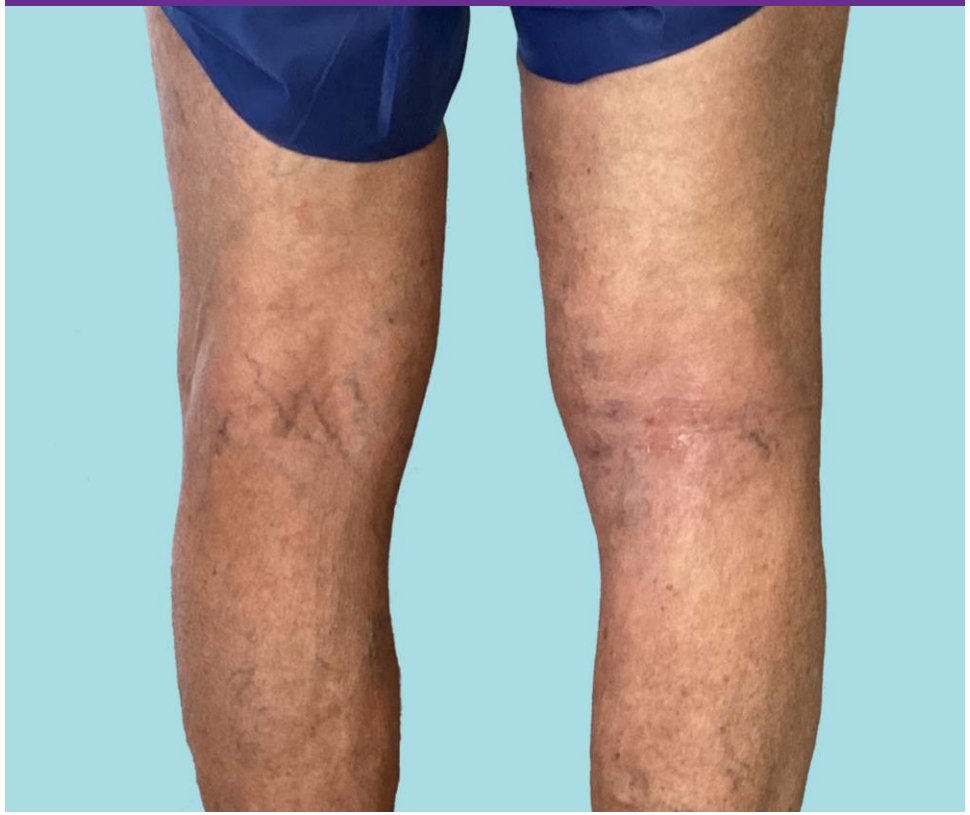
Venclose™ RF Ablation Catheter Video

Patients Treated with the Venclose™ RF Ablation Catheter

Before Treatment



After Treatment*



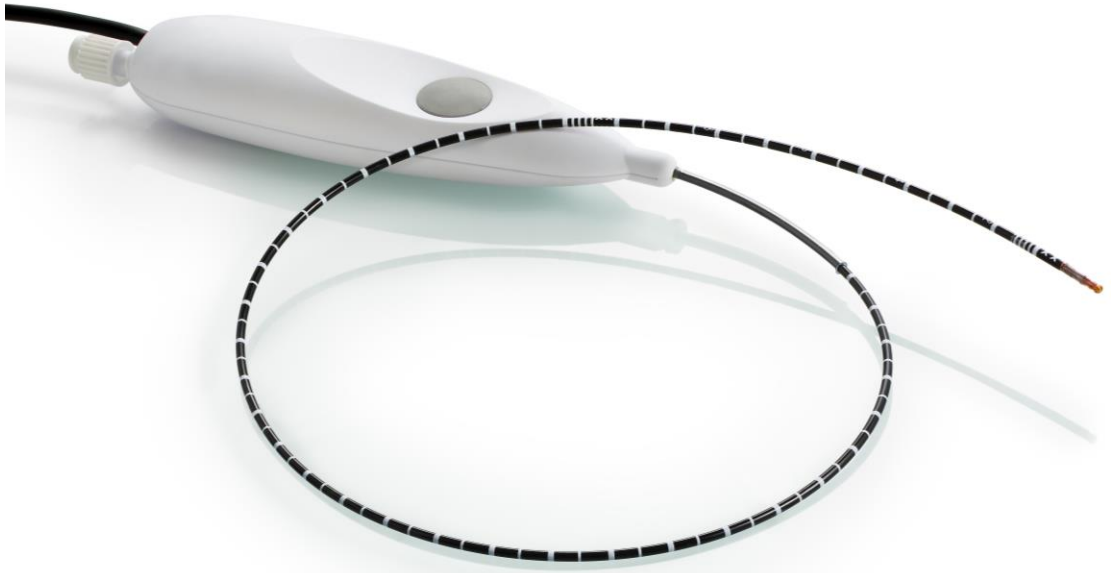
* After treatment image was taken 2 weeks post-op

