CONSENT FOR TREATMENT: EVLA/TCC/USGS

I authorize the performance of one or combination of the following procedures to be performed on me at Vein Clinic PA by a Phlebologist (a qualified board certified Physician, Nurse Practitioner, or Physician Assistant): Endovenous Laser Ablation (EVLA), Transcatheter Closure (TCC), Ultrasound Guided Sclerotherapy (USGS), and microphlebectomy. It has been explained to me, that during the course of my treatment, an alteration in the appropriate course of effective treatment may occur and may be altered and I agree, by my consent, to pursue this course of treatment as recommended. If I do not acknowledge this, I agree to verbalize this to my Phlebologists and ask that a separate consent be dated and signed by me.

The following is a list of categories of potential, theoretical and known risks which may occur and are difficult to predict in individual patients. I have reviewed the attached information which has been provided in the “Disclosure of Possible Risks and Complications” (pages 3-7). I have also carefully reviewed my medical history and have provided accurate information about my past medical history. All my questions concerning any part of my history, the procedure, alternatives and the risks and potential complications have been fully discussed and answered to my satisfaction. Further, it has been discussed and I fully understand that the treated area may likely look worse, before it looks better and that this treatment is not for cosmetic reasons.

General Risks and Complications (for all injections and Vein Clinic PA procedures), include: firmness or “lumps” under the skin, in the vein, an ulceration or sore at the site of the injection, a blister and/or inflammation of hair follicles at the site of the tape compression, brown pigmentation (or hyperpigmentation) at the treated site, neovascularization or “matting”, allergic reactions to sclerosing agents, visual disturbances, accidental injection into the artery instead of a vein in ultrasound guided sclerotherapy, superficial thrombophlebitis. In very rare instances, a portion of the clot can travel to the deep system and cause a DVT. Blood clots in the deep venous system, DVT or Deep Venous Thrombosis has been reported (0.001%) with Sclerotherapy. A pulmonary embolus may result from a blood clot in the deep vein. For most people, needle punctures into the vein do not cause any serious problems. However, dizziness, minimal bleeding, bruising, itching, discomfort, pain and rarely, infection, may occur. Local anesthesia will be used to minimize discomfort. In rare cases, people may have an allergy to lidocaine and/or sodium bicarbonate and/or a preservative used by manufacturers in the preparation of medications. If an allergic reaction occurs, very rarely this can cause a systemic allergic reaction or toxicity. Nitroglycerine topical cream is sometimes used to relax and dilate the vein in preparation of accessing the vein for the procedure. Patients will occasionally complain of a headache or feeling of “racing heart” during or following the procedure. Swelling of the ankle or foot may occur temporarily following a series of injections. As with any medical procedure, there are statistically remote events which could theoretically occur and, without proper medical treatment, in the rare occurrence of a serious complication, may result in permanent injury or death. Therefore, I agree to notify Vein Clinic PA if I experience any complication or side effect.
Disclosure of Possible Risks and Complications

In Addition to Above – The Following are Risks and Complications Associated with EndoVenous Laser Ablation (EVLA) and Transcatheter Closure (TCC):

EndoVenous Laser Ablation (EVLA) may cause a thermal injury (burn) to the overlying skin or intervening tissue, paresthesia (numbness of an area of skin), nerve damage, breakage of the laser fiber and/or laser tip, loss of guidewire and/or catheter inside the vein, cutting of the laser tip, and perforation of the catheter. Loss of guidewire can also occur during a Transcatheter Closure (TCC).

Laser therapy carries a risk of damage to the unprotected eye. You will be provided with safety goggles designed to greatly reduce any risk to the eyes from the laser. On occasion, patients have experienced light-headedness, nausea, sweating, possible shortness of breath, heart palpitations, and syncope.

I certify that I have carefully read this consent and I understand the risks associated with treatment, as well as the alternative treatment methods. I certify that I am a competent adult of at least 18 years of age. In addition, I agree that any pictures taken of my treatment site may be used for publication or teaching purposes; however, my name will not be disclosed and complete confidentiality will be maintained.

By my signature below, I certify that I have read and fully understand the contents of this Consent for Treatment pages 1-7 and I hereby authorize the Phlebologist to carry out this treatment. In the event I do experience any complications or side effect I will notify Vein Clinic PA and my Phlebologist(s) immediately. I am aware that a printed copy of the Consent for Treatment is available to me upon request, as well as an electronic copy is viewable at www.VeinClinicPA.com

Patient Signature

Sign here

Date: ________________

Witness Signature

Date: ________________

Practitioner’s Use Only:

I have discussed the patient’s medical history and condition, the proposed treatment and available alternatives, and answered all questions including those concerning this consent. I am satisfied with the patient’s understanding of this information.

