Product Overview

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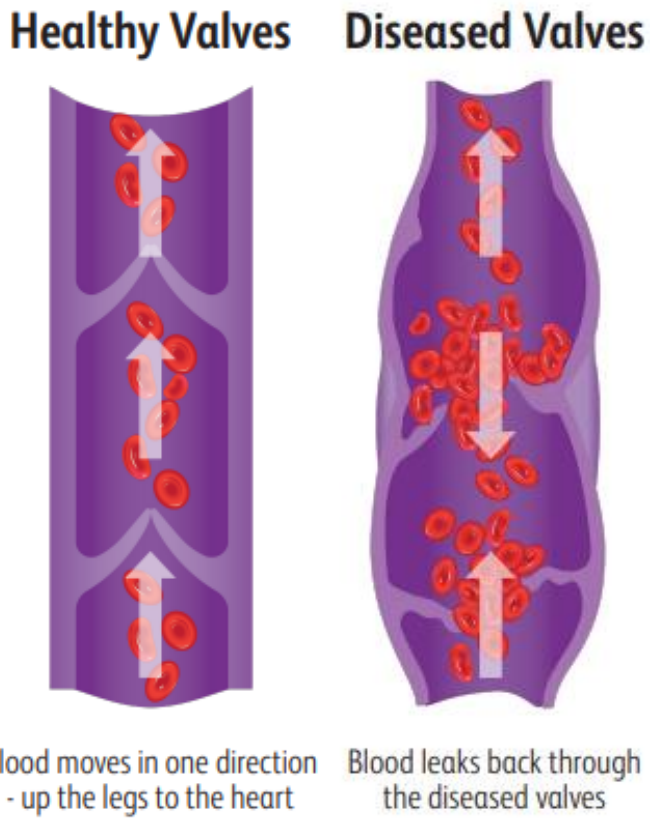
Chronic Venous Disease

Chronic Venous Disease

Statistics

- An estimated **175 Million** U.S. Americans are affected[1]
- Risk of CVD **increases with age**, but can begin as early as childhood[2]
- The annual cost of venous disease calculates to **$30-$90 Billion** in the U.S.[1]
- Visible venous disease is **far more** than a cosmetic problem[1,3]

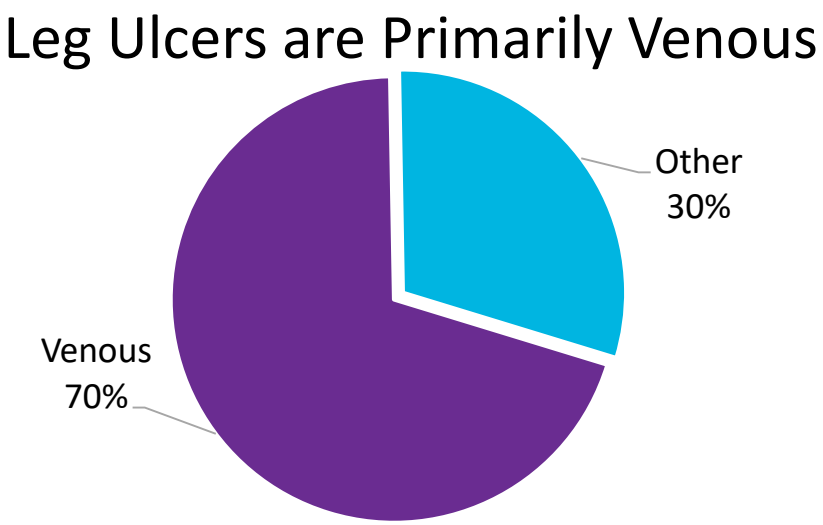


Left untreated, chronic venous disease can progress, causing venous ulcers for patients.

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

Disease Prevalence

- **70-90%** of all lower extremity ulcers are estimated to be venous[1,2]
- The prevalence of venous ulcers is **4.8 Million** in the U.S. and estimated cost is **$38 Billion** per year[3]
- At **2.0 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 and diabetic foot ulcers at **1.0 Million** new cases[3]
- Venous leg ulcers are estimated to recur in **60%-70%** of patients[4]



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

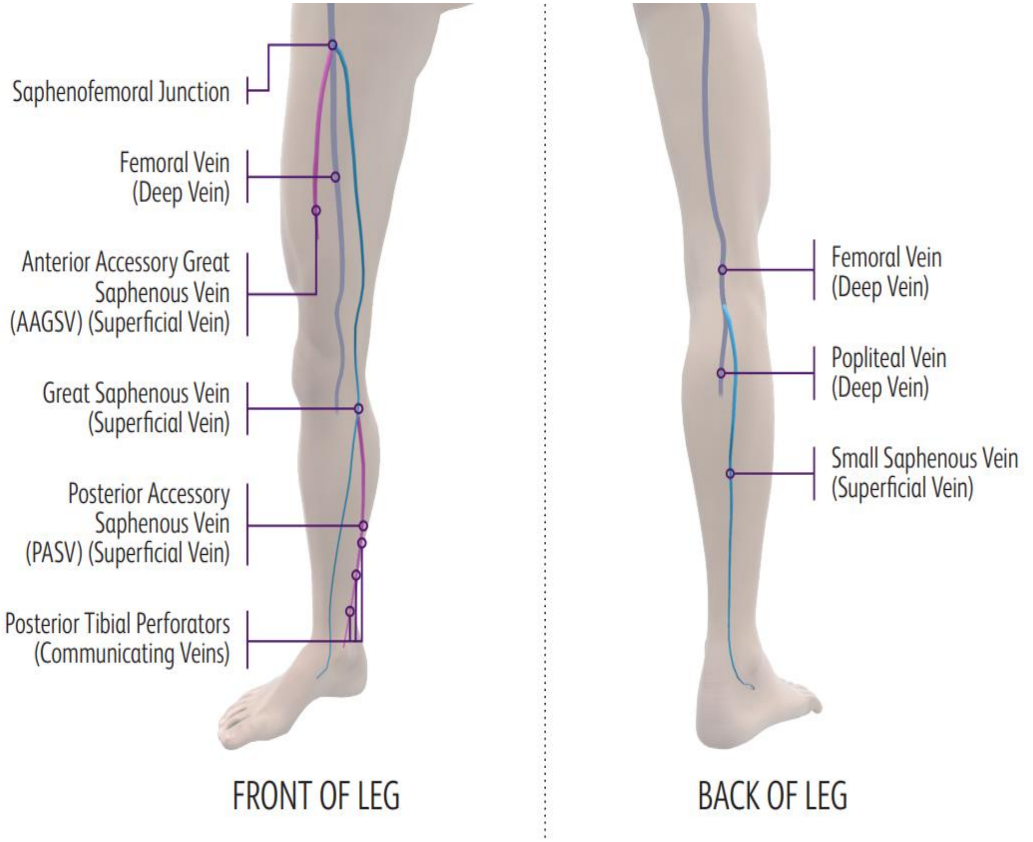
Venous Anatomy

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

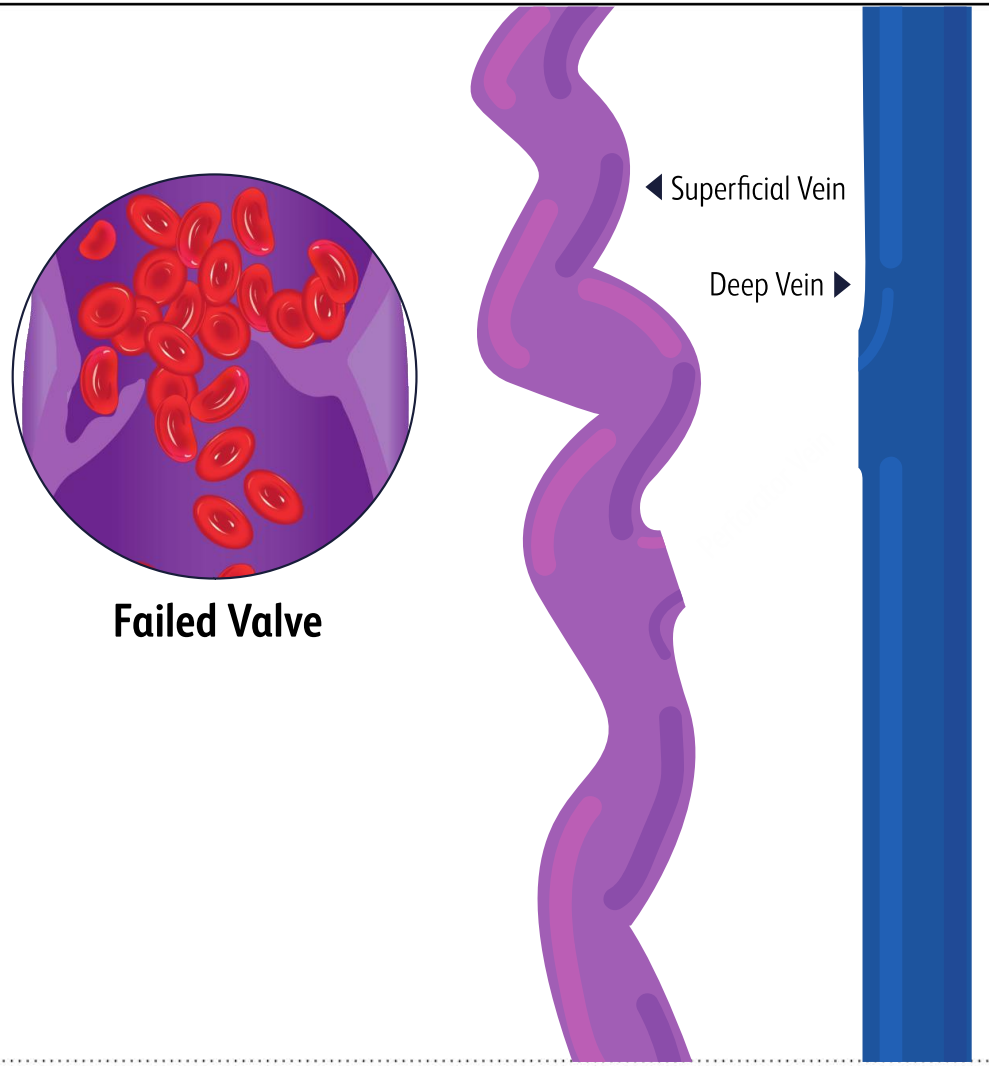
- Begins posterior to the lateral malleolus
- Travels up calf between two heads of gastrocnemius muscle
- May have thigh extension
- Usually drains into the Sapheno-popliteal Junction