Individual treatment results may vary. Images courtesy of Matthew Wise, MD (Advanced Vein Center – Orange, CA)

Venclose Maven™ Perforator Catheter

Venclose Maven™ Perforator Catheter is a minimally invasive treatment solution for patients with perforator and tributary vein reflux.

The device is unique by providing physicians circumferential resistive heating in one treatment cycle as compared to 4 treatment cycles required for bipolar electrodes.



Treating Late-Stage Venous Disease with the Venclose Maven™ Perforator Catheter

Catheter is placed in the perforating vein

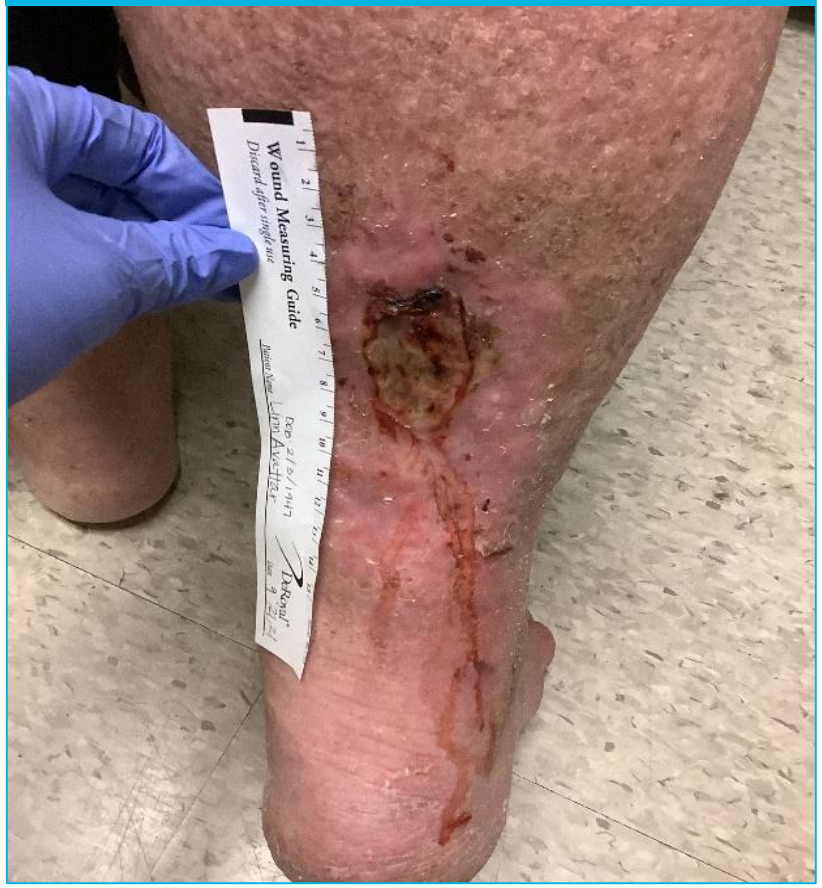
Heat is delivered to the incompetent perforator vein and causes the diseased vein to shrink

