ENDOVENOUS LASER ABLATION / PHEBECTOMY INFORMED CONSENT

Patient Name: ____________________________________________ Date: ____________

INTRODUCTION: Lasers have been used for numerous medical applications throughout the body. Over the last few years, a technique utilizing laser energy delivered endovenously (directly inside the vein) has been developed to treat varicose veins. In this procedure, a laser will be used to deliver the laser energy via a small laser fiber that is inserted into your vein to permanently close the vessel. Endovenous laser ablation (EVLA) treatment and phlebectomy are performed under local anesthesia in the doctor’s office. Sedation medication is entirely optional. Generally you should be able to walk immediately following the laser procedure. EVLA treatment does not include actual removal of the varicose veins and is generally performed on the deeper subcutaneous veins whereas phlebectomy actually removes the secondary superficial ropy varicose veins.

PROCEDURE DESCRIPTION: At your first visit, the doctor interviewed you, which included a pertinent medical history to venous disease. This also included a physical examination including a pertinent examination of your venous disease. The work-up included a duplex ultrasound-imaging exam of your venous anatomy. Images of this exam were saved in the ultrasound and stored. Your results of the history, physical exam, and ultrasound exam confirmed that you have significant venous reflux disease and are a candidate for the endovenous laser ablation procedure and phlebectomy. Photographs of your leg may have (or may be) taken before you undergo the procedure.

On the day of the procedure, your leg may be pretreated with some nitro-paste and 15 minutes of walking to help dilate the vein in the area of needle access. Your leg to be treated will be first cleansed and draped for a sterile procedure. Next, the vein to be treated will be accessed with a needle and a tiny guidewire will be threaded into the vein. The area along the path of the treated vein will be anesthetized with the local anesthetic, Lidocaine. A sterile laser fiber will be inserted into the problem vein and positioned using ultrasound guidance in the leg, generally at a place above where you see your varicose veins. The laser energy will be delivered selectively to treat the target vein. The actual laser treatment only takes a short time. Subsequently phlebectomy will then be performed. After injecting a local anesthetic agent (lidocaine) around each of the problem varicose veins, a small incision is made over each varicose vein or in the vicinity of a cluster of varicose veins. A phlebectomy hook and other instruments are then used to destroy, disrupt, or remove the secondary varicose veins. This treatment removes the segment of varicose vein or disrupts the flow of blood along the varicose vein causing the residual removed vein segment to close off. Healing takes a few weeks. Improvement is usually seen within a few weeks. The number of diseased veins that can be treated at any one time depends upon whether the veins are small or medium or large varicose veins and the extent of varicose veins to be treated. After the procedure, a tight bandage wrap will be applied to your treated leg, and must be worn continuously for a period specified by the doctor. You will return to the office within 2 weeks and the doctor will re-examine the treated vein with ultrasound and gross visual inspection. Additional photos may be taken. In less than 5%, a repeat endovascular laser treatment or alternate vein closure procedure may be needed to treat the problem vein if it has not completely permanently sealed shut. Remember this is usually the first step in treating your venous disease.

RISKS AND DISCOMFORT: If you undergo endovascular laser therapy or phlebectomy for varicose veins, your symptoms of varicose veins typically improve, sometimes remain the same, and rarely worsen.

The potential risks of the laser procedure are: thermal injury (burn) to the overlying skin or surrounding tissue which could lead to scarring; perforation of the vein leading to bruising and bleeding; breakage of the laser fiber requiring retrieval; superficial phlebitis (self-limited inflammation of the superficial vein); paresthesias (numb or prickling sensation or a section of the skin of the leg); hyperpigmentation (darkening of the overlying skin); infection; creation of a blood clot in the deep veins that could dislodge and cause a pulmonary embolism (a clot to the heart and lungs). Some of the potential complications such as skin burns, vessel perforation, and blood clots (deep venous thrombosis, pulmonary embolism) may need to be treated with additional surgery or medicines. Of all of the preceding potential complications named, bruising and superficial phlebitis are the most common. The others mentioned are rare.

The potential risks of phlebectomy are: Brown spots (hyperpigmentation) may appear that look like bruises or follow the path of the vein. These brown areas take a few weeks to months to go away. It is rare for any discoloration to be permanent. Wearing compression stockings will reduce hyperpigmentation. Blistering, infection, skin necrosis / ulceration, and scarring may develop the small incisions. This is usually not a problem except possibly in smokers.
Tenderness, bruising, or firmness (especially along the larger vessels) in the treated area may last for varying periods of time. This can be minimized by the use of support hose after the treatment. Sometimes blood may accumulate in the larger superficial veins treated by sclerotherapy, causing a superficial phlebitis (blood clot). Accumulations maybe able to be treated by the physician to decrease any discomfort by aspirating or incising the vein and extract the clot. Strict use of support hose minimizes this possibility. Additional charges to treat the phlebitis may apply if treatment is necessary.

