VENCLOSE MAVEN™

VC-0.5-6F

Instructions for Use

LB-0045.D

Venclose, Inc.

Symbols Glossary located in the back of this Instructions for Use (IFU).

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VENCLOSE®

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INSTRUCTIONS FOR USE: VENCLOSE MAVEN™ Perforator RF Ablation Catheter

Contents: (1) VENCLOSE MAVEN Catheter, for use with the Venclose digiRF™ Generator

Sterile, Single-Use Only

NOTE: Thoroughly read all instructions, including the Venclose digiRF Radiofrequency Generator's (model VC-RFG-1) User Manual, before using the Venclose system. Observe all warnings, precautions and cautions noted throughout these instructions. Failure to do so may result in patient complications. These instructions are designed as a general guideline, they do not supersede institutional protocols or professional clinical judgment concerning patient care.

CAUTION: Contents are sterile unless package is damaged or open.

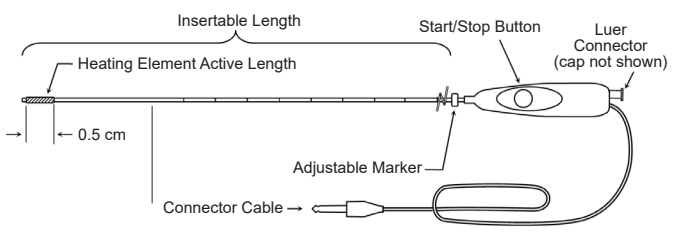
DEVICE DESCRIPTION

The Venclose MAVEN Catheter [the catheter] is a sterile single-use disposable medical device for endovenous radiofrequency ablation, a procedure in which a refluxing vein is thermally coagulated to permanently eliminate the vein from blood circulation. The catheter has a long shaft for insertion into a vein, a handle with start/stop button and a connector cable. The catheter shaft has a heating element that is energized by the digiRF Radiofrequency Generator [the generator], which is a multi-voltage energy delivery system with touchscreen control that automatically sets the non-adjustable treatment parameters for the Venclose MAVEN Catheter. 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 130°C and the treatment stops automatically when complete. The catheter is used within a sterile operative field while the generator remains outside the sterile operative field at all times. The catheter connector cable exits the sterile field and connects to the generator.

INTENDED USE

The Venclose MAVEN Catheter is intended to be used with the Venclose digiRF Generator as a system.

DEVICE COMPONENTS



Catheter Model:	**VC-0.5-6F**
Heating Element Active Length	0.5 cm
Heating Element Diameter (max. catheter outer diameter)	6F (2.0 mm)
Insertable Length (cm)	40 cm

INDICATIONS FOR USE

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.**

CAUTIONS

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

POTENTIAL 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.

SUPPLIES AND EQUIPMENT

The following supplies are necessary for the procedure but are not provided with the catheter:

- Venclose digiRF Generator
- Duplex ultrasound console
- Supplies for sterile procedure
- Tilt table (recommended)
- 6F introducer sheath, with appropriate dilator, guidewire and percutaneous access needle
- Local or general anesthesia
- Post-operative compression as recommended by physician
- 12 gauge IV catheter (optional for IV catheter access)

GENERATOR SET-UP

Refer to the digiRF Generator's User Manual for startup instructions.

DIRECTIONS-FOR-USE

Patient Preparation

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.

Catheter Inspection & Preparation

1) Inspect catheter packaging and pouch for damage. If the packaging is damaged, call customer service and return the device with complete packaging to the company.
2) Open pouch and remove product using aseptic technique.
3) Inspect catheter. Although the catheter will function properly if the shaft becomes kinked once, IF CATHETER IS PHYSICALLY DAMAGED IN ANY OTHER WAY, DO NOT USE.
4) Pass the catheter cable connector out of the sterile field and connect to the generator by plugging fully into the catheter connector jack.

CAUTION: If fluid contacts the cable connector, wipe it clean and dry before inserting into the generator.

5) 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.
6) 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 tip of the catheter.

CAUTION: 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.

7) 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.

Local Anesthesia Administration

8) 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. 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.

Final Catheter Positioning

9) 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.

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

10) 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 at least 0.5 cm from the deep venous system.

Thermal Treatment

CAUTION: 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.

CAUTION: The portion of the catheter shaft within 2.0 cm of the heating element may exceed 41°C during treatment. Testing of this region has shown that a maximum temperature of 42°C can be reached.

11) 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.
12) 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 mains power cable from the generator.
13) 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 step 12), 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

CAUTION: 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.

14) Continued temperature readings below the set temperature may indicate the presence of blood within the vein that has a cooling effect on treatment. This may be caused by large vein diameter and/or a high rate of reflux blood flow.
15) If low temperatures are observed, or if the digiRF 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 0.5 cm to the heating element or a skin burn may occur.

16) 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.

17) 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.
18) 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 0.5 cm from the vein access point and energy delivery cycles should not be administered.
19) Repeat steps 12 through 18 above until the intended total length of vein treatment is complete.

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.

20) Once the recommended treatment is complete, remove catheter and introducer sheath from vein.
21) Obtain *hemostasis* at the access site.
22) Apply external compression (wrap, stockings or other) if and as prescribed by physician.

FOLLOW-UP CARE

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

MAXIMUM CATHETER USAGE

Each catheter is electronically limited to a single usage instance of at least 50 cycles over a time span of 1.5 hours after the catheter is plugged in and electronically activated.

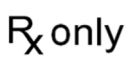
OPERATING CONDITIONS

- Temperature: 10° to 30° C (50° to 86° F)
- Relative Humidity: 15% to 90%
- Pressure: ambient atmospheric pressure of 700 hPa (10k ft) to 1000 hPa (sea level)

DISPOSAL

The Venclose MAVEN Catheter contains an embedded internal Lithium Ion battery (non-serviceable) that is not intended to be removed or replaced by the user. Dispose of contaminated device, components and packaging materials using standard hospital practices for bio-hazardous waste and in compliance with all applicable local, state, and federal regulations for electronics and batteries. Never incinerate discarded batteries.

SYMBOLS GLOSSARY

Symbol	Title	Reference Number	Standard Reference
	CATALOG NUMBER	5.1.6	ISO 15223-1
	BATCH CODE	5.1.5	ISO 15223-1
	USE BY	5.1.4	ISO 15223-1
	STERILIZED BY ETHYLENE OXIDE	5.2.3	ISO 15223-1
	DO NOT USE IF PACKAGE IS DAMAGED	5.2.8	ISO 15223-1
	DO NOT RE-USE, SINGLE USE	5.4.2	ISO 15223-1
	DO NOT RESTERILIZE	5.2.6	ISO 15223-1
	FEDERAL (U.S.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN	N/A	21 CFR 801.109
	TYPE BF APPLIED PART	IEC 60417-5333	IEC 60601-1
	REFER TO INSTRUCTIONS FOR USE	5.4.3	ISO 15223-1
	DEVICE MANUFACTURER	5.1.1	ISO 15223-1
	DATE OF MANUFACTURE	5.1.3	ISO 15223-1
	GUIDEWIRE	N/A	N/A
	TEMPERATURE LIMIT	5.3.7	ISO 15223-1
	HUMIDITY LIMITATION	5.3.8	ISO 15223-1
	ATMOSPHERIC PRESSURE LIMITATION	5.3.9	ISO 15223-1
	PACKAGING UNIT	2794	ISO 7000

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