



# THE Closure<sup>®</sup> PROCEDURE

*> A minimally invasive treatment  
for venous reflux disease*

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## PROVEN TECHNOLOGY

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For many of the 25 million people suffering from symptoms associated with superficial venous reflux and varicose veins, the Closure procedure offers a minimally invasive alternative to vein stripping.

More than 75,000 patients treated <

5 year patient follow-up <

3 randomized trials vs. vein stripping <  
demonstrate proven benefits of Closure



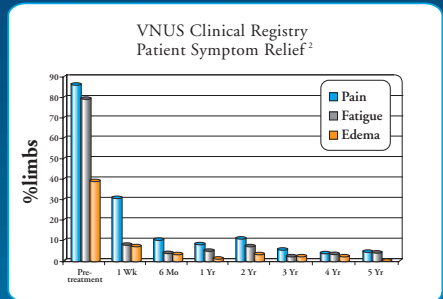
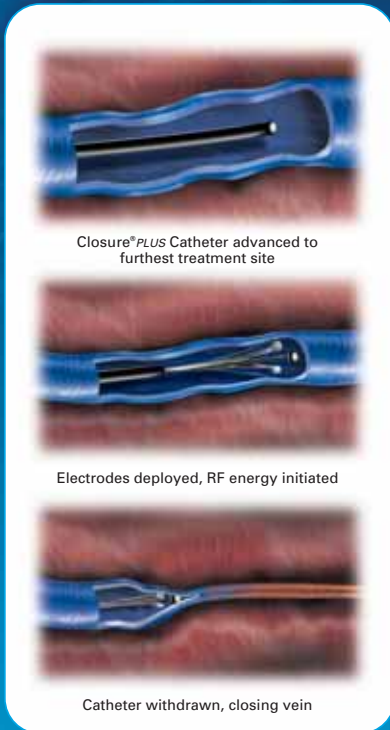
## > PROCEDURE OVERVIEW

The Closure procedure is an outpatient (day surgery) treatment which can be performed under local anesthesia in a variety of clinical settings including physician offices, ambulatory surgery centers and hospitals. Using an endovenous approach and VNUS' patented advanced radiofrequency technology, the Closure system occludes veins, thereby eliminating reflux.



## > 98% PATIENT SATISFACTION

98% of patients polled in a published report would recommend the Closure procedure to other patients with similar leg vein problems.<sup>1</sup> Clinical data demonstrates long-term patient symptom relief.



## > INSURANCE REIMBURSEMENT

As an alternative to conventional surgery, the Closure procedure has some of the broadest and most complete insurance coverage available. Coverage is now available with multiple insurers nationwide, and is continually growing as more insurers decide to cover the procedure. Please check with the VNUS Medical Reimbursement Specialist team for specific insurer information.

## CLINICAL EVIDENCE

Evidence for evidence-based medicine: the Closure procedure is validated and proven by an extensive body of clinical data.



### > MULTIPLE SINGLE CENTER RESULTS

Reference	Follow-Up Term	Occlusion/Reflux-Free Rate
Weiss <sup>1</sup>	2 years	90.5%
Rosenblatt <sup>3</sup>	2 years	95.7%
Kistner <sup>4</sup>	1 year	97%
Whiteley <sup>5</sup>	1 year	99.2%

<sup>1</sup>Up to 2 years

### > MULTI-CENTER INTERNATIONAL REGISTRY DATA

The VNUS international, multi-center data results continue to demonstrate a highly effective, stable outcome with **5 year follow-up**. Of patients reflux-free at 1 year follow-up, 92% remain reflux-free at latest follow-up out to 5 years.<sup>9</sup>

### > RANDOMIZED TRIALS PROVE BENEFITS OF THE CLOSURE PROCEDURE VS. VEIN STRIPPING

Three randomized trials of the Closure procedure vs. vein stripping, including the most recent multi-center comparative trial, show very similar results.<sup>5, 7, 8</sup>