Perforator Veins

- 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”

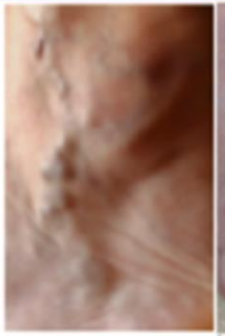
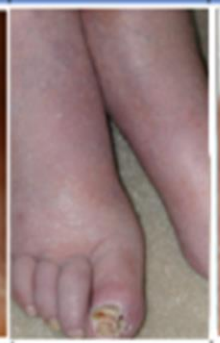
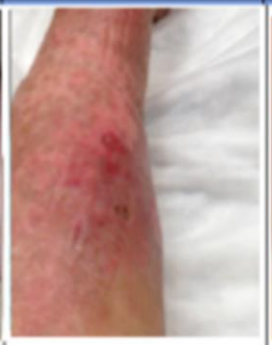
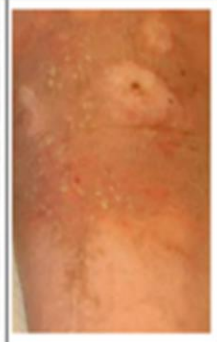
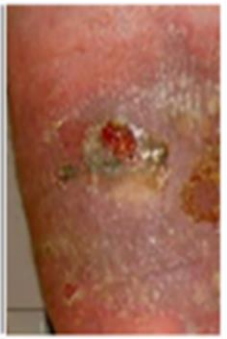
- These guidelines recommend ablation of pathologic perforator veins when located beneath or associated with potential ulcer beds in lipodermatosclerosis (C4b), healed ulcers (C5), or active ulcers (C6)



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.

CEAP Scale

Classification of CVD: CEAP Class 0-6

CEAP Class	0	1	2	3	4	5	6
Description	No visual or palpable signs of CVD	Telangiectasia or reticular veins	Varicose Veins	Edema	Pigmentation: Skin changes assigned to venous disease	Skin changes with healed ulceration	Skin changes with active ulceration
Visual							

Wittens C, Davies AH, Baekgaard N, et al. Clinical Practice Guidelines from the ESVS, *Eur J Vasc Endovasc Surg* 2015;49:678-737

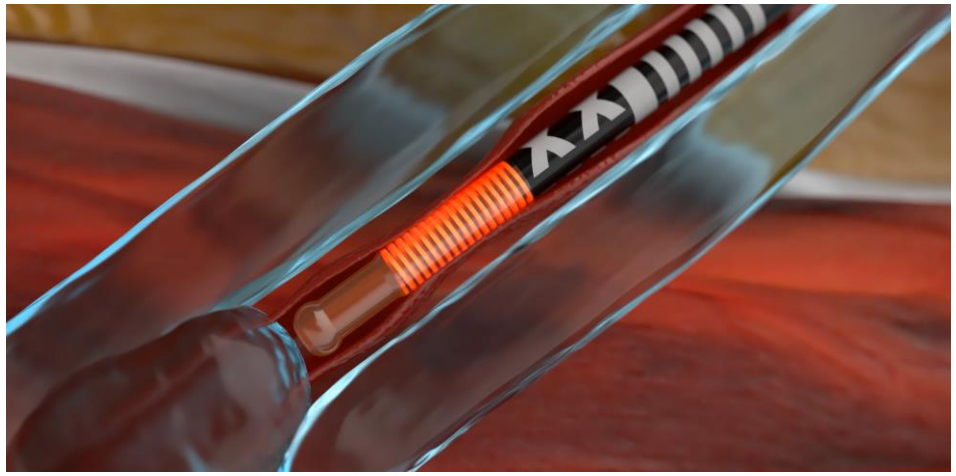
Presence of an active or healed ulcer is a potential indicator of incompetent perforator veins*

* 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.

Technology Overview

What is Radiofrequency (RF) Ablation?

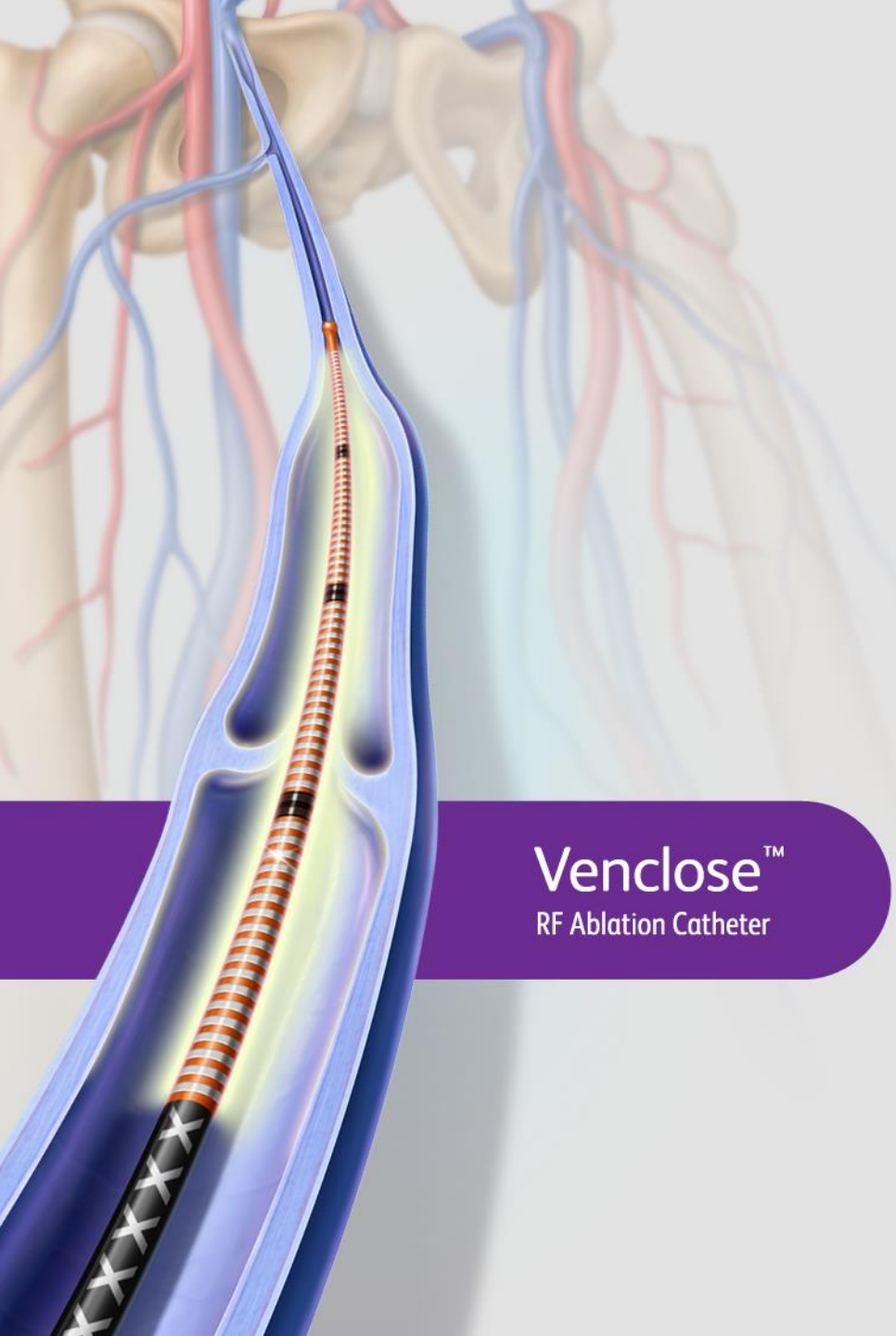
- RF ablation is a minimally invasive endovenous thermal procedure for treating venous reflux
- A refluxing vein is thermally coagulated, by delivering heat to the vein, permanently eliminating the vein from blood circulation, which causes a fibrotic occlusion of the vein wall
- Because this procedure closes the vein, the blood will then re-route itself to other healthy veins



Mechanism of Action (MOA)

How it works:

- The heating element is energized by the Venclose™ RF Generator, which is a multi-voltage energy delivery system with touchscreen control that automatically sets the non-adjustable treatment parameters for the Venclose™ System Catheters
- A button on the catheter (or a foot pedal attached to the generator) begins an automated treatment cycle 20 seconds long at a set temperature of 120°C (Venclose™ RF Ablation Catheter) or 130°C (Venclose Maven™ Perforator Catheter). The treatment stops automatically when complete


Venclose™
RF Ablation Catheter

Venclose™ RF Ablation Catheter

The **ONLY** RF device with dual heating lengths to treat long and short refluxing vein segments with **one catheter***

Indications For Use

- The Venclose™ RF Ablation Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux

