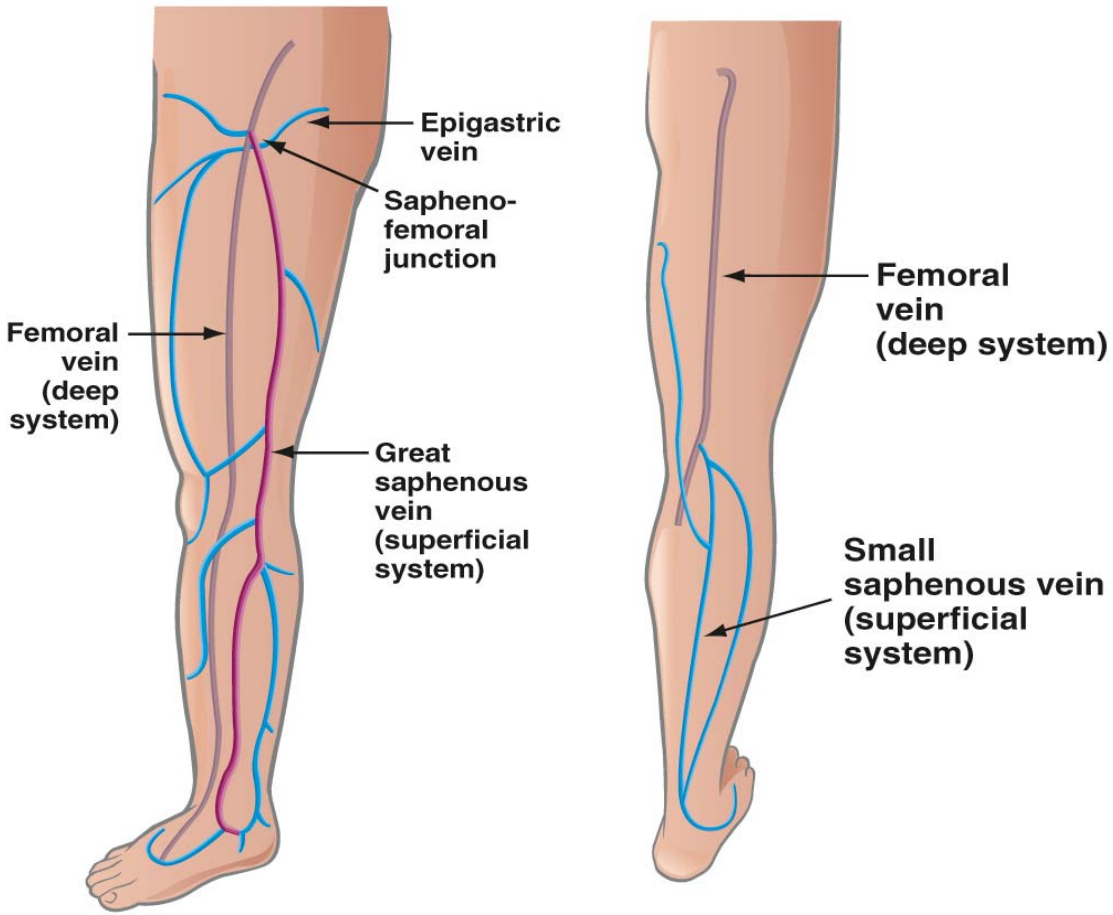
Venous Reflux Disease and Current Treatments

