
Advance
Clinical Training & Education Program
BD-55448
BD
INTERVENTIONAL

Disclaimer

The opinions and techniques presented herein are for informational purposes only and the decision of which technique to use in a particular procedural or surgical application should be made by the physician based upon individual facts and circumstances of the patient and previous surgical experience.

Please consult product inserts and labels for any indications, contraindications, hazards, warnings, cautions and directions for use. Procedural or surgical techniques should follow the directions for use section of the IFU/eIFU and appropriate risk information should be an integral part of the piece.

Disclaimer

The results from case studies may not be predictive for all patients. Individual results may vary depending on variety of patient specific attributes.

The speaker's presentation today is on behalf of BD Peripheral Intervention. The physician has been compensated today by BDPI for the time and effort to present this information.

Physician Training

Venclose Maven™
Perforator Catheter

Venclose Maven™ Perforator Catheter Physician Training

1. Anatomy Review
2. Perforator Vein Function
3. Evolution of Perforator Vein Treatment
4. Perforator Vein Diagnosis
5. Venclose Maven™ Perforator Catheter

Anatomy

Perforating Veins of the Lower Extremity

The **perforating veins of the lower limb** (PV or "perforators") are numerous veins in variable arrangements, connections, sizes, and distributions.

There are many perforator systems in each extremity with approximately **150 perforator veins** in each lower extremity identified by van Limborgh.

Perforator veins are distributed approximately as follows:

60 perforator veins in the thigh,

8 in the popliteal fossa,

55 in the leg, and

28 in the foot

Of these veins, about **30 become incompetent** and may be identified in clinical practice

(Gasparis and Labropoulos, p. 45)

Gasparis, A., Labropoulos, N. Perforator vein incompetence in CVD patients. Endovascular Today. 2011(July): 45-49.

Medial Leg Perforators

The calf contains 4 groups of perforators:

- **"Paratibial perforators** connect the main great saphenous trunk with the posterior tibial veins"[1]
- **"Posterior tibial perforating veins** connect the posterior accessory great saphenous vein of the calf with the posterior tibial veins and form the lower, middle, and upper groups"[1]
- **Anterior leg perforators**
- **Lateral leg perforators**

"The medial calf perforators, including the *paratibial* and *posterior tibial* are clinically most important"[2]

1. Gloviczki P, Comerota AJ, Dalsing MC, 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;53(5 Suppl):2S-48S. doi: 10.1016/j
2. Meissner MH. Lower extremity venous anatomy. Semin Intervent Radiol. 2005;22(3):147-56. doi: 10.1055/s-2005-921948.

Posterior Leg Perforators

The posterior leg contains 4 groups of perforators:

Medial gastrocnemius perforators (in the medial calf)

Lateral gastrocnemius perforators (in the lateral calf)

Intergemellar perforators: Connecting the small saphenous vein with the calf veins

Para-Achillean perforator

(MacManus and Skalina, p.1)

MacManus, D., Skalina, T. Perforators of the leg and calf (venae perforantes cruris). Reference article, Radiopaedia.org. (accessed on 28 Feb 2022) https://doi.org/10.53347/rID-74272

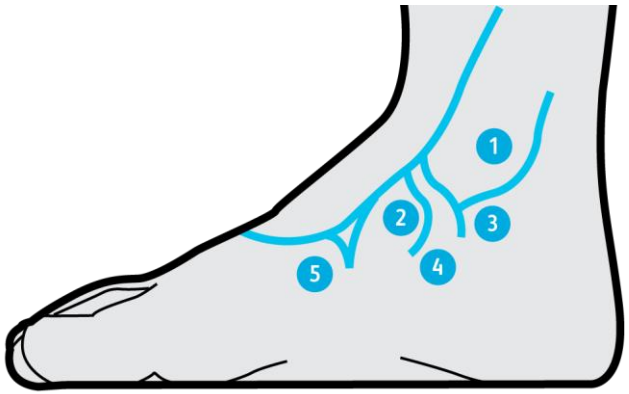
Foot Perforators

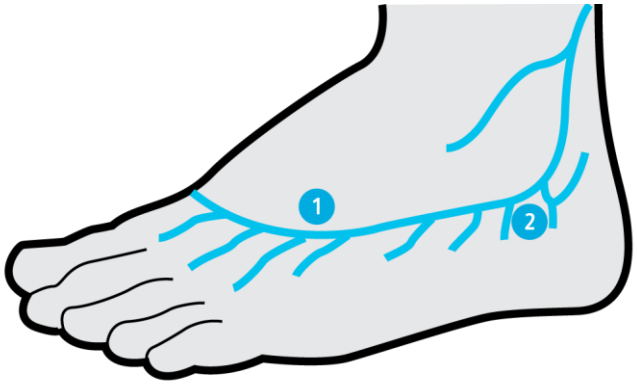
Medial surface of the foot[1]

1. Medial malleolus
2. Navicular bone
3. Posterior group
4. Median group
5. Anterior group

Lateral surface of the foot[1]

1. Metatarsal group
2. Calvaneal group





"Foot perforators are unique in that some are either valveless (bidirectional flow) or have valves in the inverted position directing flow toward the superficial veins"[2]

1. Perforating veins of the foot. Accessed February 2, 2022. Available at https://www.phlebologia.com/veins-of-the-foot/perforating-veins-of-the-foot
2. Uhl JF, Gillot C. Anatomy of perforating veins of the lower limb. Phlebologie 2021;50:59-71

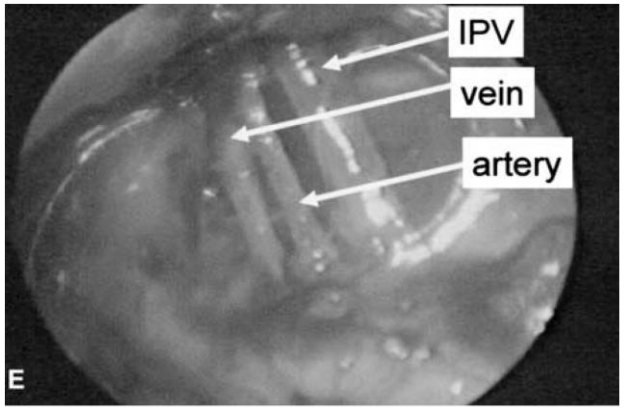
Twin Perforators

Endoscopic Anatomy of Perforating Veins in Chronic Venous Insufficiency of the Legs: "Solitary" Incompetent Perforating Veins Are Often Actually Multiple Vessels

- Prospective, single center study
- 173 limbs in 152 subjects were examined
- Examined anatomy and features of 128 incompetent perforating veins (IPVS) during subfascial, endoscopic, perforating-veins surgery for lower extremity chronic venous insufficiency

Haruta, N., Shinhara, R., Sugina, K., et al.. Endoscopic anatomy of perforating veins in chronic venous insufficiency of the legs: "Solitary" incompetent perforating veins are often actually multiple vessels. International Journal of Angiology. 2004;13: 31–36. DOI: 10.1007/s00547-004-1045-3

Twin Perforators



Haruta, et al. 2004 © Georg Thieme Verlag KG. International Journal of Angiology . Reprinted with permission.