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

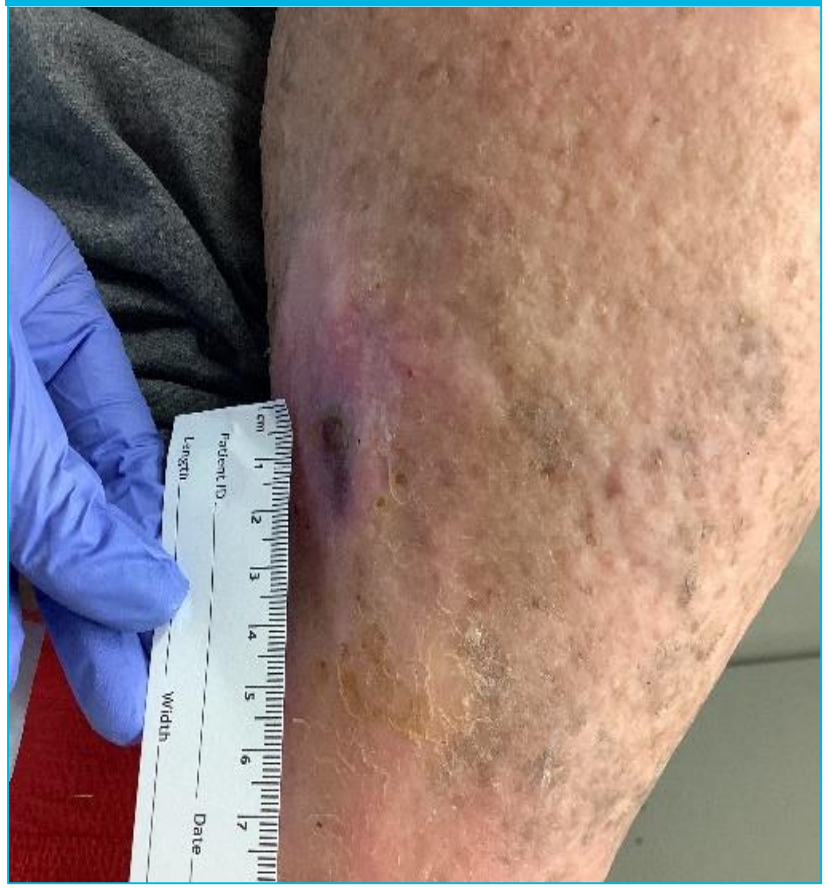
Venclose Maven™ Perforator Catheter Video

Patients Treated with the Venclose Maven™ Perforator Catheter

Before Treatment



After Treatment*

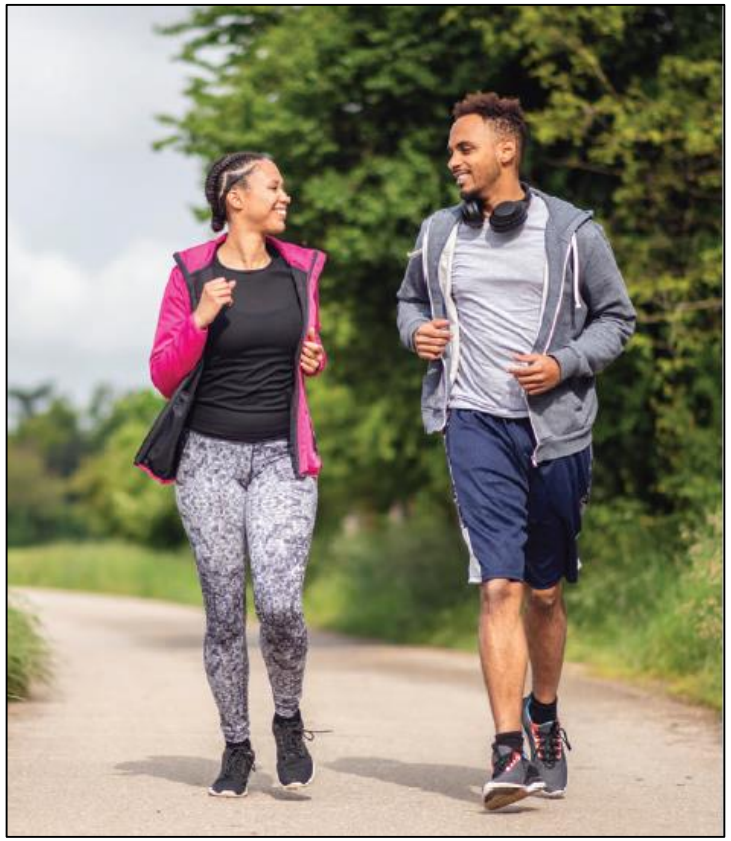


* After treatment image was taken 3 months post-op

Individual treatment results may vary. Images courtesy of Nathan Tomita, DO (Pacific Vascular Institute – Kona, HI)

Patient Outcomes with RF Ablation

While individual results may vary, patients can typically resume normal activities within a few days of an RF ablation procedure.



1 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.