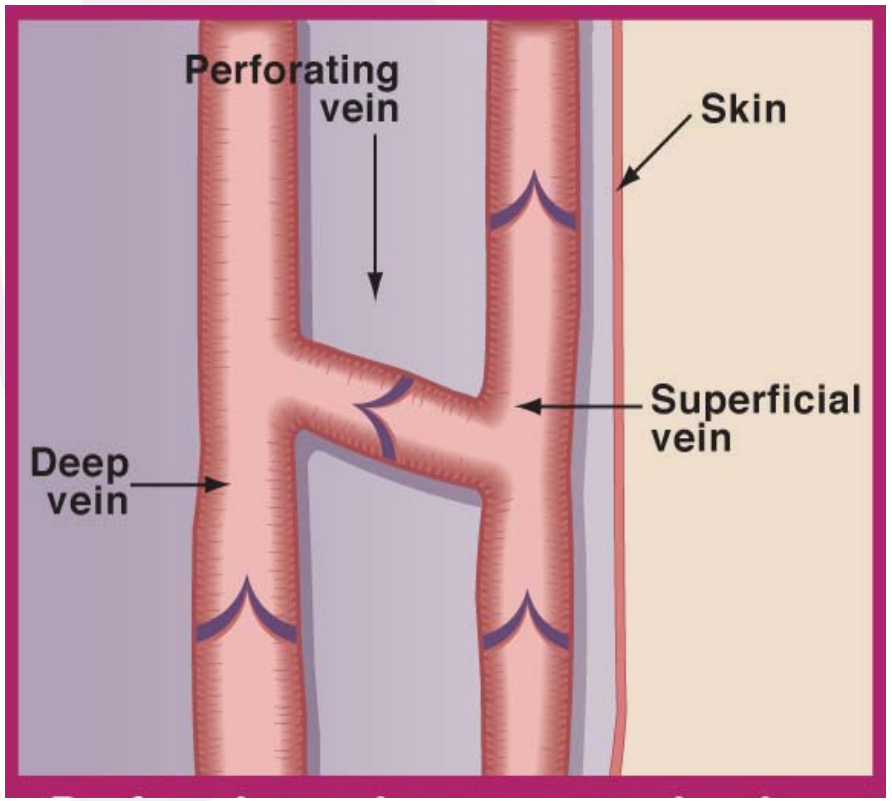
Leg Vein Anatomy

- Your legs are made up of a network of veins and vessels that carry blood back to the heart
- The venous system is comprised of:
  - Deep veins
  - Veins closer to the skin (superficial veins)

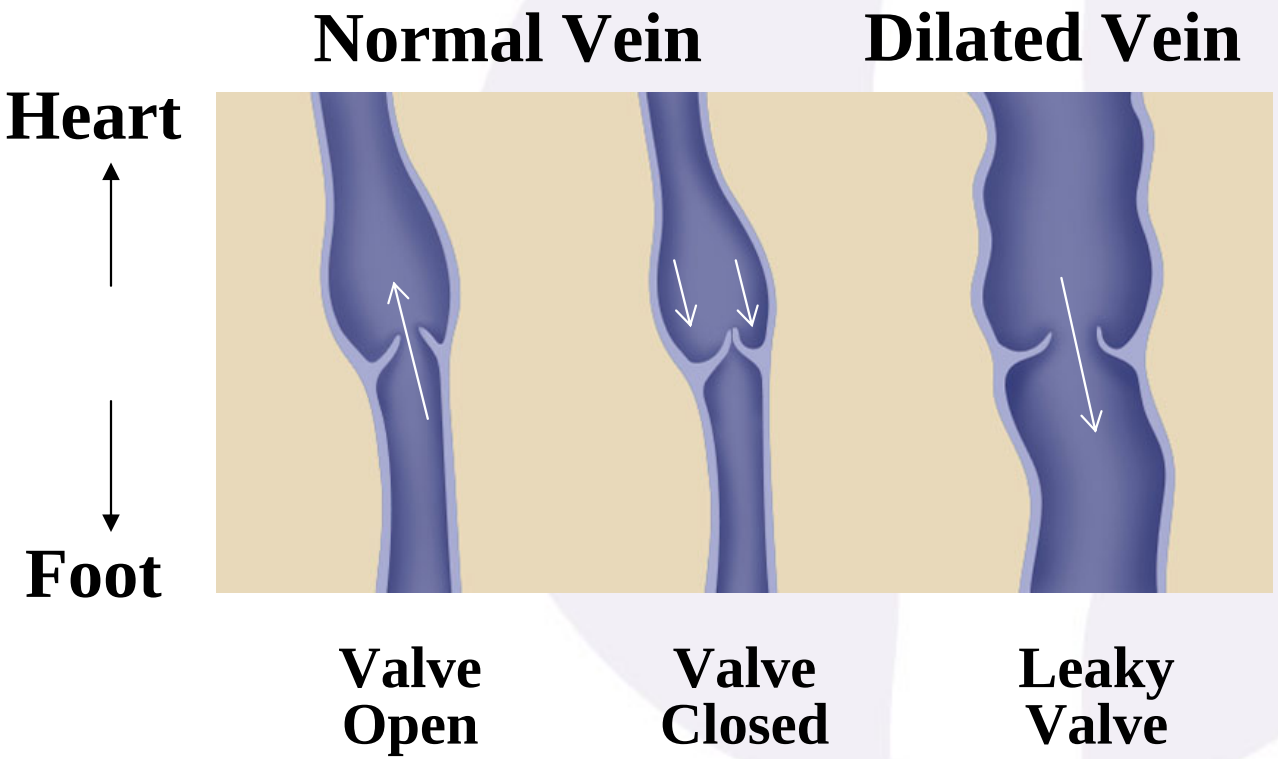


Leg Vein Anatomy

- Perforating veins connect the deep system with the superficial system
- They pass through the deep layer of muscular fascia tissue at mid-thigh, knee and ankle



Venous Reflux Disease



1. Vein valves become damaged or diseased, resulting in vein valve failure
2. Reflux or backward flow in the veins occurs
3. Pooling of blood causes pressure in leg veins
4. Increased pressure may cause surface veins to become dilated (varicose)

Patient Demographics

- It is estimated that in America, 72% of women and 42% of men will experience varicose veins by the time they are in their 60s.[1]
- Prevalence is highly correlated to age and gender
- Risk factors:
  - Multiple pregnancies
  - Family history
  - Obesity
  - Standing profession

[1] 1 Barron HC, Ross BA. Varicose Veins: A guide to prevention and treatment. NY, NY: Facts on File, Inc. (An Infobase Holdings Company); 1995;vii.