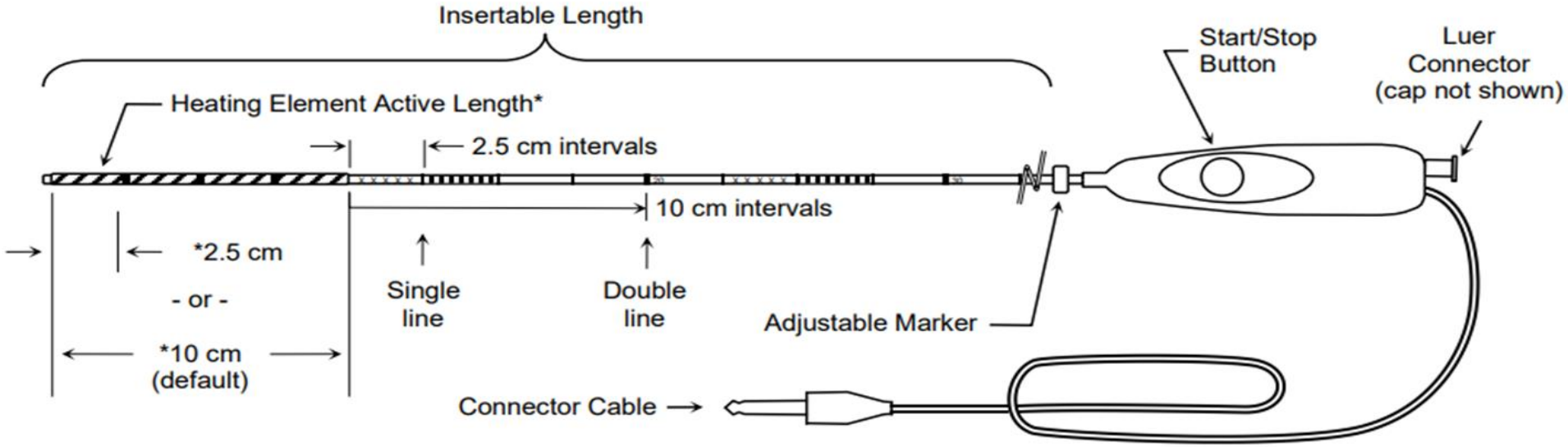
Contraindications

- The Venclose™ RF Ablation Catheter is contraindicated in patients with thrombus in the vein segment to be treated

* As of November 2022

Catheter Specifications & Overview

Catheter Model:	VC-10A2.5-6F-60	VC-10A2.5-6F-100
Heating Element Active Length	Adjustable, 10 cm or 2.5 cm	Adjustable, 10 cm or 2.5 cm
Heating Element Diameter (max. catheter outer diameter)	6F (2.0 mm)	6F (2.0 mm)
Insertable Length (cm)	60 cm	100 cm



Catheter Design Features

6F Profile Design

- Offers flexibility to navigate tortuous anatomy
- Helps to minimize invasiveness

10 cm Heating Length

- Ablate more vein during each heating cycle*
- Lower the total number of ablations*

Dual Heating Lengths

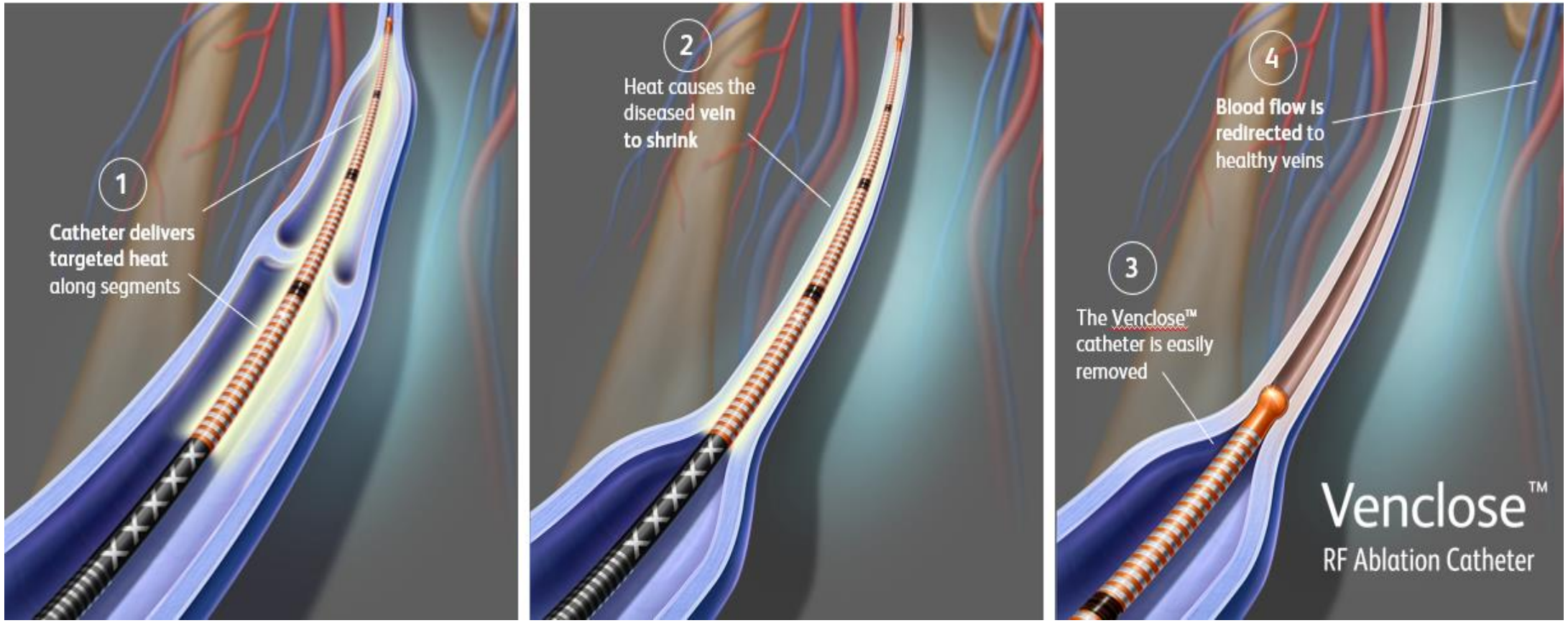
- Eliminate need for more than one catheter
- Reduce practice inventory burden
- Treat long and short segments with the same catheter

Markings and Curved-Tip

- Provides maneuverability within the vein
- Helps to ease navigation and positioning

*Compared to ClosureFast™

Radiofrequency Energy Delivered by the Venclose™ RF Ablation Catheter



Venclose™ RF Ablation Generator

Simplified Setup and Operation

- Touchscreen display providing real-time procedure data to help inform physician treatment decisions
- Simple catheter connection port allows quick and easy catheter plug-in
- Nearly instant power-up
- Compact design
- Audible tones for thermal delivery allows physicians to focus more on the patient, and less on the display

Venclose™ RF Generator
Provides real-time procedure data, providing actionable feedback to the clinician throughout the procedure

Venclose™ RF Ablation Generator

Home Screen

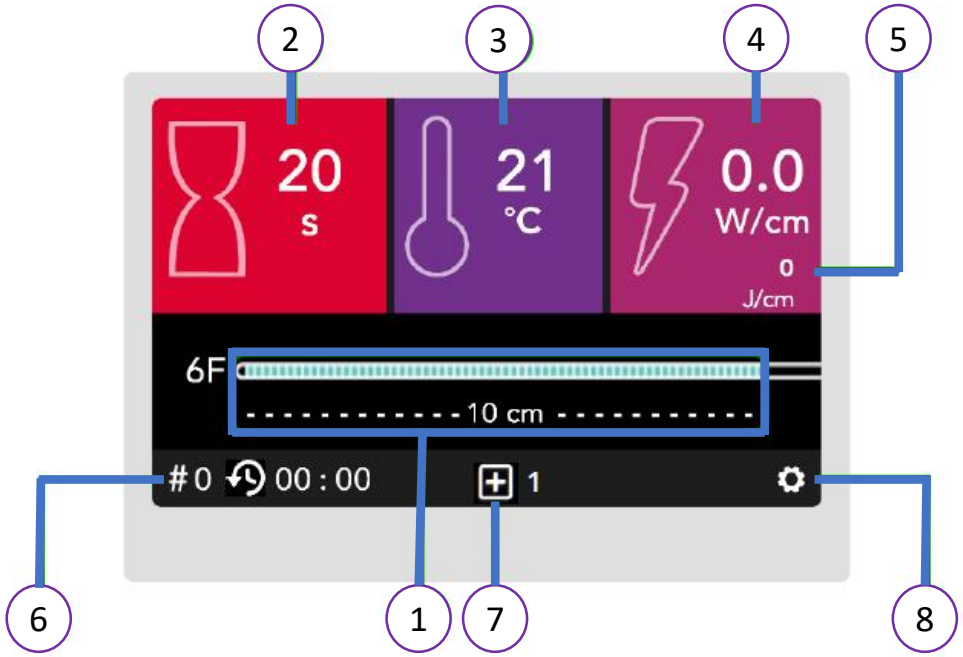
- When the generator is powered up and the Power-On Self-Test (POST) sequence is complete, the Home Screen appears:

1	Power	Press this button to turn on power to the Venclose™ RF Ablation Catheter
2	Port	Plug Venclose RF Catheters into this input port; this is <u>not</u> an audio output jack
3	Settings	**Touch** this icon to go to Settings Screen
4	History	**Touch** this icon to go to History Screen
5	Revision	This field identifies the current revision of the Venclose™ RF Ablation Generator

Venclose™ RF Ablation Generator

Ready Screen

- Upon plugging in an RF catheter, the following treatment Ready Screen will appear:



1 DEVICE

2 TIME

3 TEMPERATURE

4 POWER

5 TOTAL ENERGY

6 COUNTER

7 VESSEL HISTORY

8 SETTINGS

Venclose™ Catheter Key Procedural Steps

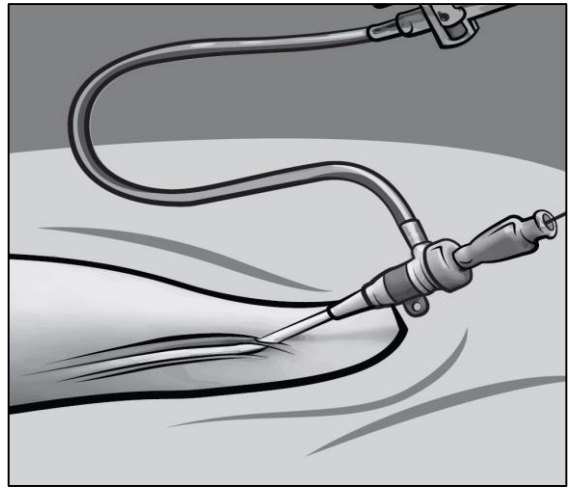
1. Tip: Position the patient for vein access. Lowering the patient's legs below the level of the heart will increase vein diameter, which may facilitate vein access.

