

INFORMED CONSENT FOR ENDOVENOUS LASER TREATMENT (EVLT)

This form is designed to provide you with the information you will need to make an informed decision about whether to have treatment performed. If you have any questions or do not understand any potential risks, please ask for an explanation.

PREGNANCY/NURSING

This procedure will carry risk to a fetus if performed on pregnant women. It is the patient's responsibility to inform the staff if pregnant or if there is even a remote chance of pregnancy.

Furthermore, some medications can be released into breast milk. If you are currently nursing, please notify the staff.

SIDE EFFECTS / RISKS OF THE PROCEDURE

The nature of the procedure(s) to be performed has been explained to me. I understand that complete resolution of my vein problem cannot be guaranteed. I understand that the treatment plan may change depending on my response to treatment, and that a variety of treatments over time is very commonly needed. It is not unusual for the treatment plan to change over time. I understand that there are expected side effects and also risks associated with the proposed treatment. I understand that the complications listed below do not represent an all-inclusive list, and unforeseen complications can occur in any medical procedure.

The most common side effects of EVLT include post-operative bruising and pain. Complete resolution of varicose veins is typically not the result of EVLT. Many patients require further treatments after successful EVLT to resolve their problems.

It is also important to understand that saphenous veins are often used by surgeons to create bypasses for a variety of bypass operations such as coronary bypass surgery and leg bypass operations. Not all saphenous veins are actually suitable to be used for such operations and there are alternatives to using saphenous veins as well. However, if we close a saphenous vein with the EVLT procedure it will no longer be usable in the future for a bypass operation.

Deep vein thrombosis is a rare complication (<1/1000). The dangers of deep vein thrombosis include the possibility of pulmonary embolus which can be fatal. Post-phlebotic syndrome resulting in a permanent swelling of the leg can also result. Treatment requires the use of blood thinners (anti-coagulants). Clots in superficial skin veins (phlebitis) is not unusual and represents limited medical risk.

Thermal injury is a rare complication of laser treatment which can result in skin burns and/or ulceration. Thermal injury can result in permanent scar formation.

Nerve Injury can result in either tingling (paresthesia) or numbness in the area affected. Nerve injury is not typically serious but the symptom can be long lasting, often a year or more in duration, and occasionally is permanent.

Recanalization can also occur. This results in the re-opening of the treated vein. This may require repeat EVLT or other treatments.

Skin Discoloration can result. This is almost always temporary but permanent skin discoloration can occur in the skin overlying the treated vein.

ALTERNATIVE TREATMENTS

I understand that alternative treatments for varicose veins exist. Because varicose veins and

spider veins are not typically life-threatening conditions, treatment is not mandatory in most patients. Many patients get adequate relief of symptoms from wearing graduated support stockings.

Surgical vein ligation and stripping is an alternative treatment for large varicose veins. This usually requires a hospital stay and is performed while the patient is under general anesthesia. Risks of vein ligation and stripping are similar to that of ambulatory phlebectomy and sclerotherapy with the additional risk of the general anesthetic and painful surgical wounds. General anesthesia has some associated serious risks, including the possibility of paralysis, brain damage, and death. The other option is to receive no treatment at all.

PROPOSED TREATMENT RESULTS

I know the practice of medicine and surgery is not an exact science, and therefore, reputable practitioners cannot guarantee results. While the overwhelming number of patients have noted gratifying symptomatic and cosmetic improvement, Dr. Cohen and his staff cannot promise nor guarantee any specific result and do not attempt to do so. I understand that treatment of vein problems frequently requires a variety of treatments over a period of time. I understand it is important to, and agree to, keep Dr. Cohen and staff informed of any changes in my medical condition and cooperate with them in my after care, including keeping appointments, wearing my compression stockings as advised. I understand that I need to be accessible for follow up visits for expected or unexpected problems so that Dr. Cohen and staff can adequately follow up and provide treatment as necessary.

INFORMED CONSENT

By signing below, I acknowledge that I have read the foregoing informed consent form and that I understand the nature and risks of the proposed treatment, alternative methods of treatment, and the risks of not treating my condition, and I hereby consent to endovenous laser treatment. I hereby authorize David E. Cohen to perform Endovenous Laser Ablation Therapy (EVLT) for the purpose of closing my incompetent vein.