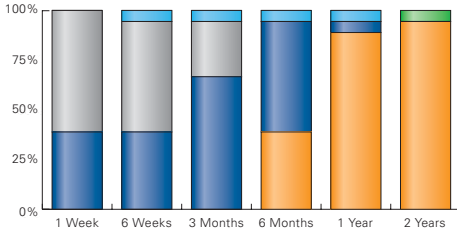
#### The Closure procedure resulted in:

- Less post-operative recuperation time
- Faster return to work and normal activity
- Higher quality of life scores than vein stripping
- Less post-operative pain and limitation of physical activity

In addition, the multi-center comparative trial showed fewer complications and adverse events in the Closure-treated patients than patients receiving vein stripping:

- In every comparison of the two procedures in which statistically significant differences were observed, the result was always in favor of the Closure procedure
- 80.5% of Closure-treated patients returned to normal activities within one day<sup>6</sup>

Sonographic GSV Trunk Morphology<sup>10</sup>



- Segmental trunk reflux
- Segmental trunk recanalization signs
- No flow - hypoechogenic
- No flow - hyperechogenic, shrunken
- Complete sonographic disappearance

## > 94% SONOGRAPHIC VEIN DISAPPEARANCE

94% of Closure-treated saphenous veins were sonographically invisible at 24 month follow-up (89% invisible at 12 month follow-up).<sup>9,10</sup>

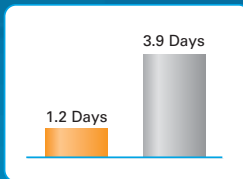
## > 0.5% NEOVASCULARIZATION

The rate of neovascularization, reportedly a cause of reflux recurrence in stripping and ligation procedures, was 0.5% at 24 month follow-up in limbs treated with the Closure procedure.<sup>9,11</sup>

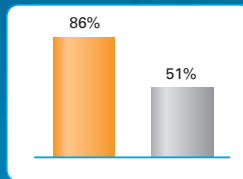
## > CLOSURE — EVOLVeS RANDOMIZED TRIAL<sup>6,12</sup>

Two year follow-up of the EVOLVeS randomized trial comparing Closure to vein stripping demonstrates clear benefits for Closure

**70% Faster Recuperation**  
Days to Return to Normal Activity

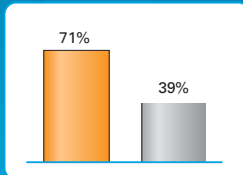


**Greater Pain Reduction at 2 Years**

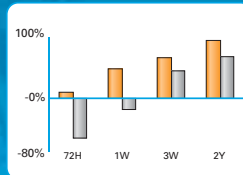


■ VNUS Closure ■ Vein Stripping

**52% Fewer Complications**  
Freedom from Adverse Events at 3 Weeks

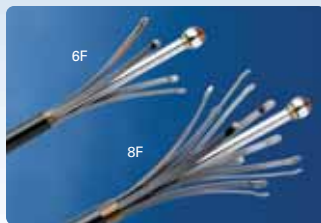


**Better Improvement in Quality of Life Scores**



Equivalent Elimination of Venous Reflux at 2 Years

# THE CLOSURE SYSTEM



*Collapsible electrode design maximizes vein wall contact*

## > RFG PLUS™ RADIOFREQUENCY GENERATOR

Continuous temperature and impedance feedback and automatic power adjustment deliver tailored treatment along the length of the vessel.