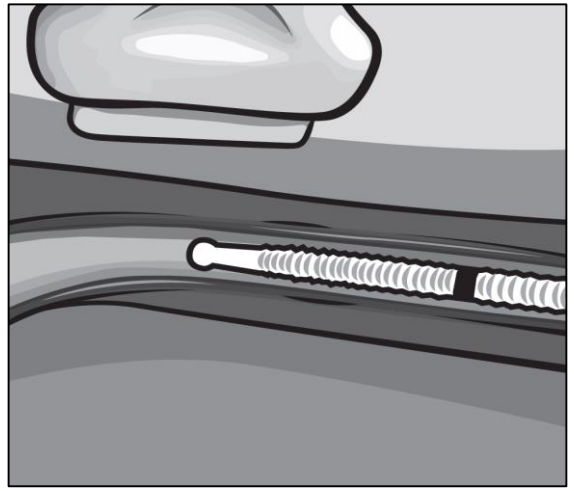
2. Tip: Gain vessel access with a compatible introducer sheath per the sheath manufacturer's instructions. Use an aseptic technique.

3. Prepare the catheter lumen by flushing with sterile physiologic saline and then cap the lumen at the handle. Wipe the surface of the shaft with saline and a sterile wipe.

4. Insert catheter through the introducer sheath and advance the catheter tip to the desired treatment area at least 2 cm away from the junction with the deep venous system. Use direct ultrasound guidance to ensure the catheter remains in desired treatment location.

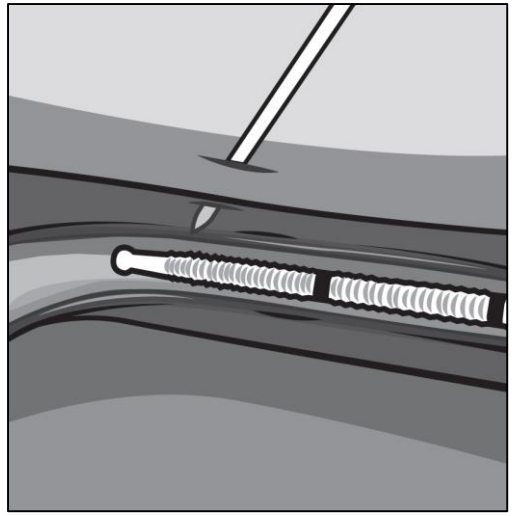
CAUTION: Do not deliver fluid through the catheter lumen during treatment or treat while the guidewire is within the catheter lumen at the heating element.





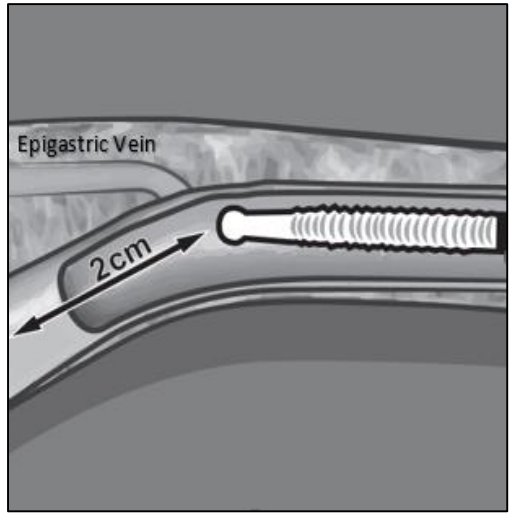
Venclose™ Catheter Key Procedural Steps

5. 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 and to achieve contact between the catheter heating element and the vein wall. Ensure there is a 1 cm distance between the vein wall and the skin.



6. Maximally empty the treatment vein of blood, creating direct contact of the vein wall with the heating element, such as by raising the patient's legs above the level of the heart in Trendelenburg position.

Caution: Do not begin treatment without verifying that the length of the heating element that will actively heat remains inserted at least 2.5 cm from the vein access point.



7. Before starting energy treatments with the catheter, verify that the catheter and heating element are in the desired position within the desired vein. For Great Saphenous Vein (GSV) treatment, a tip position at least 2 cm distal to the SFJ is recommended. Verify the desired position under ultrasound guidance with both transverse and longitudinal views.

WARNING: Do not treat the deep venous system. Verify that the heating element is not within the deep venous system.

These key procedural steps are not intended as a replacement for the full product directions for use. Please consult the Venclose™ RF Ablation Catheter's IFU for complete product description, instructions for use as well as all safety related information, including warnings, precautions and contraindications

Venclose™ Catheter Key Procedural Steps

8. Press the image of the heating element on the generator touchscreen to toggle between the two lengths, 10 cm and 2.5 cm. Verify that the screen shows the desired heating length.

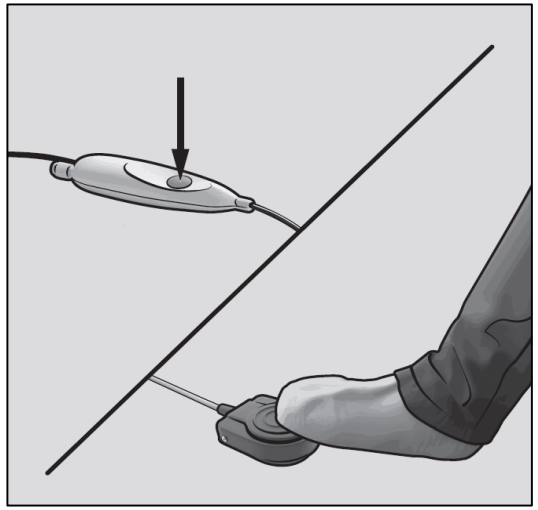
CAUTION: Do not begin treatment without verifying that the length of heating element that will actively heat remains inserted a length of at least 2.5 cm from the vein access point.

9. Begin an RF treatment by pressing the button on the catheter handle or by stepping on the foot pedal. Treatment will stop automatically after 20 seconds.

10. 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 generator.

11. 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 low temperatures are observed, or if the generator displays an indication of fluid around the heating element, repeat exsanguination methods to maximally empty the vein. Direct external compression may be employed, provided the compression is evenly applied along the entire active length of the heating element.

CAUTION: If using direct external compression, do not compress the skin closer than 1 cm to the heating element or a skin burn may occur.



Venclose™ Catheter Key Procedural Steps

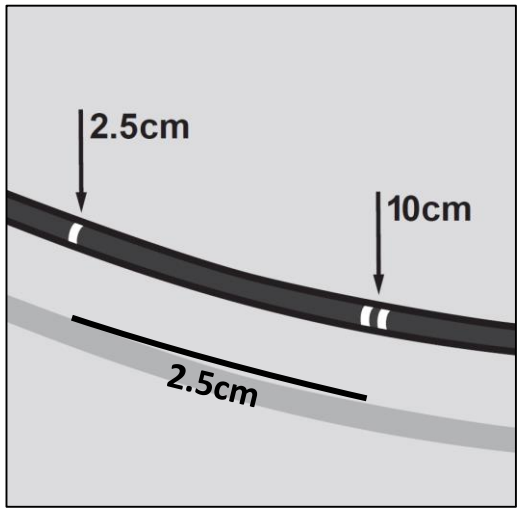
12. A recommended protocol for vein treatment is to administer a number of treatment cycles to each section of vein based on the maximum diameter of that vein section according to the following table, although the user may administer up to three treatments per vein section as desired.

CAUTION: Do not administer more than three energy delivery cycles within any vein section.
CAUTION: Do not re-advance the catheter and re-treat an acutely treated vein section or it may increase risk of embolism.

Recommended vein section treatment protocol:

Vein Section Diameter	*Section nearest SFJ or reflux source*	*Remaining sections*
Less than 10 mm	2 treatments	1 treatment
10 mm - 17.9 mm	3 treatments	2 treatments
18 mm and larger	3 treatments	3 treatments

13. 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 double lines to indicate distances at 10 cm intervals from the heating element and single lines to indicate distances at 2.5 cm intervals from the heating element. Numbers printed on the catheter shaft represent the distance from the distal end of the heating element.

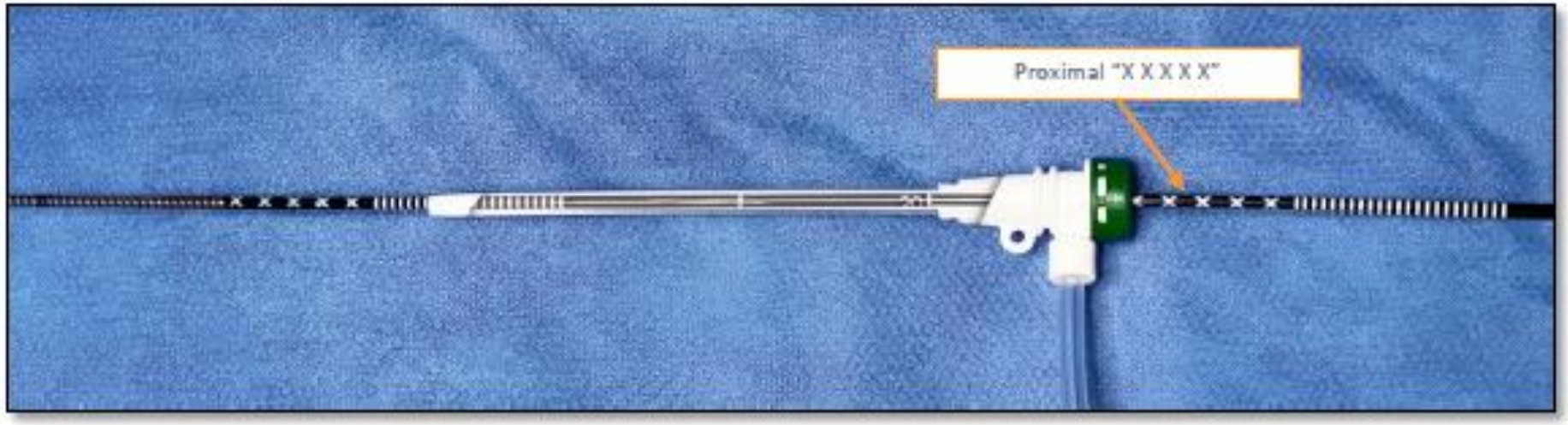
Venclose™ Catheter Key Procedural Steps

14. Note that there are two sets of patterned markings on the shaft.

CAUTION: 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.

