

VNUS® ClosureFAST™ Catheter
VNUS® ClosureFAST LT™ Catheter
INSTRUCTIONS FOR USE

Sterile, Single-Use Only

NOTE: Thoroughly read all instructions, including the VNUS RFGPlus™ RF Generator Operator's Manual, prior to using the Closure® System. Observe all warnings, precautions and cautions noted throughout these instructions. Failure to do so may result in patient complications.



Attention: Contents of package are sterile unless package is open or damaged. For use with the VNUS RFGPlus Radiofrequency Generator with software version 4.0.0 or higher. ClosureFAST LT package contains primary lithium batteries. Dispose of battery in accordance with federal, state, and local regulations.

INDICATIONS-FOR-USE

The ClosureFAST and ClosureFAST LT catheters are intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

DEVICE DESCRIPTION

The VNUS Closure system consists of two main components: The ClosureFAST catheter and the RFGPlus RF generator. The ClosureFAST catheter is provided sterile, and is a single-use, disposable device. The ClosureFAST catheter function is to provide thermal energy to the desired treatment site via RF heating of the catheter heating element and to relay temperature back to the RF generator. The RF generator remains out of the sterile field during use, and is provided non-sterile. The catheter is connected to the RF generator via the cable connector. The ClosureFAST LT catheter incorporates an LED on the distal tip of the catheter that is powered by a lithium battery contained in the handle of the device.

CONTRAINDICATIONS

- Patients with thrombus in the vein segment to be treated.

CAUTION: THE VEIN WALL MAY BE THINNER IN AN ANEURYSMAL SEGMENT. TO EFFECTIVELY OCCLUDE A VEIN WITH AN ANEURYSMAL SEGMENT, ADDITIONAL TUMESCENT INFILTRATION MAY BE NEEDED OVER THE ANEURYSMAL SEGMENT, AND THE TREATMENT OF THE VEIN SHOULD INCLUDE SEGMENTS PROXIMAL AND DISTAL TO THE ANEURYSMAL SEGMENT.

CAUTION: NO DATA EXISTS REGARDING THE USE OF THIS CATHETER IN PATIENTS WITH DOCUMENTED PERIPHERAL ARTERIAL DISEASE. THE SAME CARE SHOULD BE TAKEN IN THE TREATMENT OF PATIENTS WITH SIGNIFICANT PERIPHERAL ARTERIAL DISEASE AS WOULD BE TAKEN WITH A TRADITIONAL VEIN LIGATION AND STRIPPING PROCEDURE.

SUPPLIES AND EQUIPMENT



Attention: The Batteries Directive, 2006/66/EC, which is applicable to the ClosureFAST LT™ Catheter only, introduced new requirements, effective September 26, 2008, regarding removability of batteries from waste equipment in EU Member States. To comply with this Directive, this device has been designed for safe removal of the batteries at end-of-life by a waste treatment facility. Infected units should be de-contaminated before they are sent for recycling. In the event that it is not possible to decontaminate the unit for recycling, the hospital should not attempt to remove the batteries from waste equipment. Continued disposal of small amounts of portable batteries to landfill and incineration is allowed under the Batteries Directive and Member State regulations.

- VNUS RFG*Plus* RF generator (software version 4.0.0 or higher)
- Tilt table
- Duplex ultrasound scanner
- Sterile ultrasound gel
- Sterile ultrasound transducer cover
- 19G ultra thin-walled needle (for percutaneous access)
- 7F introducer sheath (11 cm length recommended)

Catheter Model	CF7-7-60 CF7-7-60-LT	CF7-7-100 CF7-7-100-LT
Introducer Sheath (Minimum ID size)	7F (2.33mm)	7F (2.33mm)
Insertable Length (cm)	60cm	100cm
Heating Element Diameter	2.25mm	2.25mm
Heating Element Length	7cm	7cm

GENERATOR SET-UP

Note: Refer to the RFG*Plus* RF Generator Operator’s Manual.

1. Plug in RF Generator.
2. Turn power “ON” using toggle switch on rear panel.
3. Confirm software version on screen – Software must be version 4.0.0 or higher.
4. The temperature range for the ClosureFAST catheter is: 95-120°C. Reference the RF generator Operator’s Manual for instructions on changing the settings, if desired.
Note: The default settings will not be displayed until a catheter is connected to the RF generator. Treatment settings may be adjusted according to physician preference.