RF Insurance Coverage

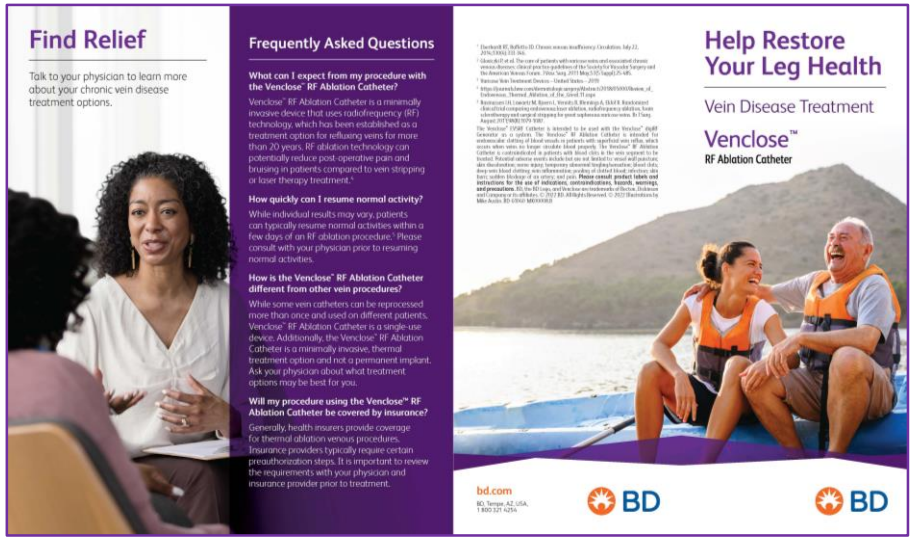
- Generally, health insurers provide coverage for thermal ablation venous procedures.
- Insurance providers typically require certain preauthorization steps.
- It is important for the patient to review the requirements with their physician and insurance provider prior to treatment.

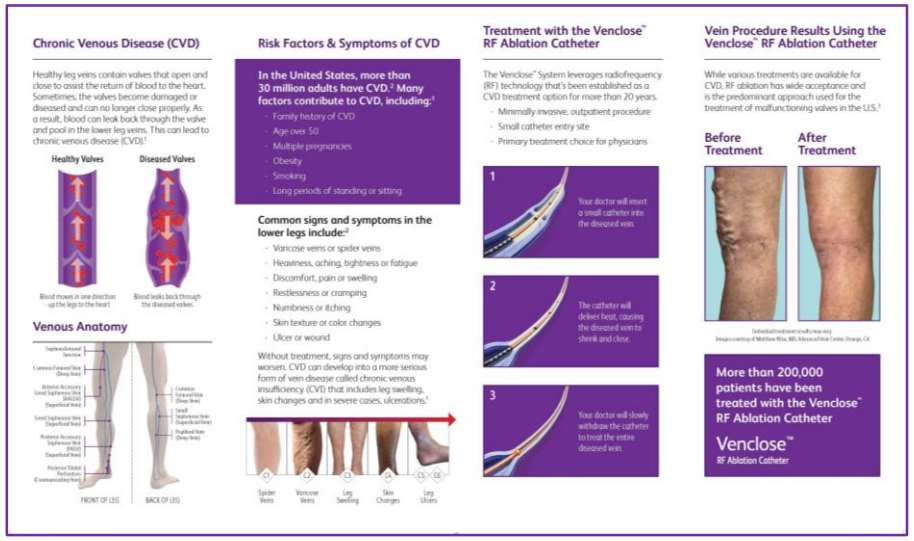
What Can You Do

- Spread CVD awareness in the community
- Detect early signs and symptoms of CVD
- Identify the right multi-disciplinary team
- Build a wound treatment & management plan
- Help improve quality of life for your patients