Tip: When treating with 7 cm introducer sheath:

- The proximal “X X X X X” markings can be seen, and additional cycles are required, remove sheath while maintaining catheter position.



Venclose™ Catheter Key Procedural Steps

Tip: When treating with 7 cm introducer sheath:

- SHEATH IS REMOVED and treating with 10 cm heating length: When you have reached the last of the distal "||||||||||||||" lines treat with final 10 cm treatment cycle.

Venclose™ Catheter Key Procedural Steps

Tip: When treating with 7 cm introducer sheath:

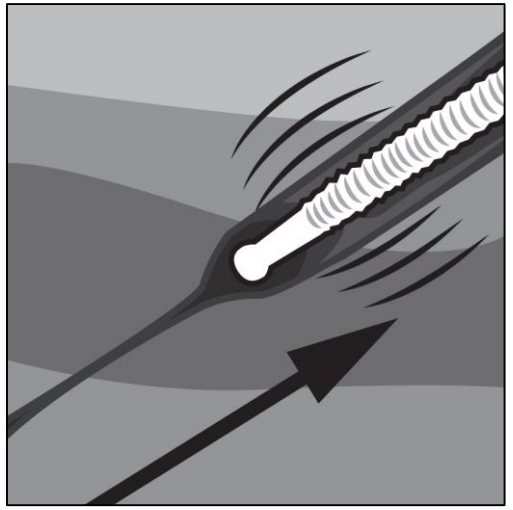
- SHEATH IS REMOVED and treating with 2.5 cm: When you can see the second coil marker band, treat with final 2.5 cm treatment cycle.

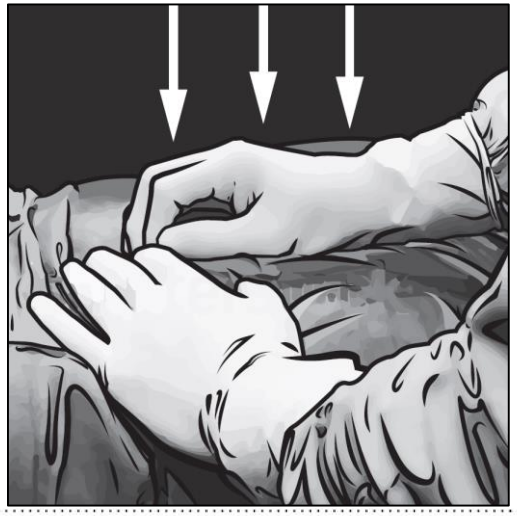
Venclose™ Key Catheter Procedural Steps

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

16. Obtain hemostasis at the access site.

17. Apply external compression if and as prescribed by a physician.



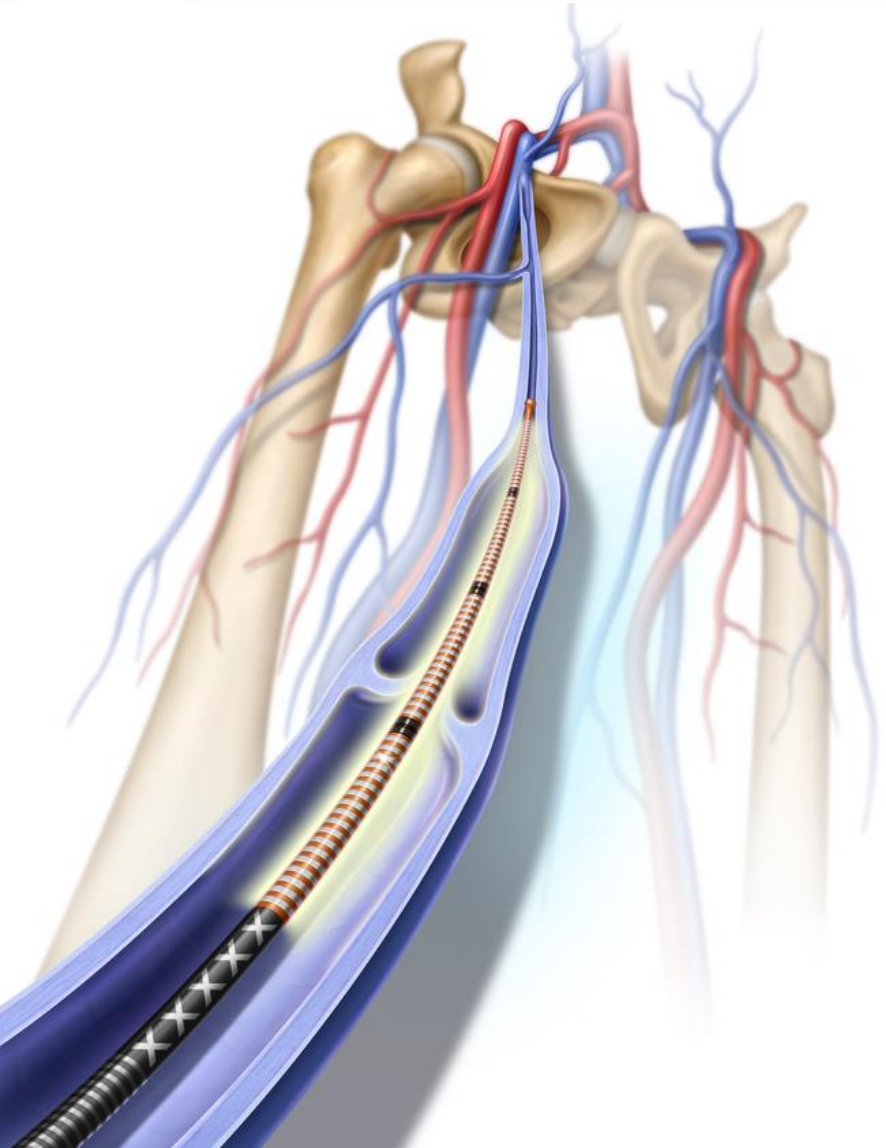


Venclose™ RF Ablation Catheter Tips and Reminders

- Always double check that your desired heating length is displayed on the Venclose™ RF Ablation Generator
- Literature recommends 10-12 cc of tumescent for every 1 cm of catheter*
- Verify heating element is at least 2.5 cm from vein access point prior to last treatment
- Prior to starting Great Saphenous Vein treatment, verify that the catheter tip position is at least 2 cm inferior of the sapheno-femoral junction
- Check for deep vein thrombosis (DVT) before treating/testing superficial veins
- When viewing in the transverse plane, point the ultrasound orientation notch (probe) towards the patient's right side
- If low temperatures are observed, or if the Venclose™ RF Ablation Generator displays an indication of fluid around the heating element, repeat the following exsanguination methods to maximally empty the vein:
  - Ensure that the patient is placed in Trendelenburg position
  - Direct external compression may be employed
  - Apply direct compression evenly along the entire active length of the heating element
- 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
- Recommended follow-up care includes post-operative compression as prescribed by physician; frequent ambulation for several days after treatment; and refraining from strenuous activity for several days

* Nyamekye I. A practical approach to tumescent local anaesthesia in ambulatory endovenous thermal ablation. *Phlebology*. 2019;34(4):238-245.