Two or More Vessels

- "The incompetent perforating vein (IPV) often appears to be a single vessel, when it is actually two or more vessels"[1]
- In study by Haruta et al (2004) it was observed that 97 out of 110 IPVs (88.2%) involved a concomitant artery[1]

Ultrasound Assessment Challenges

- Demonstrates the importance of marking in centimeters (cm) up and over on prior perforators treated – could be perforators in pairs
- One perforator treated successfully, now the twin is incompetent, and the perforator artery is still patent

1. Haruta, N., Shinhara, R., Sugina, K., et al.. Endoscopic anatomy of perforating veins in chronic venous insufficiency of the legs: "Solitary" incompetent perforating veins are often actually multiple vessels. International Journal of Angiology. 2004;13: 31–36. DOI: 10.1007/s00547-004-1045-3

Perforator Vein Function

Perforator Definition & Anatomy

Perforating Vein (PV):

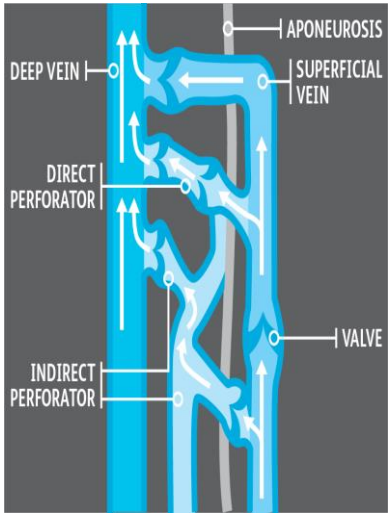
- Join the deep to the superficial system, which perforates the deep fascia, also referred to as aponeurosis
- Have unidirectional valves along the entire limb
- Oriented **superficial to deep**, with exception of PVs located in the foot[1]

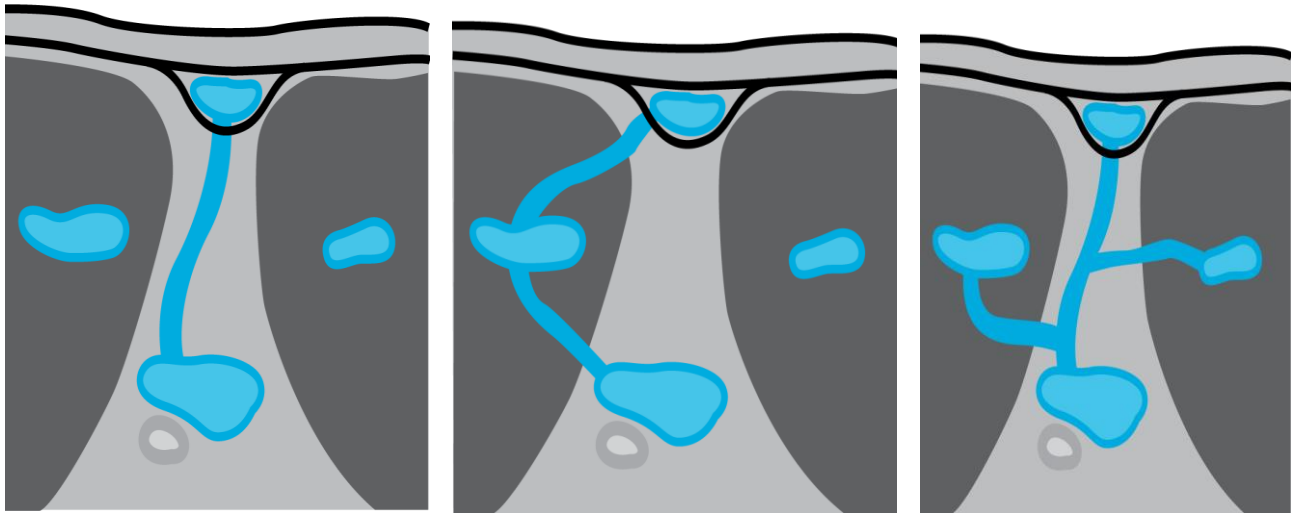
1. Uhl JF, Gillot C. Anatomy of perforating veins of the lower limb. Phlebologie 2021;50:59-71

Types of Perforators: Direct

Two types of perforating veins can be distinguished:[1]

- **Direct Perforating Veins (classical):** **"**they directly connect superficial veins with deep intermuscular veins (anterior or posterior tibial veins, peroneal veins, and tibioperoneal trunk)[1]
- **Indirect Perforating Veins (connected to intramuscular veins):** **"**they connect superficial veins with gastrocnemius or soleus veins and often have multiple branches connecting superficial, intermuscular, and intermuscular networks"[1]



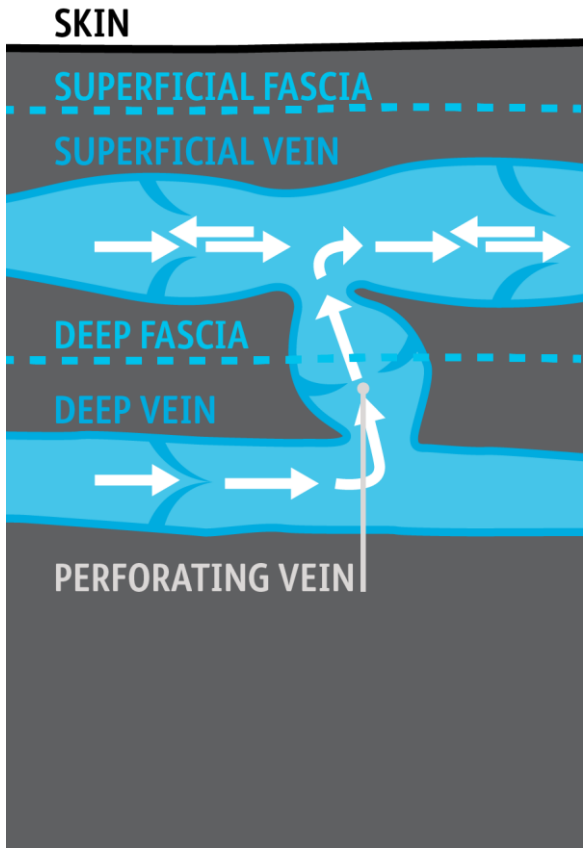


"At the transfascial segment, perforating veins run closer to their accompanying artery and nerve"[2]