DIRECTIONS-FOR-USE: USE ASEPTIC TECHNIQUE

PATIENT PREPARATION

1. Flush disposable accessories with sterile, physiologic saline (0.9% sodium chloride).
2. If local anesthetic is employed, administer local anesthetic at the vein access site. Mild sedation may also be given.
Note: Venospasm may hinder the ability to access the target vein. Factors which may induce venospasm, such as certain drugs, a cold environment or patient anxiety, should be avoided.
3. 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.
4. Access the vein to be treated via a percutaneous stick using a 19G ultra thin-walled needle or via a small cut-down.
5. Prepare and place introducer sheath per manufacturer instructions for use.

CATHETER INSPECTION & PREPARATION

1. Remove pouch from box and inspect for damage (i.e., tears, punctures etc.). If pouch is open or damaged, do not use catheter.
2. Open pouch and remove tray.
3. Inspect catheter. **IF CATHETER IS DAMAGED, DO NOT USE.**
4. Using aseptic technique, pass the cable connector out of the tray and connect to the RF generator.
Note: If using ClosureFAST LT, this will automatically turn on LED light at catheter tip.
CAUTION: AVOID ANY FLUID CONTACT WITH CABLE CONNECTOR.
5. Remove catheter from tray and place into the sterile field.
6. Using sterile Normal Saline, flush and fill catheter lumen, cap the lumen at the handle, and wipe the outer surface of the catheter shaft.
CAUTION: USE OF A FLUSH THROUGH THE CATHETER WHILE THE HEATING ELEMENT IS ACTIVE WILL 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.

7. Insert the ClosureFAST catheter into the introducer sheath and advance the catheter tip to the most proximal point of treatment. Catheter navigation to the treatment site can be performed using ultrasound guidance, palpation, or with a guidewire.
8. If using a center lumen guidewire to assist catheter advancement, 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.
9. If using the ClosureFAST LT, illumination through the skin indicates the catheter tip location. In some cases, mild pressure on the illuminated area of skin, or rotation of the catheter shaft to face the light towards the skin, may increase the precision of tip visualization.

CAUTION: DO NOT ADVANCE THE CATHETER OR GUIDEWIRE AGAINST RESISTANCE, OR VEIN PERFORATION MAY OCCUR.

TUMESCENT INFILTRATION AND CATHETER TIP POSITION

1. Use tumescent infiltration of dilute local anesthetic or saline into the perivascular space to create a circumferential fluid layer around the vessel to be treated. To achieve contact between the catheter heating element and the vein wall, an approximate volume of 10cc per cm of vein to be treated is recommended. Infiltrate up to approximately 5cm distal to the Saphenofemoral Junction (SFJ) or Saphenopopliteal Junction (SPJ); infiltration over and beyond the SFJ or SPJ will be performed after confirmation of final tip position.

Note: When the vein is located near the skin surface, a subcutaneous distance of ≥ 1 cm between the anterior vein wall and skin should be created by tumescent infiltration/solution of saline or dilute local anesthetic solution.

2. Verify the catheter tip position using the measurement calipers of the ultrasound machine. When treating either the Great Saphenous Vein (GSV) or Small Saphenous Vein (SSV), the tip should be placed 2.0cm inferior to the junction.

CAUTION: TRANSILLUMINATION OF THE ClosureFAST LT THROUGH THE SKIN IS NOT SUFFICIENT TO MEASURE THIS POSITIONING; USE ULTRASOUND FOR ACCURATE POSITIONING.

3. Infiltrate tumescent fluid over and beyond the junction using ultrasound guidance.

TREATMENT

1. Place the patient's legs above the level of the heart to facilitate vein collapse, apposition, and exsanguination.
2. While maintaining catheter tip position, partially withdraw the introducer sheath until the sheath hub is aligned with the first visible shaft marker or draw a mark on the skin at the level of the first visible shaft marker. Secure sheath to skin (optional).
3. Create a near-bloodless field by applying external compression along the full length of the heating element using the ultrasound transducer longitudinally aligned with the heating element, plus two fingertips of compression distal of the transducer.