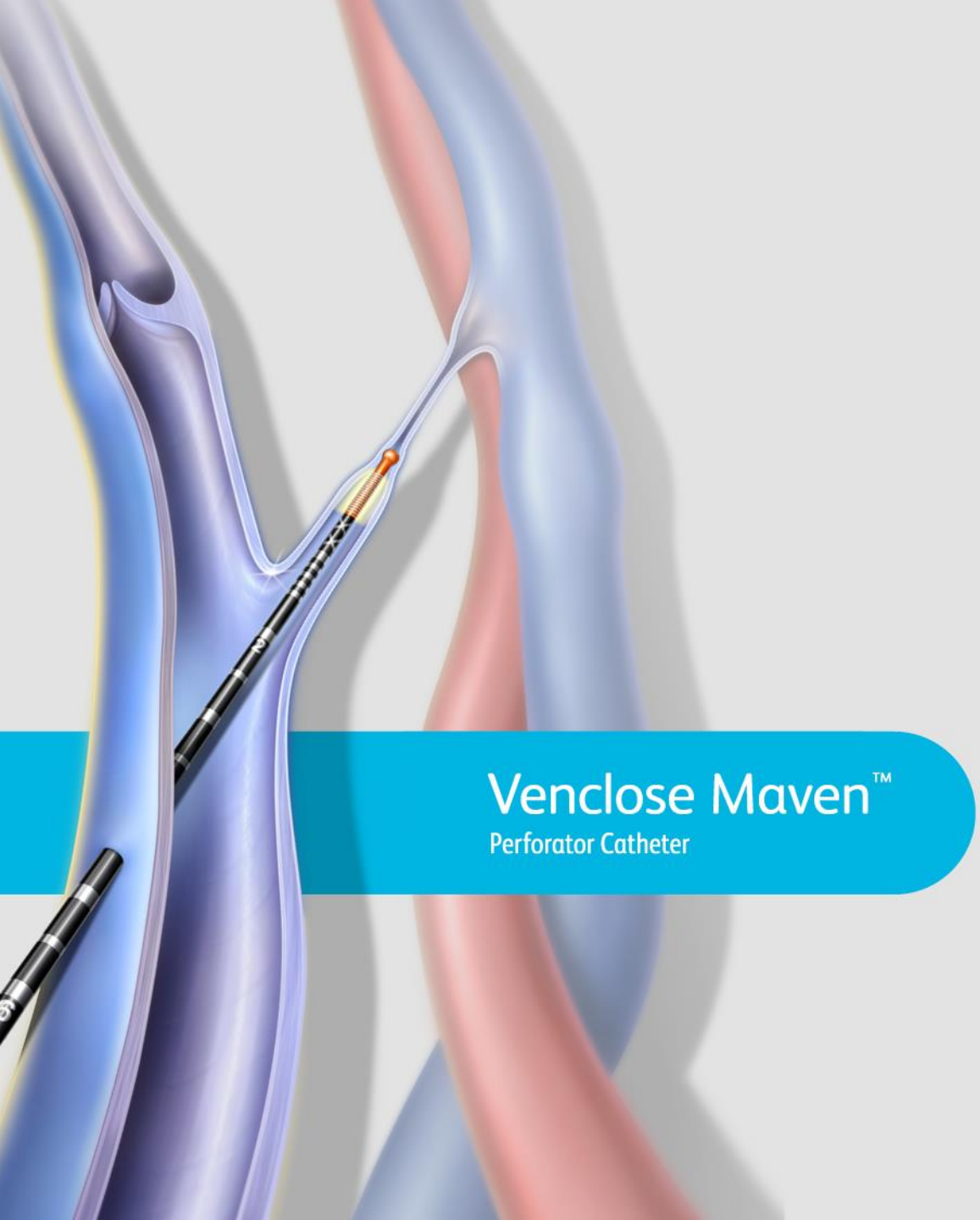
Ordering Information



Description	Product Codes
Venclose™ RF Generator	☐ VC-RFG-1
Venclose™ RF Ablation Catheter (60 cm)	☐ VC-10A25-6F-60
Venclose™ RF Ablation Catheter (100 cm)	☐ VC-10A25-6F-100
Venclose™ Procedure Packs with 7 cm Access Kit	☐ VC-PPH-6F7A
Venclose™ Procedure Packs with 12 cm Access Kit	☐ VC-PP-6F12
Venclose™ 7 cm Micro Introducer Kit	☐ VC-ISH-6F7
Venclose™ 12 cm Micro Introducer Kit	☐ VS-IS-6F12

Venclose™

RF Ablation Catheter



Venclose Maven™

Perforator Catheter

Venclose Maven™ Perforator Catheter

The Only 360º RF Solution for the Treatment of Incompetent Perforator Veins*

Indications for Use

- The Venclose Maven™ Perforator Catheter is intended for use in endovascular coagulation of blood vessels in patients with perforator and tributary vein reflux

Contraindications

- The Venclose Maven™ Perforator Catheter is contraindicated in patients with thrombus in the vein segment to be treated

* As of November 2022

Catheter Design Features

0.5 CM RESISTIVE HEATING COIL

- Provides circumferential resistive heating in one treatment cycle as compared to 4 treatment cycles required for bi-polar electrodes
- 130 °C treatment temperature with 20-second cycles

6F PROFILE

- Small profile helps to minimize invasiveness
- Guidewire compatible with both 0.018“ and 0.025”

40 CM FLEXIBLE CATHETER SHAFT

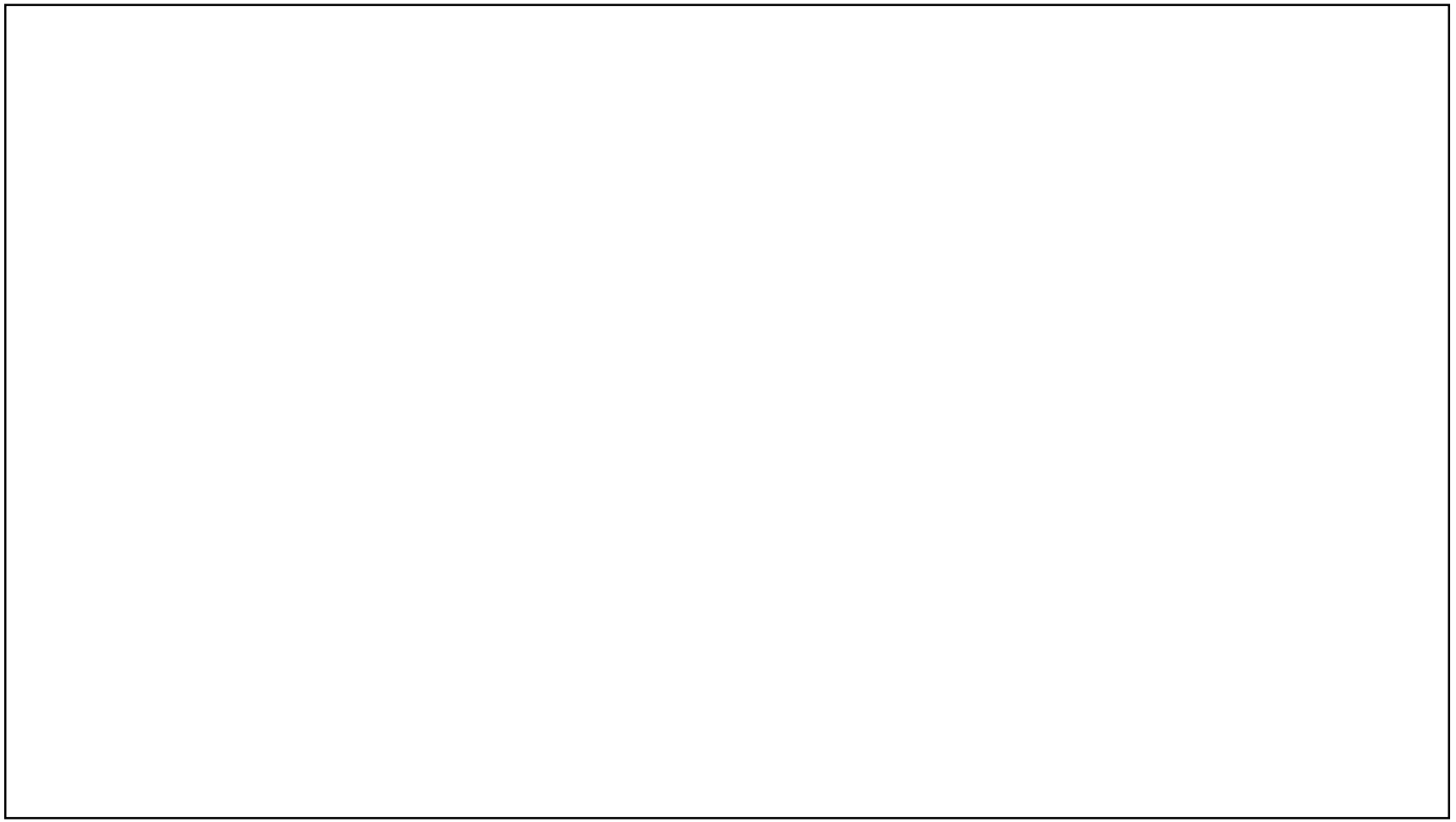
- Helps facilitate efficient treatment for varying vein lengths and anatomies

Venclose Maven™ Perforator Catheter

Venclose™ RF Ablation Generator

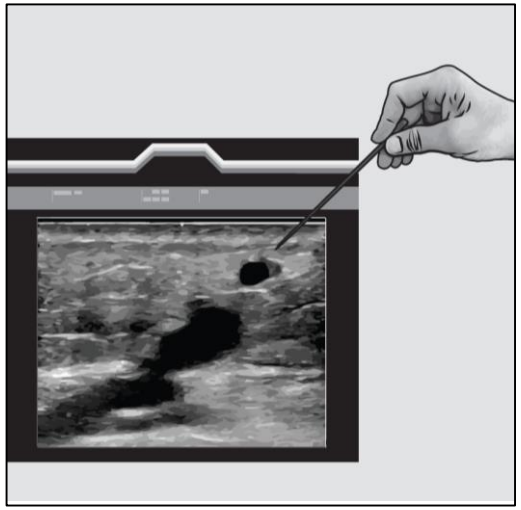
The **Venclose Maven™ Perforator Catheter** and **Venclose™ RF Ablation Catheter** use the same Venclose™ RF Ablation Generator to leverage the simplified setup and operation.

Venclose Maven™ Perforator Catheter Animated Video



Venclose Maven™ Catheter Key Procedural Steps

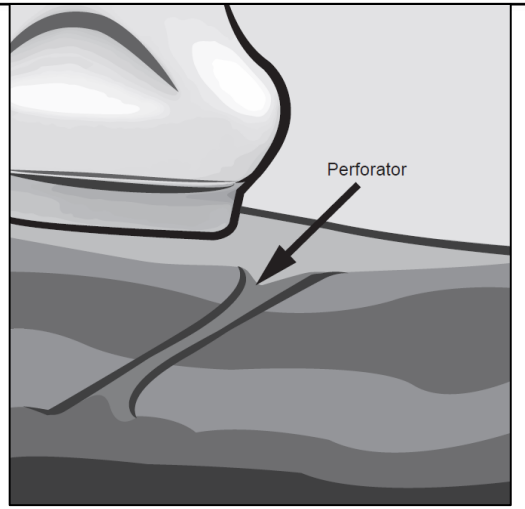
1. Tip: Visualize the incompetent perforator vein under ultrasound guidance.
2. Tip: Align the perforator with the corner of the ultrasound screen and determine if a leg bump is required for access.
3. Tip: Mark the skin overlying the perforator with an indelible marker.
4. Tip: Physician may apply a tourniquet and/or Nitro-Bid®.



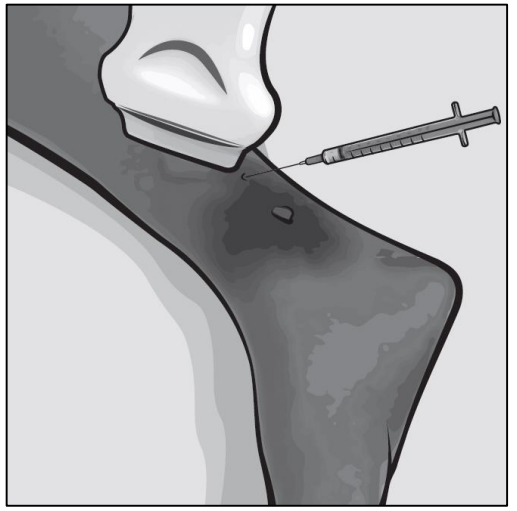
These key procedural steps are not intended as a replacement for the full product directions for use. Please consult the Venclose Maven™ Perforator Catheter's IFU for complete product description, instructions for use as well as all safety related information, including warnings, precautions and contraindications

Venclose Maven™ Catheter Key Procedural Steps

5. Tip: For the procedure, use duplex ultrasound to obtain a clear view of the incompetent perforator vein at the level of the deep fascia and identify the deep venous system.