1. https://www.phlebologia.com/short-saphenous-territory/below-the-popliteal-fossa
2. Uhl JF, Gillot C. Anatomy of perforating veins of the lower limb. Phlebologie 2021;50:59-71

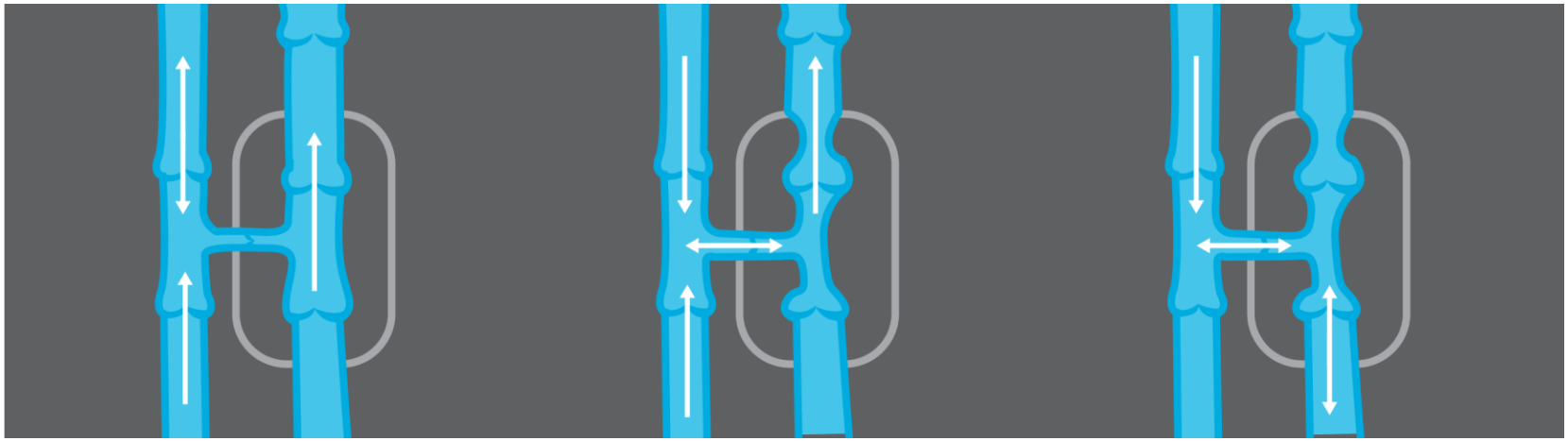
Pathologic Perforator

Society for Vascular Surgery® and the American Venous Forum clinical practice guidelines for the care of patients with varicose veins and associated chronic venous disease currently define a **"pathologic perforator** as having **reflux ≥500 milliseconds with a vein diameter of ≥3.5 mm and location near healed or active ulcer (CEAP class 5 and class 6)"**



Gloviczki P, Comerota AJ, Dalsing MC, 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;53(5 Suppl):2S-48S. doi: 10.1016/j

Pathologic Perforator Antegrade Overload Pattern

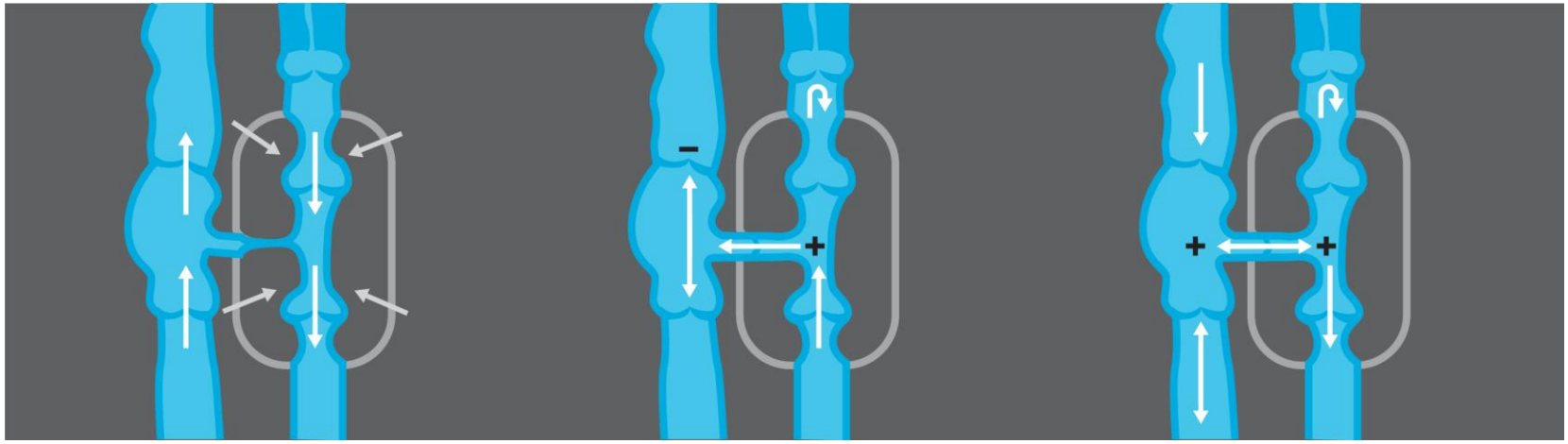


"Retrograde flow in a superficial varicosity decompresses through a re-entry perforator resulting in perforator dilatation and eventual valvular incompetence."[1]

"If an incompetent perforator results from antegrade overload, correction of the superficial reflux alone is often sufficient to normalize perforator hemodynamics and permit return to normal function"[1]

