



### VENASEAL™ CLOSURE SYSTEM (Cyanoacrylate ablation)

This form is intended to provide you with information necessary to assist you in making an informed decision about whether to undergo Venaseal™ treatment of the saphenous vein. Sign this consent only after you have read and understood this information and all of your questions have been answered to your satisfaction.

#### Procedure Description

Duplex ultrasound imaging is used throughout the procedure to visualize the veins and guide treatment. The treatment catheter is inserted near the lower part of the vein to be treated using local anesthesia and a small puncture. The treatment catheter is then threaded up the vein and positioned near the upper part of the vein to be treated. While being carefully monitored, small amounts (.1 ml. aliquots usually totaling 1-2 ml.) are injected into the targeted vein and compression applied to the segment.

#### Potential Risks and Complications

If you undergo Cyanoacrylate Ablation, your symptoms may improve, remain the same, or worsen. However, the long term success rate of saphenous vein closure is greater than 90%. The procedure is quite safe and complications are very rare, but possible. Some potential side effects or complications are allergic reaction to the anesthetic, allergic reaction to the cyanoacrylate, bruising of the overlying skin (some mild temporary bruising is anticipated), perforation of the vein, breakage of the treatment catheter, arteriovenous fistula, superficial phlebitis (inflammation of the vein), leg swelling, pulmonary embolism, infection, bleeding, hyperpigmentation (darkening of the overlying skin), neovascularization (growth of new veins), and nerve injury resulting in numbness and tingling or muscle weakness. Rarely, a clot may form in the deep vein (DVT) requiring blood thinners or other treatment. Other complications not known at this time may occur. Also, treatment of the great saphenous vein would make it unavailable or unsuitable for use in heart surgery should it be needed at a later date.

#### Potential Risks of Not Undergoing Treatment

Usually, there are no serious health consequences of not undergoing treatment except that your condition may worsen. Progression of chronic venous insufficiency may lead to more serious consequences such as skin changes, ulcers or sores, swelling, phlebitis, or bleeding.

#### Potential Benefits

The purpose of the procedure and potential benefits are reduction in size or closure of treated varicose veins, improvement in varicose vein related symptoms, and prevention or treatment of ulcers, swelling, and other more serious conditions associated with chronic venous insufficiency.

#### Alternative Treatment

Some patients may get adequate relief of venous insufficiency symptoms by wearing graduated compression stockings. Alternative treatments for varicose veins include surgical stripping, ambulatory phlebectomy, sclerotherapy, and other treatments similarly aimed at removing, destroying, or closing the great or small saphenous veins, including radiofrequency and laser ablation.

I acknowledge that I have read and understand the above and that I have been adequately informed of the nature, intended purpose and significant risks and consequences of Endovenous Cyanoacrylate Ablation (Venaseal), as well as alternative treatment methods. I acknowledge that I have been given ample opportunity to ask questions about my condition and treatment options. I hereby authorize and consent to Endovenous Cyanoacrylate Ablation performed by Dr. Arnold P. Robin MD or Dr. Dean T. Velis MD. I also authorize the taking and use of photographs.

Patient Name	Signature	Date
Witness	Signature	Date

I have discussed the nature and purpose of Endovenous Cyanoacrylate Ablation (Venaseal™) and the associated risks, consequences, and available alternatives with the person signing above, and I am satisfied that he/she understands.

Physician	Date
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