Practitioner’s Signature: ____________________________ Today’s Date: __________
DISCLOSURE OF POSSIBLE RISKS AND COMPlications

Varicose Vein Treatments including Endovenous Laser Ablation (EVLA), Transcatheter Closure (TCC), Ultrasound Guided Sclerotherapy (USGS), and Microphlebectomy

PLEASE READ CAREFULLY

Varicose veins and venous insufficiency are chronic, recurrent conditions; there is no definite cure but rather these conditions are controlled by treatment. Heredity is the major cause of this vein defect and new veins may develop in the future depending on your genetic predisposition and aggravating factors, not because you have had treatment. Additional treatment, or “maintenance,” may be necessary in the future. Our aim is to give you a minimum of 70% improvement of your current condition. However, as with any medical treatment or procedure, an individual’s result cannot be guaranteed. In rare instances you may have a recurrence of your veins to some degree. Therefore, we are unable to give any promise or guarantee as to the final results. Additional or follow-up treatments outside of the estimate quoted may be needed; these services are at an additional fee.

Alternative Procedures to Endovenous Laser Ablation (EVLA), Transcatheter Closure (TCC), Ultrasound Guided Sclerotherapy (USGS), and Microphlebectomy are available.

There are alternative treatments for various veins. The treatment of varicose veins is often medically necessary, but it is not generally considered a life-threatening condition. The procedure is for therapeutic benefit and not required. There are conservative forms of treatment which may provide some benefit including compression stockings, leg elevation, and others such as exercise. There are alternative medical procedures for the closure or removal of varicose veins, such as conservative therapy, surgical ligation and surgical stripping, endovenous chemical ablation, endovenous thermal ablation with radiofrequency or a combination of treatments and procedures. The other option is to receive no treatment at all.

Although, the chances of a serious adverse reaction to EVLA, TCC, USGS, and Microphlebectomy are remote, the following is a list of adverse reactions that may occur and are difficult to predict in individual patients:

General Risks and Complications for all Injections and Procedures:

1. Firmness or “lumps,” also known as “nodularity” or trapped blood, in the vein under the skin can occur with or without local tenderness. This collection of blood in the vein is an expected part of the treatment process. Needle aspiration can be done to hasten dissolution. Expected clearance may take weeks or months.

2. An ulceration or sore (cutaneous necrosis) at the site of the injection can be caused by infiltration of the solution into the tissues around the vein, may take several months to heal and may leave a scar. It is a rare occurrence in our patients.
3. Although using tape is avoided whenever possible, a blister and/or inflammation of hair follicles at the site of the tape compression area may occur. This is usually associated with “hairy” areas of the skin.

4. Patients may experience moderate to severe pain following the procedure. However, pain is variable by procedure and pain tolerance level. Efforts are made through technique and numbing practices to reduce the amount of pain that patients experience during the procedure. After the procedure the treated area may be painful and produce uncomfortable sensation along the vein route or treated region. This discomfort is usually temporary and resolves in a few weeks.

5. Brown pigmentation (hyper pigmentation) or staining at the treated site occurs 10-15% of the time. This may be increased in patients with dark complexions. The pigmentation fades with time, sometimes lasting up to 12-24 months. Rarely is the pigmentation permanent. (Avoiding tanning is recommended during treatment since tanning can worsen this condition. If unavoidable, using a complete sun block, such as zinc oxide, over these areas when in the sun will hasten the fading of this pigmentation.)

6. Neovascularization – growth of new veins or “matting” may occur when the body responds to the injection of varicose veins by making new, fine, red capillaries seen on the surface of the skin. This occurs to some degree in approximately 15% of all patients. When this occurs, the area will be pink, red or purple. Matting does not cause any of the symptoms of varicose vein disease. Therefore, if treatment is desired, this is considered cosmetic and would be at the patient’s expense. If matting occurs, the following options will be reviewed and the Phlebologist will make a recommendation: a) Allow time for the area to clear up on its own, usually 3-6 months; b) Injection treatments directly into the fine veins; c) Referral for laser and/or intense pulsed light treatment.

7. The primary sclerosing agent (solution) used in at Vein Clinic PA is Sodium Tetradecyl Sulfate (STS). When it is deemed necessary, other FDA approved sclerosing agents may be used. Allergic reactions are possible but rare, occurring on average in .3% of all patients. In order to provide more information on STS and its actions, we have compiled for you a summary of its general properties.

STS is a long-chain fatty acid salt. It works initially by causing the vein to spasm, then by causing a fibrous cord to develop inside the treated vein, which prevents blood from flowing through the vein. Over a period of several months, the vein will be reabsorbed by the body. This solution has been used for over 40 years in Europe, and for over 25 years in the U.S. Its effects have been extensively studied on both animal and human veins, and it has been proven to be safe when used by experienced Phlebologists.

STS is effective for a limited distance from where it is originally injected. Because of this, STS will not travel to your heart, lungs, liver or other internal organs and cause damage.
Disclosure of Possible Risks and Complications

to them. The damage that STS causes is limited to the general area where it is injected, which in turn limits the risks involved in using it.