1. Fan, C. How I decide to ablate a refluxing perforator. Endovascular Today. 2015 (July) 68-74.

Pathologic Perforator Retrograde Blow-out Pattern



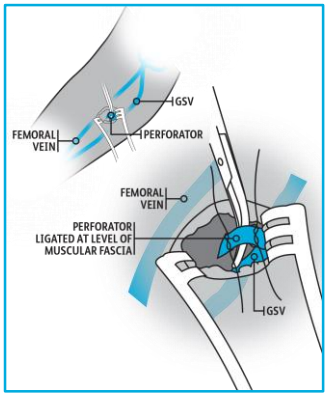
"Chronic deep venous hypertension stresses the perforator from a retrograde direction causing perforator dilatation, valvular incompetency, and secondary superficial venous hypertension manifesting as varicose veins and inflammatory changes."[1]

"If the perforator incompetence develops secondarily to uncorrectable deep venous hypertension, eliminating the associated superficial venous reflux does not address the underlying cause of the problem, the perforator cannot recover normal function, and active intervention may be needed"[1]

1. Fan, C. How I decide to ablate a refluxing perforator. *Endovascular Today*. 2015 (July); 68-74.

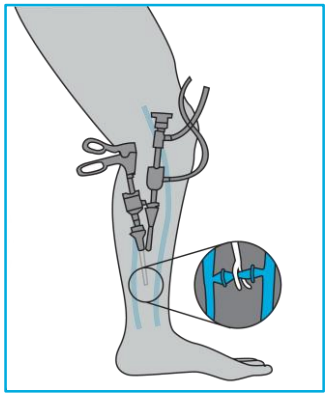
Evolution of Perforator Vein Treatment

Procedures



Linton initially described open surgical perforator ligation technique[1]

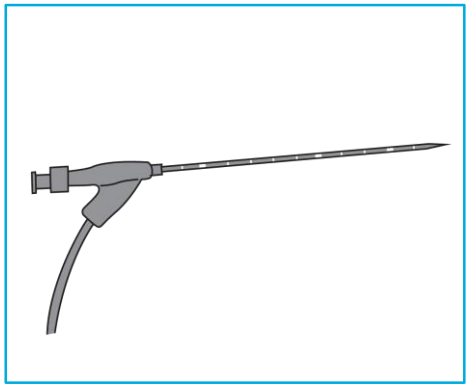
"The open surgical technique remained the gold standard of managing perforator vein incompetence for almost half a century despite the associated morbidities including ulcer recurrence, wound breakdown and neuropathy"[2]



"Subfascial endoscopic perforator surgery (SEPS) displaced the open surgical perforator ligation due to significant reduction in operative morbidity and shorter hospital stay"[1]

A systematic review of 20 studies (1 RCT and 19 case series) treated 1140 limbs indicated that SEPS *with or without saphenous ablation* led to an 88% chance for ulcer healing and 13% changes for recurrence at short term[3]

The same study also showed the associated adverse effects of SEPS included wound infection (6%), hematoma formation (9%), neuralgia (7%), and deep vein thrombosis (1%)[4]



"The adverse effects along with the need for formal anesthesia to perform SEPS prompted the search for a less invasive treatment modality for perforator venous insufficiency"[2]

1. Linton RR. The communicating veins of the lower leg and the operative technique for their ligation. 1938 Apr;107(4):582-93. doi: 10.1097/00000658-193804000-00013.
2. Gunawardena T, Gunawansa N (2019) Incompetent Perforator Veins; To treat or not to treat. Int J Vasc Surg Med 5(1): 1-4. DOI: http://doi.org/10.17352/2455-5452.000032
3. Tenbrook JA Jr, Iafrati MD, O'donnell TF Jr, Wolf MP, Hoffman SN, Pauker SG, Lau J, Wong JB. Systematic review of outcomes after surgical management of venous disease incorporating subfascial endoscopic perforator surgery. J Vasc Surg. 2004;39(3):583-9. doi: 10.1016/j.jvs.2003.09.017

Perforator Vein Diagnosis

Perforator Scanning Lower Extremity

- Position patient upright with weight on opposing leg. Identify the transverse scanning plane for the initial set of circumferential sweeps[1]
- Image the perforator, superficial and deep vein connections[1]
- The incompetent perforator should include a wall-to-wall diameter measurement image crossing the deep muscle fascia[1]

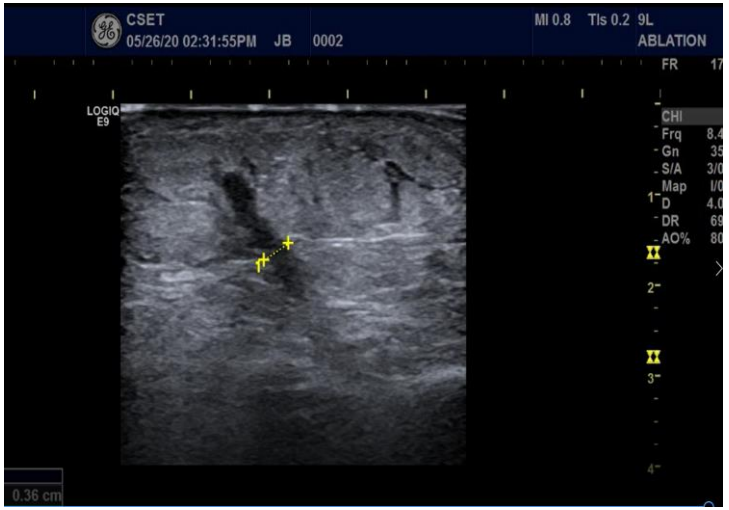
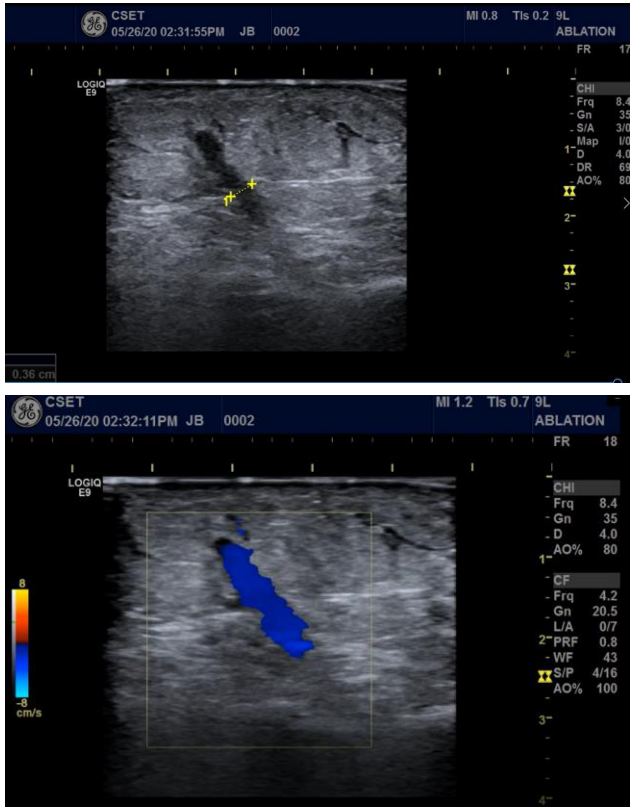


