

Closure® ...For Your Legs



A minimally
invasive
treatment
alternative to
vein stripping.



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he VNUS® Closure® procedure is a minimally invasive treatment alternative for patients with a condition



known as superficial venous reflux, which often results in varicose veins and other painful symptoms. Approximately 25 million people suffer from venous reflux.

UNDERSTANDING SUPERFICIAL VENOUS REFLUX & VARICOSE VEINS ●

Your legs are made up of a network of veins. A healthy vein contains valves which open and close to assist the return of blood to the heart. Varicose veins are caused by damaged or diseased valves which result in backward flow of blood in your legs, a condition known as venous reflux. This can cause blood to pool in your legs and lead to symptoms such as pain, swelling, and varicose veins.

Normal Vein **Dilated Vein**



Valve Open Valve Closed Leaky Valve

THE CLOSURE PROCEDURE ●

The VNUS Closure procedure, an alternative treatment option to traditional vein stripping surgery, brings state of the art technology to an age old disease.

The Closure procedure is an outpatient (day surgery) treatment performed in doctor's offices, surgical centers, and hospitals. Local or regional anesthesia is typically used to numb the treatment area. A thin catheter is inserted into the



1
*Catheter
inserted*



2
*Vein heated and
collapses*



3
*Catheter slowly
withdrawn,
closing vein*

vein through a small opening, using only a single needle stick. The catheter delivers radiofrequency (RF) energy to the vein wall, causing it to heat, collapse, and seal shut.

Once the diseased vein is

closed, other healthy veins take over and empty blood from your legs. As normal return flow is re-established, your symptoms should improve noticeably.

Following the procedure, the catheter is removed, a bandage is placed over the insertion site and your leg may be wrapped typically for 1 day to aid healing. Your doctor may ask you to walk, wear compression stockings, and to refrain from long periods of standing for a period of time following the procedure to help speed your recovery. Many patients resume normal activities within 1-2 days.

HIGHLIGHTS OF THE CLOSURE PROCEDURE ●

- Relief of symptoms
- Short recovery
- Resume normal activities within 1-2 days
- Same day procedure
- Local or regional anesthesia
- Good cosmetic outcome with minimal or no scars

WHAT OTHER PATIENTS ARE SAYING ABOUT CLOSURE

Patients are highly satisfied with the Closure procedure.

FACT: 98% of patients who have undergone the Closure procedure are willing to recommend it to a friend or family member.¹



Connie K. *Third Grade Teacher*

Nineteen years ago, Connie had her left leg surgically stripped and said, “I was in the hospital for a week, wrapped and bandaged, then off my feet for another three weeks.” Connie had her right leg vein treated with the Closure procedure. “I experienced no pain afterwards. I found that incredible in comparison with my previous experience. I had no scarring. It’s incredible, absolutely incredible. I’m looking forward to wearing a skirt this summer.”



Brad G. *Marketing Director*

Over the last three to four years Brad experienced discomfort in his left leg, including aching, swelling, itching, hair loss, and skin discolorations and sores. Brad had the Closure procedure done in December. “I can say the procedure was nearly painless. I walked out of the office and went Christmas shopping the next day. Most dramatically, my lower leg stopped swelling even after a full day on my feet. Now about twelve weeks later, the skin discolorations and vein protrusions have almost vanished and the hair has grown back where before there was none. I can hardly tell that I ever had a vein problem.”

¹Weiss, R, et al. Controlled Radiofrequency Endovenous Occlusion Using a Unique Radiofrequency Catheter Under Duplex Guidance to Eliminate Saphenous Varicose Vein Reflux: A 2-Year Follow-Up. *Dermatol Surg* 2002; 28:38-42.

²Photos courtesy of Robert Merchant, M.D.

³Data on File—VNUS Medical Technologies, Inc.

⁴Jones L, et al. Neovascularisation is the principal cause of varicose vein recurrence: results of a randomized trial of stripping the long saphenous vein, *Eur J Vasc Endovasc Surg*, 1996; 12; 442-445.

THE CLOSURE PROCEDURE – A TREATMENT THAT WORKS

Clinical results indicate that the Closure procedure can be effective at closing the vein and significantly reducing patient symptoms.

Patient Symptoms Reported at Follow-up¹

Symptom	Pretreatment	6 Weeks	2 Years
Leg Pain	85%	6%	5%
Leg Fatigue	85%	12%	5%
Edema (swelling)	19%	8%	0%

Prior to the Closure procedure, 85% of patients reported leg pain. After the Closure procedure, 94% of patients at six weeks and 95% of patients at two years, did not report residual leg pain.

Typical Cosmetic Results: Before and After the Closure Procedure²



Pre-treatment



Typical result
48 hours after the
Closure procedure

Percent of Legs Without Varicose Veins at Follow-up

The Closure procedure may be as effective as vein stripping in delaying the reappearance of varicose veins.

	1 year	2 years
Closure ³	88%	86%
Vein Stripping ⁴	85%	75%
Ligation ⁴	86%	57%

COMMON QUESTIONS & ANSWERS ABOUT CLOSURE

Q: *How is the Closure procedure different than vein stripping?*

A: During a stripping procedure, the surgeon makes an incision in your groin and ties off the veins after which a stripper tool is threaded through the saphenous vein and used to pull the vein out of your leg through a second incision just above your calf. In the Closure procedure, there is no need for groin surgery, instead the vein remains in place and is closed using a special (Closure) catheter inserted through a small puncture. This virtually eliminates the bruising and pain often associated with vein stripping (i.e. this may result from the tearing of side branch veins while the saphenous vein is pulled out). Vein stripping is usually performed in an operating room, under a general anesthetic, while the Closure procedure is performed on an outpatient basis typically using local or regional anesthesia.

Q: *Is the procedure painful?*

A: Patients report feeling little if any pain during the Closure procedure. Your physician will give you a local or regional anesthetic to numb the treatment area.

Q: *How quickly after treatment can I return to normal activities?*

A: Many patients can resume normal activities within 1-2 days. For a few weeks following the treatment, your doctor may recommend a regular walking regimen and suggest that you refrain from very strenuous activities (heavy lifting for example) or prolonged periods of standing.

Q: *How soon after treatment will my symptoms improve?*

A: Most patients report a noticeable improvement in their symptoms in 1-2 weeks following the procedure.

Q: *Is there any scarring, bruising, or swelling after the procedure?*

A: Patients report minimal to no scarring, bruising, or swelling following the Closure procedure.

Q: *Is Closure covered by my insurance?*

A: Insurance coverage is determined on a per case basis. Most insurance companies determine coverage for all treatments, including the Closure procedure, based on medical necessity. Your physician can discuss your coverage further at the time of consultation.

Q: *How effective is the Closure procedure?*¹

A: Recently published data suggests that two years after treatment, 90% of the treated saphenous veins remain closed and free from reflux, the underlying cause of varicose veins.

SAFETY SUMMARY ●

As with any medical intervention, potential risks and complications exist with the Closure procedure. You should consult your physician to determine if your individual condition presents any special risks. Although a summary of potential complications of the Closure procedure is provided, you are encouraged to review these with your doctor at the time of consultation.

Indication:

The Closure System is intended for endovascular coagulation of blood vessels in patients with superficial venous reflux.

Contraindication:

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

Potential Risks & Complications:

- Potential complications include, but are not limited to the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, paresthesia, skin burn.
- Treatment of veins located very close to the skin surface may result in a skin burn.
- Paresthesia may occur from thermal damage to adjacent sensory nerves. The risk of paresthesia is higher with treatment at or below the calf.

Consult your physician for more detailed information on the Closure procedure.



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