Some patients are concerned about having STS used on their veins when they have a Sulfa allergy. The name Sulfa comes from Sulfanilamide, which is the original Sulfa drug. A Sulfa drug is a class of antibiotics. A Sulfate is very different than Sulfanilamide—it is a naturally-occurring mineral salt compound found in numerous substances as varied as soil, drinking water, soaps, detergents, paper, glass, shampoos, and textiles. So, in short, Sulfa drugs and sulfates are not related, and a person who has an allergy to Sulfa can safely be given Sodium Tetradecyl Sulfate.

8. Although safety measures are taken to reduce the risk, there remains the remote chance of accidental injection into the artery instead of a vein in ultrasound guided sclerotherapy. This could cause extensive damage to the skin, soft tissue and/or muscle and would likely result in immediate transport to the hospital. This is an extremely rare incident.

9. Superficial Thrombophlebitis is a blood clot in the treated, superficial vein due to inflammation. This occurs secondary to venous insufficiency and varicose veins even without treatment. This occurs in approximately .05 to 1.7% of veins from small to larger blood vessels. Usual treatment is anti-inflammatory medication, ice and compression stockings. In very rare instances, a portion of the clot can travel to the deep system and cause a deep vein thrombosis (DVT).

10. Blood clots in the deep venous system may result in rare instances. DVT or Deep Venous Thrombosis has been reported (0.001%), with Sclerotherapy, but is extremely rare when compression stockings are used. Continued activity, thereby keeping blood flowing naturally and freely through the legs, can also reduce the risk of DVT. A pulmonary embolus (blockage of an artery in the lung) may result from a blood clot in the deep vein.

11. For most people, needle punctures into the vein do not cause any serious problems. However, dizziness, minimal bleeding, bruising, localized Urticaria (itching), discomfort, pain and rarely, infection, may occur. Local anesthesia will be used to minimize discomfort. In rare cases, people may have an allergy to lidocaine, used as a local anesthetic and/or sodium bicarbonate and/or a preservative used by manufacturers in the preparation of medications. If an allergic reaction occurs, it is usually temporary and can include, tingling, hives, or a brief feeling of shortness of breath. Very rarely this can cause a systemic allergic reaction or toxicity.

12. Nitroglycerine topical cream is sometimes used to relax and dilate the vein in preparation of accessing the vein for the procedure. Patients will occasionally complain of a headache or feeling of “racing heart” during or following the procedure. Tylenol or Ibuprofen is recommended for this and you are advised to inform us at your next visit of this reaction.
13. Swelling of the ankle or foot edema may occur temporarily following a series of injections and use of compression hose will reduce the chances of swelling.

14. An unusual visual disturbance may occur called Scintillating Scotomata, reported as flickering lights in the center of the vision field or an arc of shimmering lights preceding a migraine headache.

15. On occasion, patients have experienced light-headedness, nausea, sweating, shortness of breath, heart palpitations, and syncope. These can be the result of anxiety or stress or as a result from a diagnosed or undiagnosed medical condition.

16. As with any medical procedure, there are statistically remote events which could theoretically occur and, without proper medical treatment, and in the rare occurrence of a serious complication, may result in permanent injury or death. Therefore, the patient must notify Vein Clinic, P.A. if the patient experiences any complication or side effect.

In Addition to Above, the Following Are Risks and Complications Associated with Endovenous Laser Ablation (EVLA) and/or Transcatheter Closure (TCC):

17. Bruising and discoloration at the area of treatment are very common with Endovenous Laser Ablation (EVLA) and less common with Transcatheter Closure (TCC), but should disappear spontaneously in the time frame of your own normal healing process.

18. Thermal injury (burn) to the overlying skin or intervening tissue (occurring less than 1% of all patients).

19. Paresthesia (numbness of an area of skin) occurs in approximately 8-9% of all patients, which usually resolves in several months. On occasion there can be trauma to the surrounding nerves, which can result in transient numbness, and in rare situations can be permanent;

20. Loss of guidewire can occur during a Transcatheter Closure (TCC). Breakage of the laser fiber and/or laser tip, loss of guidewire and/or catheter inside the vein, cutting of the laser tip, and perforation of the catheter can occur with Endovenous Laser Ablation (EVLA). These events are possible but very remote and reduced by techniques used by Vein Clinic PA. If the tip of the laser, part of the catheter or the guide wire gets lodged inside the vein, a small incision may need to be performed to facilitate removal. It is also possible that this may result in transportation to a hospital.

21. Laser therapy carries a risk of damage to the unprotected eye. You will be provided with safety goggles designed to greatly reduce any risk to the eyes from the laser.
Disclosure of Possible Risks and Complications

There are medical conditions which may contribute to the risks from a procedure due to bleeding, being prone to infections, allergies or other complications. It is essential that patients provide complete and accurate information about their past medical history.

There may be risks associated with not undergoing treatment for a superficial venous disease, including a worsening of the condition over time, with symptoms of ankle swelling, restless leg syndrome and potential changes in the skin. If left untreated blood clots could develop, as well as venous ulcers.

Please discuss all concerns you have on the risks, complications, and side effects described above with your practitioner before signing the Consent for your procedure.