6. Administer local anesthesia.



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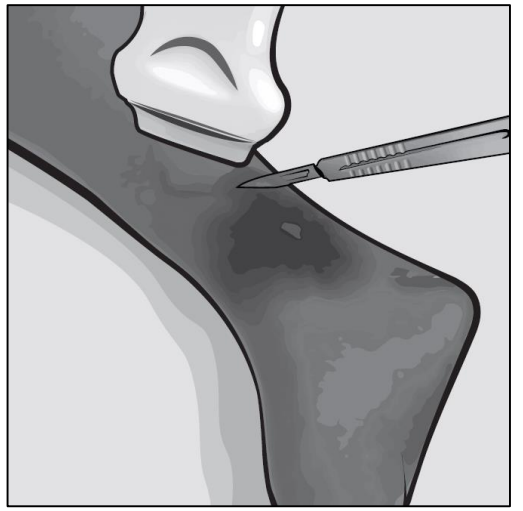
Venclose Maven™ Catheter Key Procedural Steps

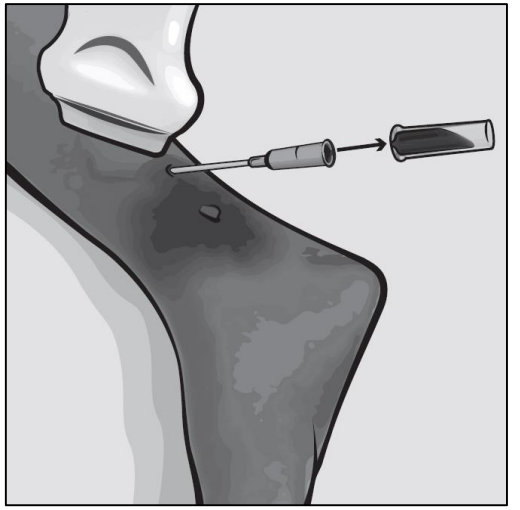
7. Prepare the catheter lumen by flushing with sterile physiologic saline and then cap the lumen at the handle. Wipe the surface of the shaft with saline and a sterile wipe.

CAUTION: Do not deliver fluid through the catheter lumen during treatment or treat while the guidewire is within the catheter lumen at the heating element.

8. Gain vessel access with a compatible introducer sheath per the sheath manufacturer's instructions or a 12-gauge IV catheter per the IV catheter manufacturer's instructions. Use aseptic technique.

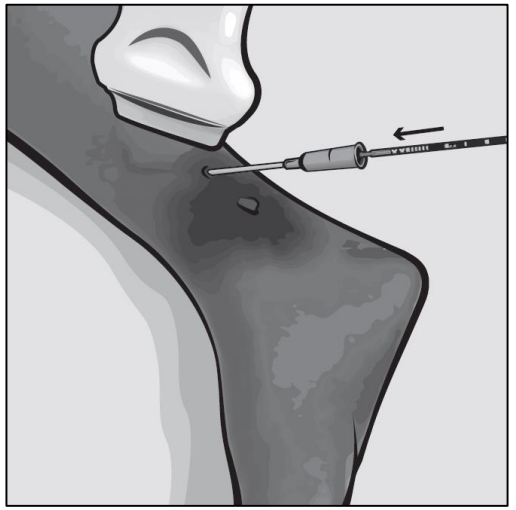
- Tip: A skin nick may facilitate insertion of introducer sheath and catheter.
- Then, if using an Angiocath™ IV Catheter, insert the Angiocath™ until flashback appears and confirm position with ultrasound. Remove needle from the Angiocath™ IV Catheter. If using an introducer sheath, insert the wire and compatible introducer sheath over the wire.





Venclose Maven™ Catheter Key Procedural Steps

9. Insert the Venclose Maven™ Catheter and advance the tip to the desired treatment start location under direct ultrasound visualization 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.



10. Tip: Pull back the introducer sheath or 12-gauge Angiocath™ IV Catheter to visualize catheter markings at the skin.

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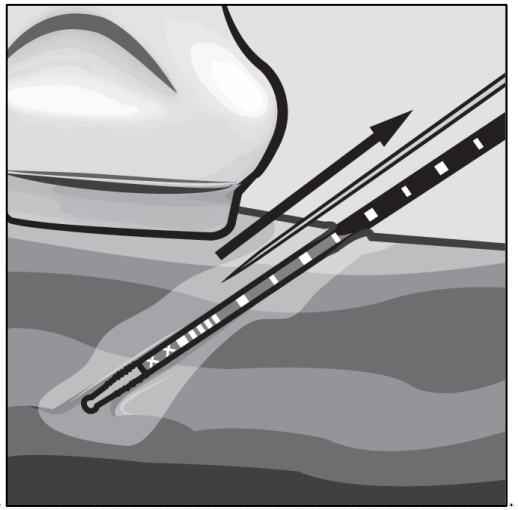
Venclose Maven™ Catheter Key Procedural Steps

11. 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.

Also, 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 labeling on the maximum injected anesthetic dose for the patient.



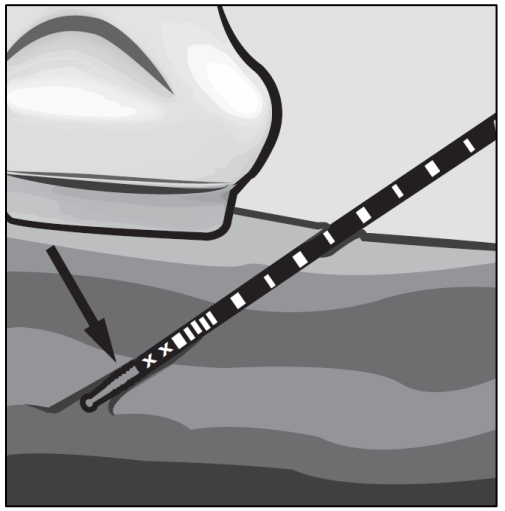
Venclose Maven™ Catheter Key Procedural Steps

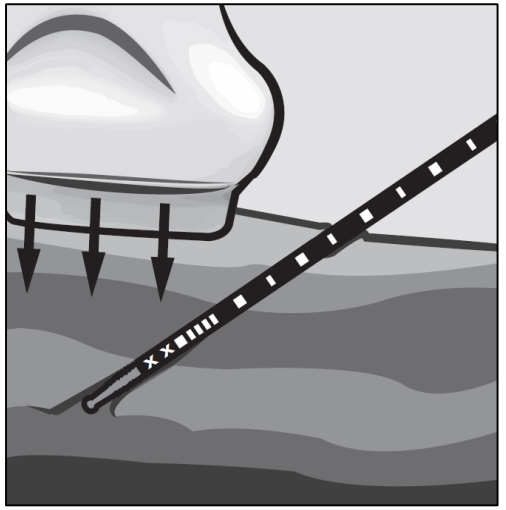
12. Tip: Maximally empty the treatment vein of blood, creating direct contact of the vein wall with the heating element, such as by raising the patient's legs above the level of the heart in Trendelenburg position or applying external compression over the treatment area.

13. 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. Ensure that the distal tip of the device is at least 0.5 cm from the deep venous system.

- Tip: Prior to treatment, if possible, place the catheter's heating element at or below the deep fascia for the first treatment segment – use fluid anesthesia to protect deep veins.





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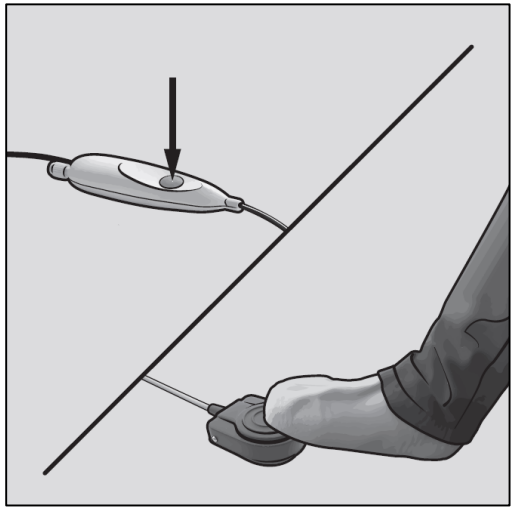
Venclose Maven™ Catheter Key Procedural Steps

14. Begin an RF treatment by pressing the button on the catheter handle or by stepping on the generator foot pedal.

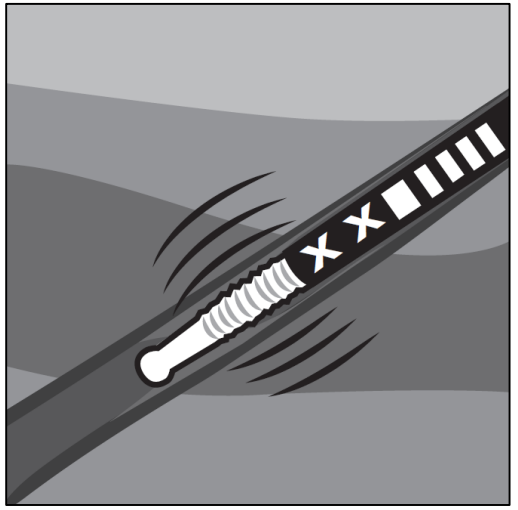
CAUTION: If using direct external compression, do not compress the skin closer than 0.5 cm to the heating element or a skin burn may occur.

- 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 Generator.
- If low temperatures are observed, or if the Venclose™ RF Ablation Generator displays an indication of fluid around the heating element, repeat exsanguination methods to maximally empty the vein.



15. 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.