Image courtesy Dr. Jeffrey Carr

"A complete history and detailed physical examination are complemented by duplex scanning of deep and superficial veins"[2]

1. Garrison, K. Duplex evaluation of incompetent perforator veins. Journal Diagnostic Medical Sonography 2008:24(5);303–310.
2. Gloviczki P, Comerota AJ, Dalsing MC, 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;53(5 Suppl):2S-48S. doi: 10.1016/j

Perforator Measuring Fascial Break



Images courtesy Dr. Jeffrey Carr

- For perforator demonstrating outward flow, obtain a diameter measurement from **wall to wall** at the level of the **deep fascia**.[1]
- Once perforator vein has been identified, obtain open image of the perforator as it is seen crossing the deep fascia.[1]
- "Utilize Color Doppler to obtain measurements and document."[1]

1. Garrison, K. Duplex evaluation of incompetent perforator veins. Journal Diagnostic Medical Sonography 2008:24(5);303–310.

Perforator
Proper Leg Markings

Images courtesy DJ Brainard

- Once an incompetent perforator vein (IPV) has been confirmed, mark the IPV to facilitate future reassessment.[1]
- Scan and obtain a B-mode image of the IPV crossing the muscular fascia."[1]
- Mark using the center of the transducer, and select an anatomical reference location (e.g., heel or medial malleolus) to indicate the first axis to aid in locating the perforator in the furture.[1]
- A second anatomical reference location that may be used is the anterior border of the tibia.[1]

1. Garrison, K. Duplex evaluation of incompetent perforator veins. Journal Diagnostic Medical Sonography 2008:24(5);303–310.

Venclose Maven™ Perforator Catheter

Indication for Use and Contraindications

Indication for Use in the United States

- The Venclose Maven™ Perforator Radiofrequency (RF) Ablation Catheter is intended for endovascular coagulation of blood vessels in patients with perforator and tributary vein reflux

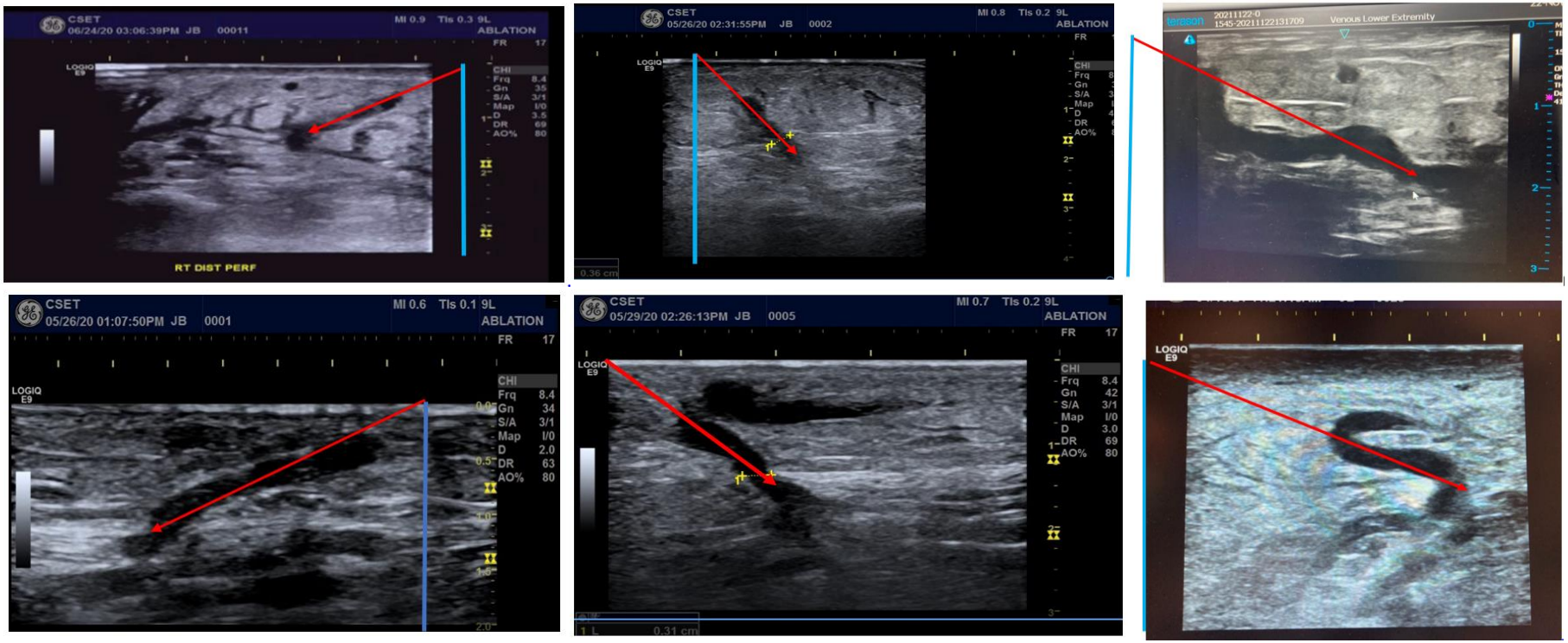
Contraindications

- Thrombus in the vein segment to be treated

Design

- 6F, handle, cable
  - Flexible shaft, slide marker
  - Up to 0.025” guidewire
- 0.5 cm coil length
- 40 cm catheter shaft
- 130^{o} C treatment temperature
- 20 seconds treatment cycle
- Generator with upgraded software

Access Angle Options



Images courtesy Dr. Jeffrey Carr

Positioning the Venclose Maven™ Perforator Catheter

Pre-map treatment zones (for # of treatment zones)

0.35 cm – inactive tip of catheter

0.5 cm – active treatment element 0.5 cm treatment zone

Ensure that the proximal end of the heating element is at least 0.5cm 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.