Symptoms

- Approximately 24 million Americans suffer from venous reflux
- Common symptoms of this progressive condition include:
  - Varicose veins
  - Pain
  - Swollen limbs
  - Leg heaviness and fatigue
  - Skin changes and skin ulcers

Photos courtesy of Rajabrata Sarkar, MD, PhD.

Conservative Treatments

- Leg elevation
- Compression stockings
- Conservative treatments often have poor patient compliance because they:
  - are difficult for patients to integrate into daily routine
  - are uncomfortable
  - require lengthy (lifelong) treatment
  - do not cure the underlying problem (pathology)

Related and Complementary Procedures

Image courtesy of Robert A. Weiss, MD

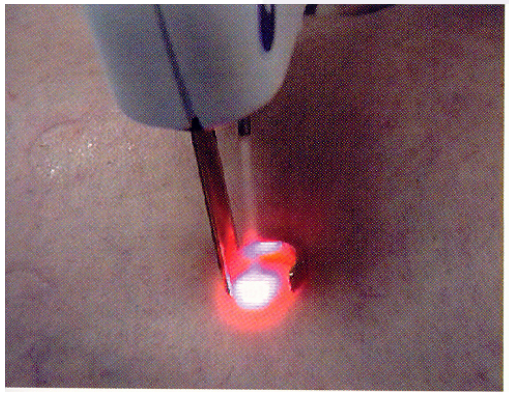
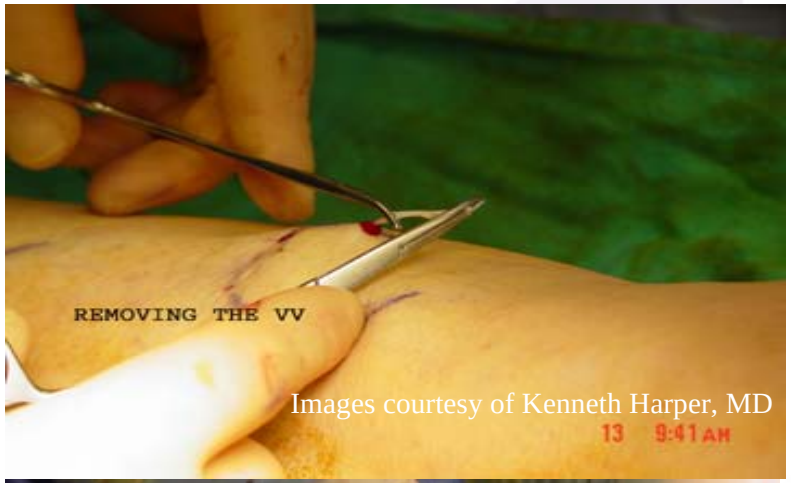


Image courtesy of Robert A. Weiss, MD

- Sclerotherapy
- External lasers and intense pulsed light
- Used to treat small superficial or “spider” veins

Related and Complementary Procedures



Images courtesy of Kenneth Harper, MD

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- Phlebectomy
  - Removal of diseased veins through a series of small incisions and use of specialized hooks to treat visible varicose veins

The VNUS Closure ® Procedure

- The VNUS Closure procedure is a minimally invasive treatment alternative to vein stripping