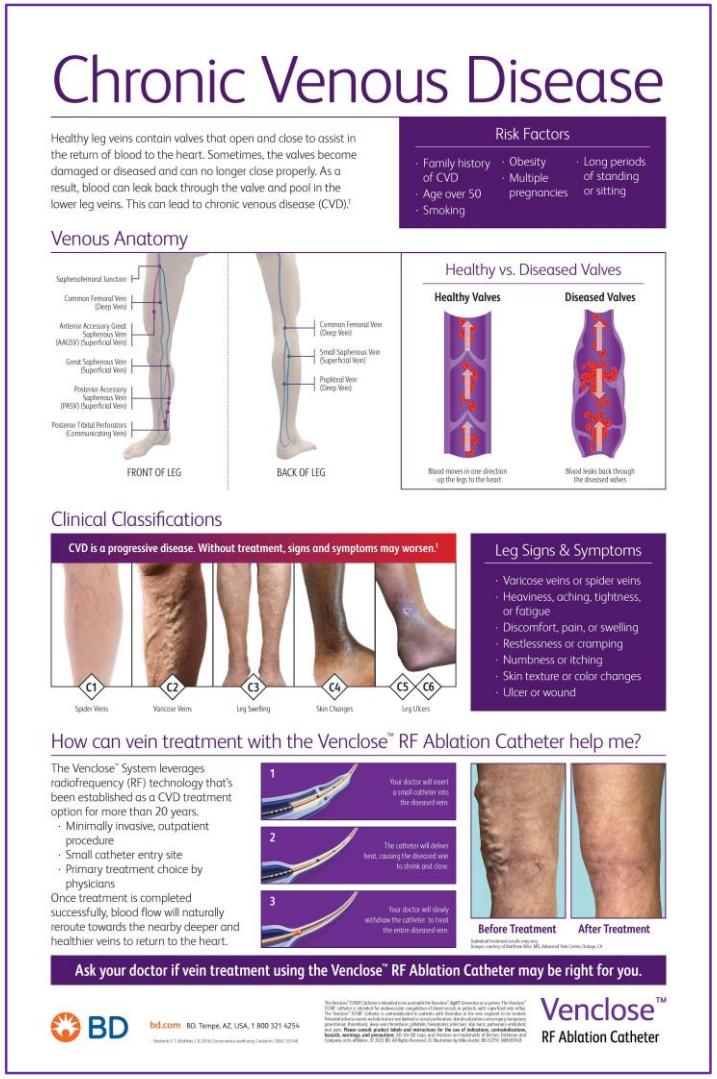
Working together across a **collaborative team** of specialists will ensure patients get the best treatment during various stages of their CVD journey.

Resources Available for Your Patients

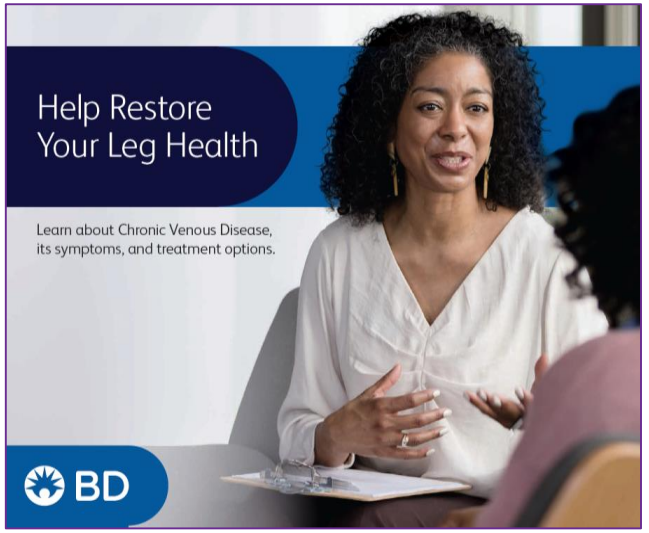


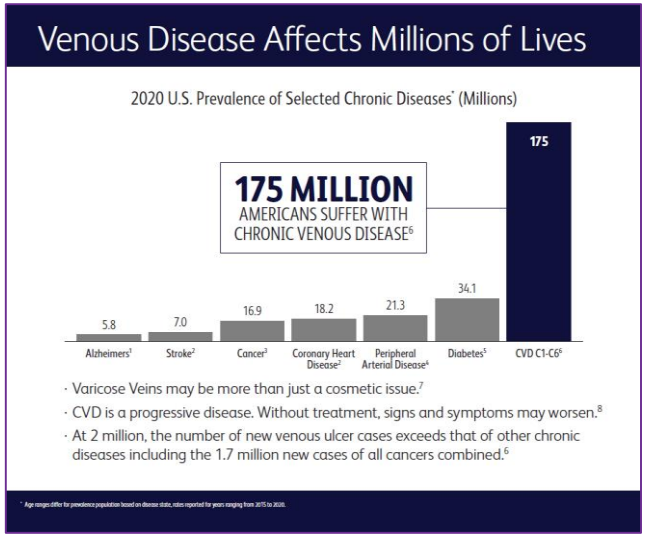


Education Brochure



Exam Room Poster





Flipchart

Venclose™
RF Ablation Catheter

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.

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 41ºC during treatment. Testing of this region has shown that a maximum temperature of 42ºC 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 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 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; and pain.

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Venclose Maven™
Perforator Catheter

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 ºC during treatment. Testing of this region has shown that a maximum temperature of 42 ºC 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 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.

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Thank you

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