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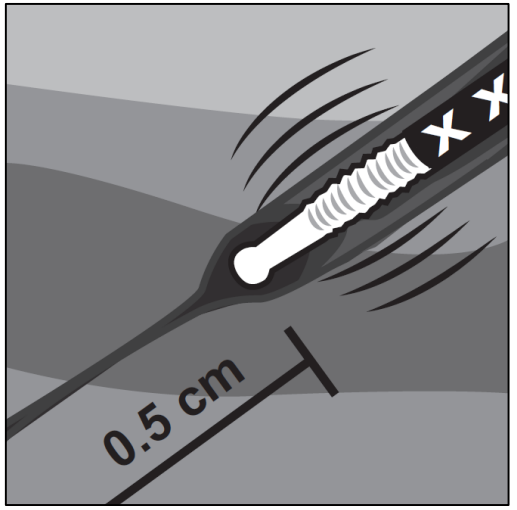
Venclose Maven™ Catheter Key Procedural Steps

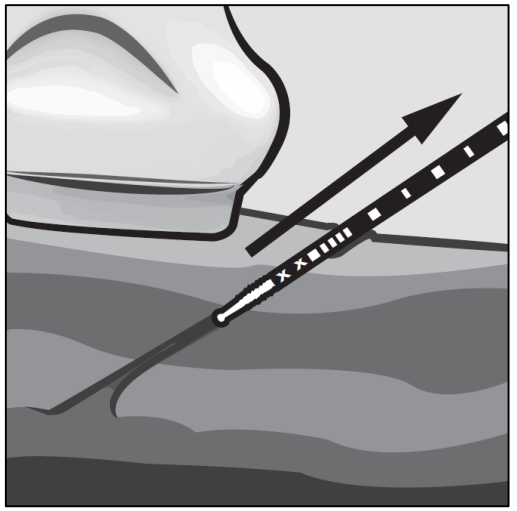
16. If multiple treatment segments are to be treated, pull the catheter back 0.5 cm so that the active heating element length is adjacent to the previous treatment location and repeat treatment.

- Thick lines on the catheter indicate distances at 1 cm intervals from the heating element and thin lines indicate distances at 0.5 cm intervals from the heating element. Printed numbers represent the distance from the distal end of the heating element.

Tip: When treating with 7 cm introducer sheath:

- The proximal “X X” markings can be seen and additional cycles are required, remove sheath while maintaining catheter position.
- SHEATH IS REMOVED and treating with 0.5 cm heating length: When you have reached the last of the distal “|||||” lines treat with final 0.5 cm treatment cycle.



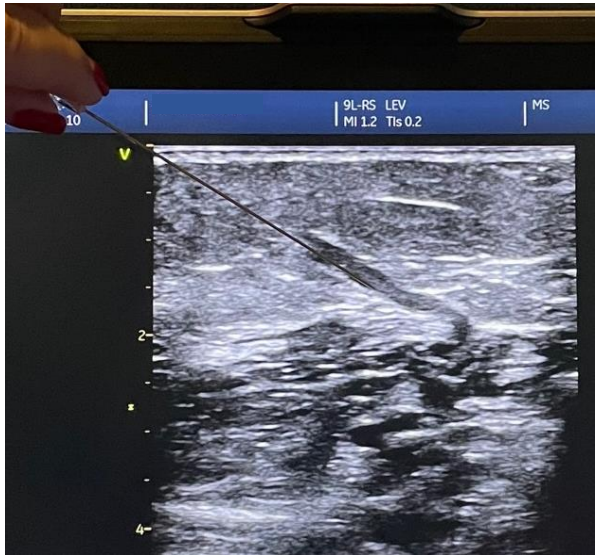


17. Once treatment is complete, remove the catheter, confirm occlusion of treated vein. Apply external compression if and as prescribed by physician.

TIP: Confirm patency of deep veins with ultrasound.

Venclose Maven™ Perforator Catheter Tips

- Hold your needle from the edge of the ultrasound screen and bring the image under your needle to determine access angle (in longitudinal view)
- Protect skin, deep veins, adjacent artery, bones, nerves with tumescent



- Pre-map treatment plan with number of treatment zones
  - 0.35 cm - inactive tip of catheter
  - 0.5 cm - active treatment element
  - 1.5 cm – total treatment zone

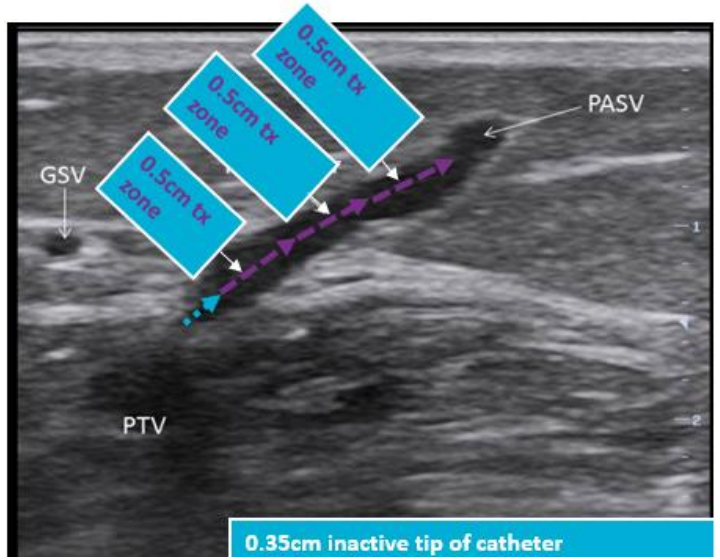


Image Courtesy of Jeff Carr, MD

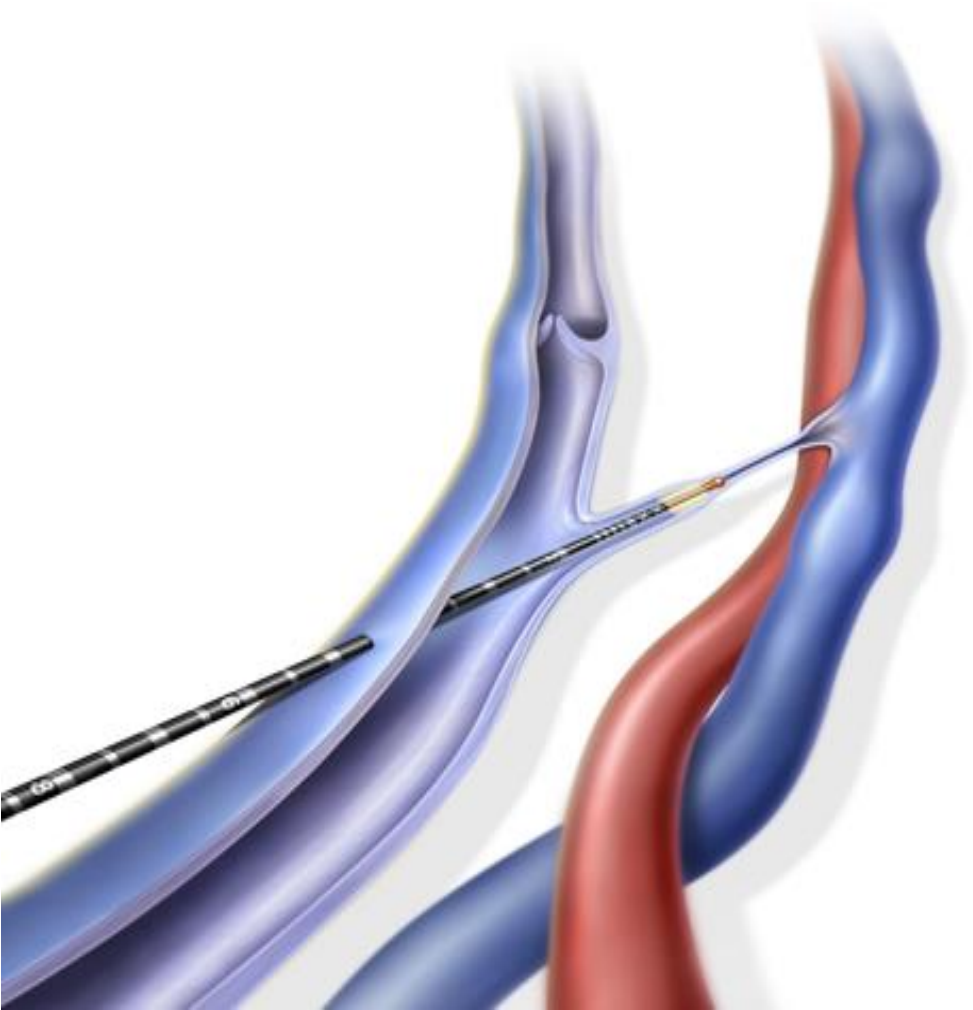
GSV - great saphenous vein; PASV - posterior accessory saphenous vein; PTV - posterior tibial vein

Venclose Maven™ Perforator Catheter Tips and Reminders

- Consider withdrawing the sheath/angiocath from the skin so that the catheter shaft markings can be seen near the point of catheter entry into the skin (for visualization of pullback length)
- If using external compression, it is recommended to not compress the skin closer than at least 0.5 cm – 1 cm distance to the heating element
- At least 0.5 cm of fluid anesthesia is used to protect surrounding structures such as nerves, arteries and bones
- Nerve injury may occur from thermal damage to adjacent sensory nerves and risk of nerve injury may be higher with treatment at or below the calf, or without perivenous fluid infiltration
- Keep the distal catheter tip 0.5 cm – 1 cm from the deep venous system to avoid damage to the Posterior Tibial Veins
- Identify accompanying arteries that may be in proximity to the perforator during treatment
- Consider noting which deep vein the perforator communicates with and marking the refluxing vessel at the beginning of the case; this may assist in post-treatment reassessment
- Recommended follow-up care includes postoperative compression as prescribed by physician; frequent ambulation for several days after treatment; and refraining from strenuous activity for several days

  Tip: Another recommended postoperative care solution is to apply compression bandages folded 4x4 over treated perforator for pressure and wrap leg from toes up (starting from top of foot to avoid pressure points on the bottom of the foot)

Ordering Information



Description	Product Codes
Venclose™ RF Generator	VC-RFG-1
Venclose Maven™ Perforator Catheter	VC-0.5-6F
Venclose Maven™ Procedure Pack	VC-PPM-12F
12G Angiocath™ IV Catheter	B-D382277Z
Foot Pedal	VC-FP-1

Venclose Maven™

Perforator Catheter

Safety Information

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 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; and pain.

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

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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 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 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.

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

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