Rarely, deep venous phlebitis and thrombosis (DVT) may occur. The risk of this occurring is less than 1%. There is an even smaller risk of thrombopulmonary embolism (clot to the lung). Following the post treatment recommendations will minimize these problems. Injury to sensory nerves may occur and is usually temporary but could be permanent. Injury to the nerves may also occur from too much compression from the worn stockings. This usually resolves spontaneously.

Contraindications: Individuals with significant arterial circulation problems in the legs, poor general health, bronchial asthma, uncontrolled diabetes, numerous severe allergies, known hypercoagulability (high risk of blood clot formation), acute deep venous thrombosis (DVT), active infection, air travel post treatment, or pregnant women or within 3 months of pregnancy should not undergo this procedure.

For most people, needle punctures into the vein do not cause any serious problems. However, the needle puncture may cause dizziness, minimal bleeding, bruising, discomfort, pain, and rarely infection. Local anesthesia (usually Lidocaine) will be used to minimize discomfort. Rarely, people have an allergy to Lidocaine. Notify the doctor if you have an allergy to lidocaine or any local anesthetic drug.

POTENTIAL COMPLICATIONS OF NO TREATMENT: Potential complications of not undergoing endovenous laser treatment are most often related to worsening of the condition over time making the venous insufficiency more difficult to successfully treat. Most commonly, there will be an increase in the size and number of varicose veins. In cases of large varicose veins, spontaneous superficial phlebitis or bleeding may occur. The bleeding has the potential to be severe. Patients with varicose veins associated with underlying venous insufficiency may develop ankle swelling, and skin changes (eczema and/or hyper-pigmentation), and if severe venous insufficiency, non-healing skin ulcers can develop and become infected.

ALTERNATIVE TREATMENTS: Since varicose veins are only life threatening if associated with non-healing ulcers that become severely infected, or cause spontaneous severe hemorrhage; endovenous laser therapy or phlebectomy are not mandatory. Some patients may get adequate symptomatic relief by wearing graduated compression stockings. There are other treatments performed for varicose veins that include surgical ligation and stripping, ultrasound-guided sclerotherapy, or a combination of these treatments. The current medical literature supports endovenous laser treatment and phlebectomy of varicose veins as having the least potential side effects, and lowest risk for recurrence within 5 years.

POTENTIAL BENEFITS: Endovenous laser treatment causes closure of and phlebectomy removes the problem vein that is causing the venous reflux thereby also reducing refluxing of blood into the secondary tributary veins. This treatment usually results in improvement in varicose vein-related symptoms. Most patients have additional venous disease requiring additional treatment such as sclerotherapy in order more completely treat all of the patients venous disease and symptoms. There is no absolute guarantee that you will receive any medical benefit as a result of endovenous laser treatment, but the majority of patients undergoing this procedure do report resolution/lessening of pain complaints, reduced or resolved swelling, and improved appearance of the treated leg.

Unforeseen conditions may arise during the course of the procedure that may lead to a need for additional or different procedures than those discussed with me. Therefore, I authorize my doctor or nurse practitioner to perform such procedures and treatments as are in his/her judgment, necessary or advisable. Rare events such as stroke, heart attack, loss of consciousness, or seizures are possible

By signing below, I acknowledge that I have read and understand the above and I have been adequately informed of the nature, intended purpose, and significant risks and consequences of endovenous laser treatment, (EVLT) and phlebectomy. I have also been informed of alternative treatment methods for my condition. I acknowledge that I do not have an allergy to Lidocaine or any of the “-caine drugs”. I acknowledge that I do not have a pacemaker, internal defibrillator, or other active implanted device. If I do have such an implanted device then arrangements with cardiology and the device manufacturer have been made through Dr Caudle’s office. I hereby authorize consent to
perform EVLT and phlebectomy. I also authorize the taking and usage of photographs of my legs, procedure, and outcome.

It is important to realize new varicosities may occur over the years. Many people will require treatments from time to time to keep their legs clear. Standing occupations, pregnancy, and estrogen increase this tendency. If you want to maximize your chance of a good long-term result, it is important in order to wear your gradient support stockings for 1 week continuously post treatment and then up to 3 weeks during the day to solidify your early results.

I hereby authorize Dr. Scott Caudle to treat: ________ my right - left - great - less - saphenous - perforator- or other accessory – vein(s) using an endovenous laser ablation technique and to treat __________ right/ left leg with phlebectomy.

Patient Signature: ________________________________ Date: __________________________

Witness: _______________________________________ Date: __________________________

I have discussed the nature and purpose of endovenous laser treatment (EVLT), and the associated risks and consequences and available alternatives, with the patient signing above. And I am satisfied that he/she understands them.

Physician Signature: ________________________________ Date: __________________________