Key features provide a high level of procedural control:

- > Intuitive color gauges
- > Simple screen layout with bold colors
- > Pleasant, informative tones
- > Intra-operative feedback provides important information throughout the procedure

## > CLOSURE PLUS™ CATHETERS

- Micro-thermocouple continuously measures vein wall temperature
- 6F & 8F sizes available
- 0.025" guidewire compatible for catheter navigation in challenging vessel anatomy
- Closure PLUS Catheter has slim, lightweight handle



*The large color screen on the RFG PLUS displays real-time temperature, impedance and power values*

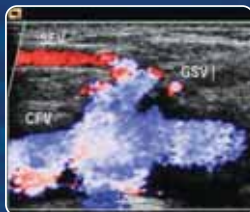
## > VEIN LUMEN CONTRACTION

Continuous feedback-controlled heating of the vein to 85°C optimizes endothelial destruction, collagen contraction and vein wall thickening, resulting in fibrotic vein occlusion.



## > COLOR FLOW DUPLEX ULTRASOUND IMAGING

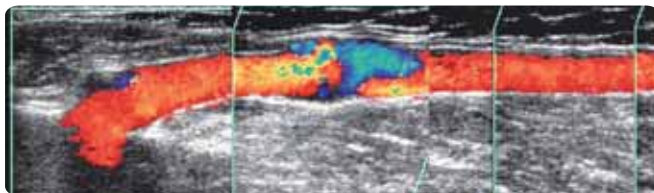
Three Year Ultrasound Follow-Up After Radiofrequency  
Obliteration of Saphenous Vein Reflux



Images courtesy of  
Nick Morrison, M.D. and  
Diana Neuhardt, RVT

Note the occluded/absent GSV, and a patent epigastric vein that may contribute to Closure's low rate of neovascularization.

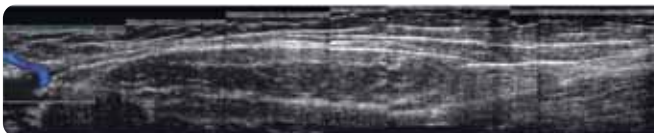
### Duplex Ultrasound Images Pre- and Post-Closure Treatment



*GSV before treatment*



*GSV one week after Closure treatment*



*GSV one year after Closure treatment*

Images courtesy of Olivier Pichot, MD, CHU de Grenoble, France.

# Ordering Information

ORDER#	DESCRIPTION	VOLTAGE
RFG2	RFG <i>PLUS</i> Radiofrequency Generator Universal	(100 – 240 V)

## Closure*PLUS* Catheters

ORDER#	DESCRIPTION	LENGTH	ELECTRODE EXPANSION DIAMETER
CL6-60	6F Closure <i>PLUS</i> Catheter with 0.025" guidewire lumen	60cm	8mm
CL6-100	6F Closure <i>PLUS</i> Catheter with 0.025" guidewire lumen	100cm	8mm
CL8-60	8F Closure <i>PLUS</i> Catheter with 0.025" guidewire lumen	60cm	12mm
CL8-100	8F Closure <i>PLUS</i> Catheter with 0.025" guidewire lumen	100cm	12mm

## ➤ To order, call toll free: 1-888-797-VEIN (8346)

**Indication:** The VNUS Closure System is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

**Contraindications:**

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

**PRECAUTION:** For patients with a pacemaker, internal defibrillator or other active implanted device, consult the cardiologist and the manufacturer of the active implanted device. Continuous patient monitoring during the procedure is recommended. Evaluate the patient and the implanted active device post-procedure. Keep all power cords and instrument cables away from the location of the pacemaker or leads, defibrillator or the implanted active device.

**CAUTION:** In patients with an aneurysm in the vein segment to be treated, the vein wall may be thinner in the area of the aneurysm. To effectively occlude a vein with an aneurysmal segment, additional tumescence 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.

**Potential Complications:**

+ Potential complications include, but are not limited to, the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, paresthesia, skin burn.

**Caution:** US Federal Law restricts this device to sale by or on the order of a physician.

**Refer to product instructions for use and operators manual for complete instructions.**

Manufactured under one or more of the following U.S. Patent Nos. 6,071,277; 6,152,895; 6,165,172; 6,179,832B1; 6,200,312B1; 6,237,606B1; 6,258,084B1; 6,401,719B1 and Patents Pending.

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