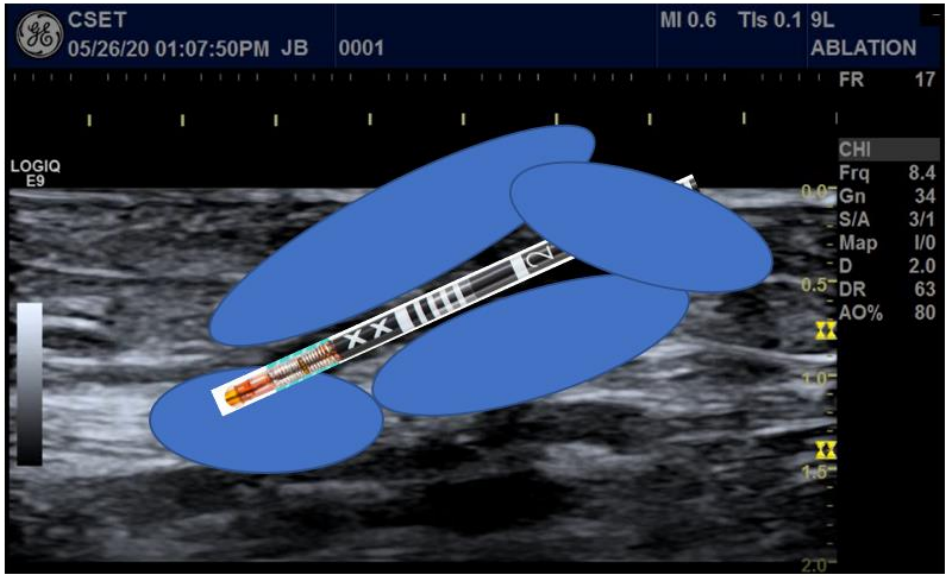


Image courtesy Dr. Jeffrey Carr

Directions For Use
Access

Catheter Inspection and Preparation

- Prepare the catheter lumen by flushing with sterile Normal Saline and then cap the lumen at the handle. Wipe the surface of the shaft with saline and a sterile wipe.
- If using a guidewire, refer to the manufacturer's instructions for use. Following removal of the wire, re-flush catheter lumen with sterile Normal Saline and cap the lumen at the end of the catheter.

CAUTION

Do not deliver fluid through the catheter lumen during treatment, as it will interfere with the treatment and deliver hot fluid from the catheter tip.

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.

Directions For Use
Access

Catheter Inspection and Preparation

- Insert the catheter through the introducer sheath or the 12-gauge IV catheter and advance the catheter tip to the desired treatment start location under direct ultrasound guidance to ensure that the catheter remains within the desired treatment vessel. Catheter navigation may be assisted by direct palpation, limb repositioning and/or use of a guidewire.

CAUTION
Do not advance the catheter against resistance, or vein perforation may occur.

Anatomy to Protect During Treatment

- **Skin:** Fluid anesthesia to keep heating element at least **0.5 cm** from the skin to prevent skin burns and assure that the heating element is at least **0.5 cm** from the access site. If using external compression, do not compress the skin closer than **0.5 cm** to the heating element
- **Bone:** Fluid anesthesia to protect bone when perforators are close to tibia or malleolus
- **Nerves:** Nerve injury may occur from thermal damage to adjacent sensory nerves. Risk of nerve injury may be higher with treatment near the calf, or without perivenous fluid infiltration
- **Arteries:** Identify accompanying arteries that may be affected by proximity to perforators
- **Deep Veins:** Keep the distal tip greater than **0.5 cm** from the deep system to avoid damage and deep vein thrombosis (DVT)

Directions For Use
Local Anesthesia Administration

Catheter Inspection and Preparation

Using ultrasound guidance, along and beyond both ends of the entire length of vein to be treated, inject local anesthetic adjacent to the vein wall to create a layer of anesthetic fluid around the vessel.

Ensure that there is at least **0.5 cm** between the vein wall and the skin. If the distance is less than **0.5 cm**, inject additional fluid between the vein and skin to achieve the acceptable distance of **0.5 cm or greater**.

Ensure that the distal tip of the catheter is at least **0.5 cm** from the deep venous system and that the proximal end of the catheter heating element is at least a **0.5 cm** distance from the skin. Consult manufacturer product labeling for maximum safe dosage.

Directions For Use
Final Catheter Positioning

- Exsanguinate venous blood from the leg, creating direct contact of the vein wall with the heating element (e.g., raising the leg above the level of the heart in Trendelenburg position or applying external compression over the treatment area).

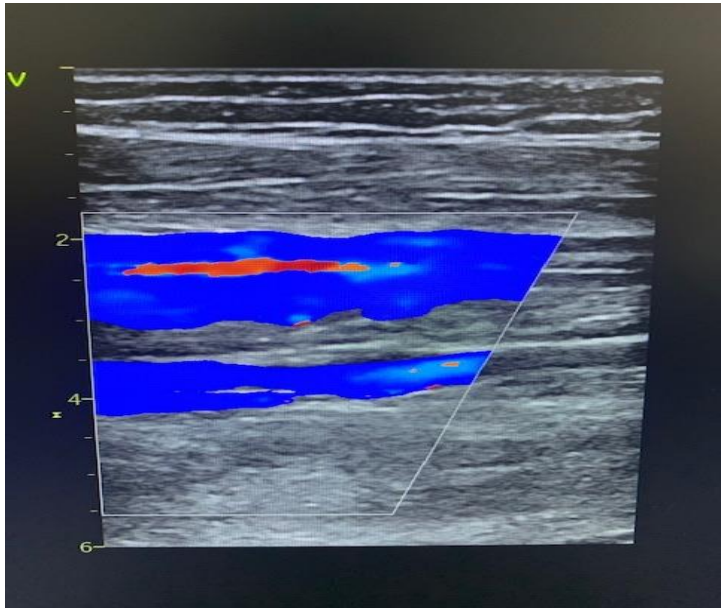
CAUTION
Uneven blood pooling or flow along the heating element may result in inconsistent effectiveness and/or may damage the catheter.