CAUTION: FAILURE TO COMPRESS THE VEIN OVER THE FULL LENGTH OF THE HEATING ELEMENT MAY RESULT IN INCONSISTENT EFFECTIVENESS AND/OR POSSIBLE CATHETER DAMAGE.

4. If using the ClosureFAST LT, visualization of the LED through the tissue indicates the catheter tip location.
CAUTION: VISUALIZATION OF THE CLOSUREFAST LT THROUGH THE TISSUE IS NOT SUFFICIENT TO MEASURE THIS POSITIONING; USE ULTRASOUND FOR ACCURATE POSITIONING.

5. Enable RF energy delivery by pressing the "RF Power" button on the RF generator, which will cause the RF Power button to start blinking. If the "RF Power" button does not light or start blinking, observe any displayed message and respond. Refer to the RF generator Operator's Manual for further detail.

6. Initiate RF energy delivery by pressing the button on the catheter handle, or by pressing the "START RF" button below the screen on the RF generator. During treatment, energy delivery can be turned off by pressing the button on the catheter handle again, or by pressing the "STOP RF" button on the RF generator, or by pressing the "RF Power" button on the RF generator.

Note: Power will typically begin at 40W and drop to below 20W within 10 seconds if compression is located correctly and the vein segment being treated has been properly exsanguinated.

Note: If the set temperature is not reached within 5 seconds after RF energy delivery initiation, or if the power level is maintained above 20W there may be flow within the vein that is cooling the treatment

segment. Terminate RF energy delivery, verify effectiveness of exsanguination methods and proper tip position, correct as necessary, and re-initiate treatment of the segment.

Note: Continuous temperature readings below the set temperature may result in incomplete treatment. If this occurs, stop the treatment and reconfirm vessel apposition to the catheter heating element and absence of blood flow in the vessel segment to be treated. Apply more firm external compression if needed and retreat the segment.

CAUTION: IF TREATMENT IS HALTED DUE TO NON-UNIFORM TEMPERATURE, REMOVE THE CATHETER AND INSPECT THE HEATING ELEMENT FOR DAMAGE. IF DAMAGE IS FOUND, REPLACE THE CATHETER.

CAUTION: FAILURE TO RESPOND TO ALERTS CAN RESULT IN SEVERE DAMAGE TO THE CATHETER.

7. After the treatment time interval, RF energy delivery will terminate automatically. Deliver a second energy cycle to the segment closest to the SFJ.
8. RF energy delivery may be repeated in a given vein segment at the physician's option.
CAUTION: DO NOT ADMINISTER MORE THAN THREE ENERGY DELIVERY CYCLES AT ANY GIVEN VEIN SEGMENT.
CAUTION: DO NOT RE-ADVANCE CATHETER THROUGH AN ACUTELY TREATED VEIN SEGMENT.
9. Quickly withdraw the catheter until the next visible shaft marker is aligned with the hub of the sheath.
Note: Some friction between the vein wall and catheter after a heating cycle is normal and may be noticed while withdrawing the catheter.
10. Treat the next vein segment according to steps 3 through 8 above, repeating the compression, treatment, and indexing sequence until all segments are treated. Diagonal lines and printed numbers correlating to the introducer sheath length on the outside of the catheter shaft indicate the last full treatment segment when they are fully visible.
Note: The presence of a triple shaft mark located 3cm from the heating element may be used to determine the minimum distance from the heating element to the puncture site.
CAUTION: TREATMENT WITH THE HEATING ELEMENT INSIDE THE SHEATH OR OUTSIDE THE BODY MAY RESULT IN SKIN BURN OR CATHETER DAMAGE.
11. Remove catheter and introducer sheath from vein and evaluate treated vein segments with ultrasound to determine treatment outcome.
CAUTION: THERE IS NO RE-TREATMENT ALGORITHM WITH THE CLOSUREFAST CATHETER; DO NOT RE-ADVANCE THE CATHETER THROUGH AN ACUTELY TREATED VEIN SEGMENT.
12. Obtain hemostasis at the access site.
13. Apply a multi-layer compression wrap from foot to groin.

FOLLOW-UP CARE

1. Instruct patient to ambulate frequently and refrain from strenuous activities or heavy lifting for several days.
2. Post-operative compression for at least 1 week is recommended.
3. Follow-up examination within 72 hours should include an assessment to ensure that there is no thrombus extension into deep veins.