Disposable catheter inserted into vein

Vein warmed and collapses

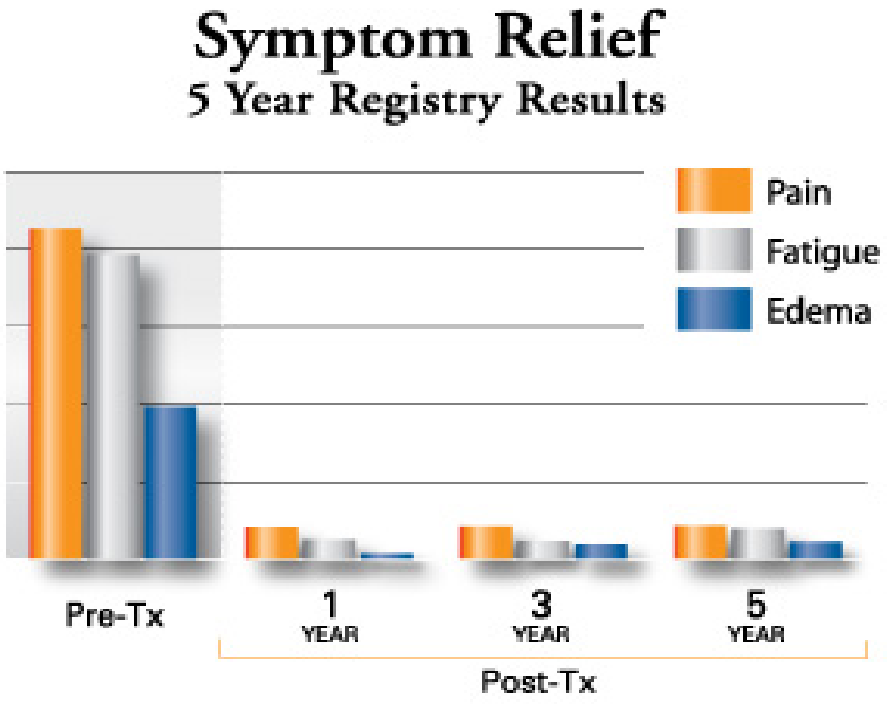
Catheter withdrawn, closing vein

Procedure Highlights

- Relief of symptoms
- Most patients resume normal activities within 1-2 days
- Outpatient procedure
- Local or general anesthesia
- Good cosmetic outcome with minimal to no scarring, bruising or swelling

Proven Benefits

Clinical data demonstrates long-term patient symptom relief:



[1] 1 Merchant RF, Pichot O, for the Closure study [illegible] Long term outcomes of endovenous radiofrequency obliteration of saphenous reflux as treatment for superficial venous insufficiency. J Vasc Surg 2(3): 502-509

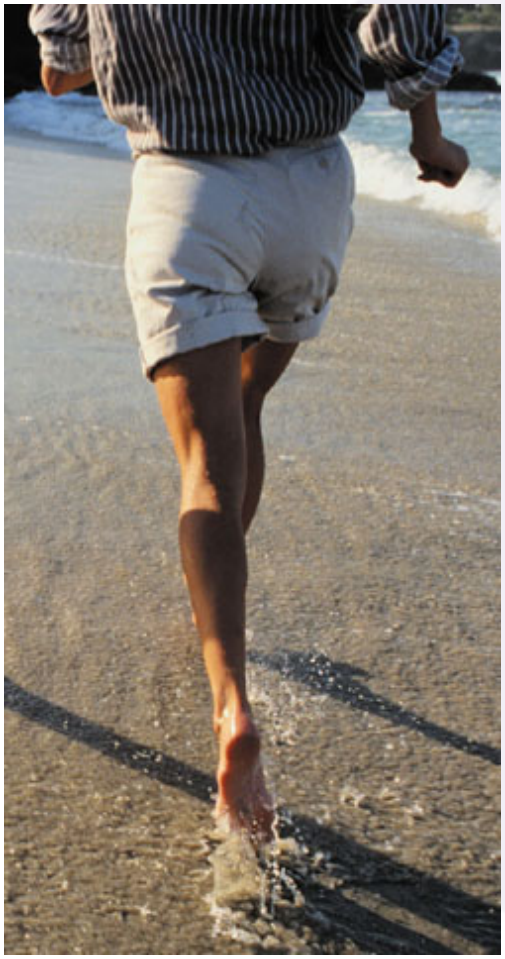
VNUS Closure ® Procedure Results

Pre-treatment

One week post-treatment*

*Individual results may vary

Patient Satisfaction



- 98% of patients who have undergone the VNUS Closure procedure are willing to recommend it to a friend or family member[2]
- The VNUS Closure procedure is covered by most insurance providers

[2] Weiss RA, 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.

Safety Summary

- Indication:
  - The VNUS Closure System is intended for endovascular coagulation of blood vessels in patients with superficial venous reflux
- Contraindications:
  - Patients with a thrombus (blood clot) in the vein segment to be treated

Safety Summary

- Potential risks and complications include, but are not limited to, the following:
  - Thrombophlebitis (reddened, warm skin caused by blood clot in the vein)
  - Thrombus extension (blood clot that sticks into the deeper vein from the treated vein)
  - Deep vein thrombosis (blood clot in one of the veins deeper in the leg muscle)
  - Paresthesia (numbness or tingling in the legs)
  - Perforation (hole through the wall of the vein)
  - Ecchymosis (bruising)
  - Edema (swelling resulting from the procedure)
  - Hematoma (collection of blood under the skin)
  - Pulmonary embolism (blood clot that travels into the arteries of the lung)
  - Skin burns