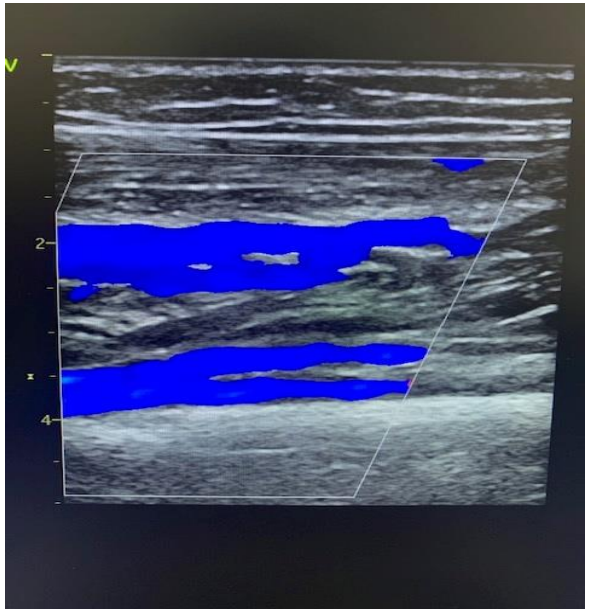
- Before starting energy treatments with the catheter, verify that the catheter and heating element are in the desired position within the desired vein.

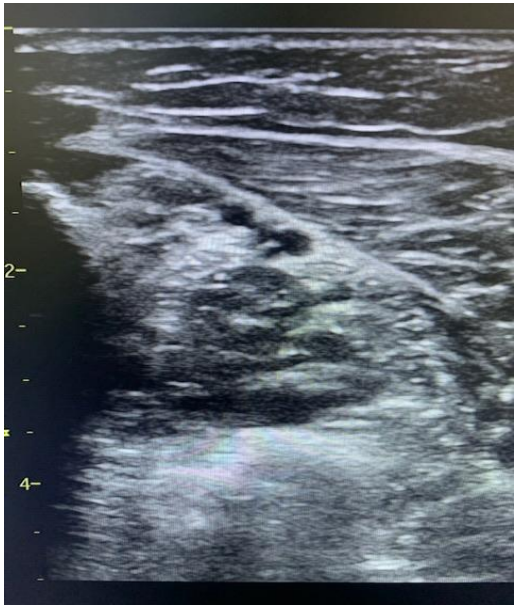
WARNING
Do not treat the deep venous system. Verify that the heating element is not within the deep venous system. Ensure that the distal tip of the device is greater than 0.5 cm from the deep venous system.

Venclose Maven™ Instructions for Use. LB-0045.D

Understand and Protect Deep Veins: Anterior Medial Leg



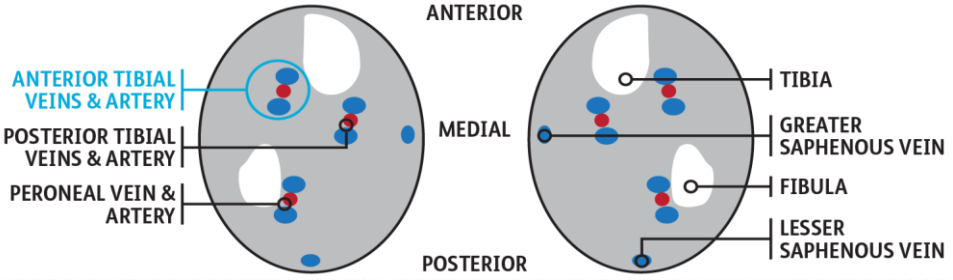




Images courtesy Dr. Jeffrey Carr

Posterior Lower Extremity

Anterior Tibial Veins & Artery Lateral of Tibia



Directions For Use
Thermal Treatment

Begin an RF treatment by pressing the button on the catheter handle or by stepping on the optional generator foot pedal. **Treatment will stop automatically after 20 seconds of heating.**

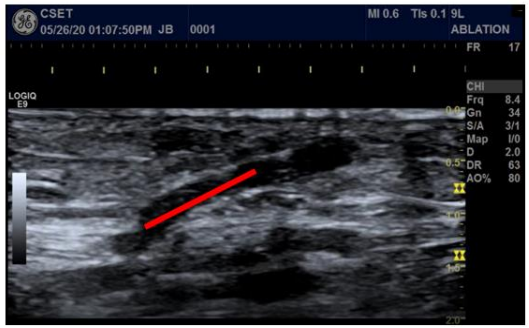
In the event of patient pain or other emergency, the **treatment cycle may be stopped** before the 20 seconds have elapsed by pressing the button on the catheter handle, by stepping on the optional generator foot pedal, or by pressing the main power button on the digiRF Generator. If none of these measures stops the RF energy delivery, disconnect the main power cable from the generator.

If the set temperature is not reached or maintained during the treatment there may be blood flow within the vein that is cooling the catheter; if so, stop the treatment (see above), verify proper catheter tip position (it should not be in the deep venous system) and effectiveness of exsanguination methods, correct as necessary, and re-start treatment of the vein section.

Directions For Use
Thermal Treatment

CAUTION
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.

Evaluate the treated vessel using duplex ultrasound to determine the existence of residual flow. **Repeat treatment if necessary** to further shrink the vessel or occlude flow.



CAUTION
Do not re-advance the catheter and re-treat an acutely treated vein section or it may increase risk of embolism.

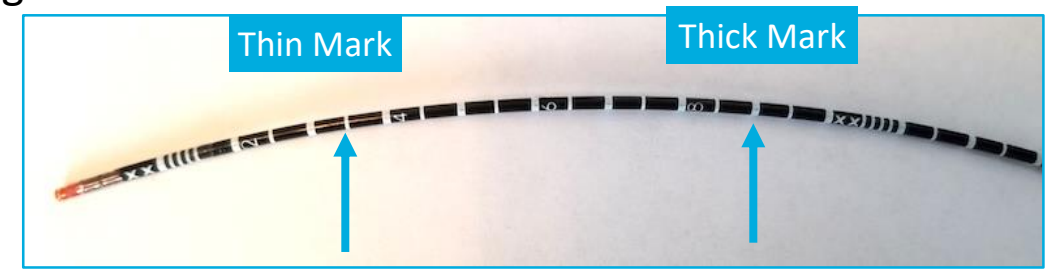
Directions For Use
Thermal Treatment

If multiple segments are to be treated, using a line on the skin or other reference with respect to the shaft markings, pull the catheter a distance equal to the active heating element length so that the active heating element length is adjacent to the previous treatment location.