WARNINGS

- TREATMENT OF A VEIN LOCATED NEAR THE SKIN SURFACE MAY RESULT IN A SKIN BURN IF THE SKIN IS NOT PROTECTED WITH FLUID INFILTRATION.
- 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.

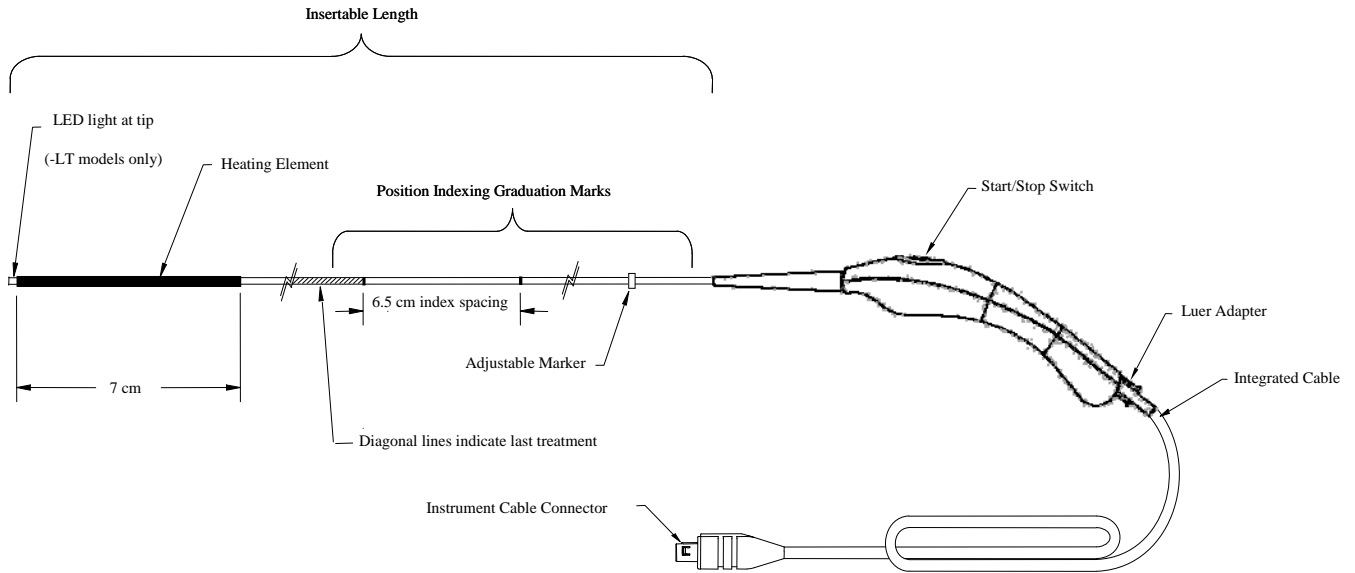
PRECAUTIONS

- Do not bend catheter into a tight radius. Kinking of the shaft may damage the catheter.
- To prevent damage to the guidewire, ensure that the guidewire does not protrude from catheter tip when inserting catheter into vein.

POTENTIAL COMPLICATIONS

The potential complications include, but are not limited to the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, infection, adjacent nerve injury, skin burn or discoloration.

FOR SINGLE PATIENT USE ONLY. DO NOT REUSE, REPROCESS OR RESTERILIZE. CLEANING, REPROCESSING OR RESTERILIZATION MAY COMPROMISE THE STRUCTURAL INTEGRITY OF THE DEVICE AND/OR LEAD TO DEVICE FAILURE WHICH, IN TURN, MAY RESULT IN SERIOUS PATIENT ADVERSE EVENTS. CLEANING, REPROCESSING OR RESTERILIZATION MAY ALSO CREATE A RISK OF CONTAMINATION OF THE DEVICE AND/OR CAUSE TRANSMISSION OF INFECTIOUS DISEASES FROM ONE PATIENT TO ANOTHER. CONTAMINATION OF THE DEVICE MAY LEAD TO INJURY, ILLNESS OR DEATH OF THE PATIENT. VNUS WILL NOT BE RESPONSIBLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR EXPENSES RESULTING FROM REUSE OF THE CATHETER.



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