If desired, withdraw the sheath from the skin so that the catheter shaft markings can be seen near the point of catheter entry into the skin.

Note that the catheter has **thick lines** to indicate distances at **1 cm** intervals from the heating element and **thin lines** to indicate distances at **0.5 cm** intervals from the heating element.

Numbers printed on the catheter shaft represent the distance from the distal end of the heating element.



Directions For Use
Thermal Treatment

The more proximal set of markings is intended to be used with access sheaths 7 cm in length; when the proximal “X X” markings can be seen, the heating element is partially within the sheath and energy delivery cycles should not be administered. The more distal set of markings is intended to be used when the sheath has been withdrawn from the vein access point; when the distal “X X” markings can be seen, the heating element is nearer than 0.5cm from the vein access point and energy delivery cycles should not be administered.

Repeat previously discussed steps until the intended total length of vein treatment is complete.

Proximal “XX”

Distal “XX”

Directions For Use
Thermal Treatment

CAUTION
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.

Once the recommended treatment is complete, remove catheter and introducer sheath from vein.

Obtain hemostasis at the access site.

Apply external compression (wrap, stockings or other) as prescribed by physician.

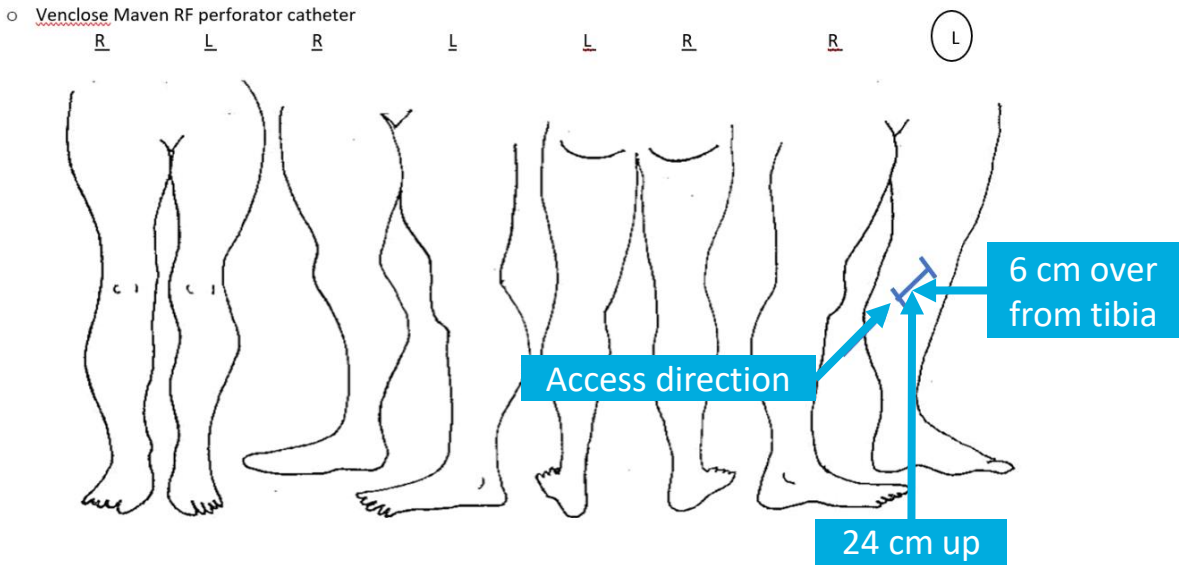
Follow-up Care

- Post-operative compression as prescribed by physician
- For DVT prophylaxis instruct patient to ambulate frequently for several days after treatment
- It is recommended that the patient refrain from strenuous activities such as heavy lifting for several days

Operative Report for Perforators

Preoperative markings (cm over from tibia and cm up from floor or bottom of the foot) **Intraoperative Parameters**

	(Circle)	(over from tibia)	(up from floor)	(Pre-op diameter)	(# Zones treated)	(# tx/zone)	(cm pullback)	(Total time)
Perforator #1	R/L	-> _____cm	↑_____cm	_____cm	____ zones treated	_,_,_,_,_ #tx	_____cm	tx time _____
Perforator #2	R/L	-> _____cm	↑_____cm	_____cm	____ zones treated	_,_,_,_,_ #tx	_____cm	tx time _____
Perforator #3	R/L	-> _____cm	↑_____cm	_____cm	____ zones treated	_,_,_,_,_ #tx	_____cm	tx time _____



Measurement is Crucial

Document appropriately for follow-up ultrasound to assure that a perforator treated is closed and a twin perforator is not the new culprit

Predictors of Failure

Factors that Influence Perforator Vein Closure Rates using Radiofrequency Ablation, Laser Ablation, or Foam Sclerotherapy

- Retrospective review of data base containing perforator vein treatment from 3 centers within a single institution, February 2013 to July 2014
- 296 perforator ablations (on 112 subjects)

Factors predictive of failure in all treatment modalities included:

- Body Mass Index (BMI) >50 (P=0.05)
- Pulsatility in the treated vein (P=0.05)

Factors that *did not* affect closure rates

- Anticoagulation
- Presence of deep vein reflux
- Perforator size
- BMI <50

Hager ES, Washington C, Steinmetz A, et al. Factors that influence perforator vein closure rates using radiofrequency ablation, laser ablation, or foam sclerotherapy. J Vasc Surg Venous Lymphat Disord. 2016;4(1):51-6. doi: 10.1016/j.jvsv.2015.08.004

Clinical Practice Points for Treating Perforators

- Clear and thorough understanding of the venous anatomy
- Understanding patterns of reflux in the lower extremities
- Having the right equipment
- Good ultrasound imaging is paramount to success
- Using the proper longitudinal technique
- Providing after care and not ignoring complications
- Understanding the guidelines of the Instructions for Use (IFU)
- Managing expectations at the first visit

Venclose Maven™ 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.

Venclose Maven™ Instructions for Use. LB-0045.D

Venclose Maven™ Catheter

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 MavenTM 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.

Venclose Maven™ Catheter

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.

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions.

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