LASER VENOUS ABLATION TREATMENT CONSENT FORM

What is Consent and what does it mean?

Consent to treatment means that you as the patient must give permission before you receive any type of medical treatment, test or examination. This must be done on the basis of and following an explanation by a clinician. You must have agreed to what actually will happen and must have been given by the person who is to be treated.

What is Endovenous Laser Treatment/Ablation?

Venous Ablation Therapy (Endovenous Laser Treatment (EVLT/EVLA)) is a minimally invasive option for treating venous incompetence (leaky valves). The first stage of your procedure will involve inserting a catheter up the affected vein under Ultrasound guidance. Your leg will then be numbed with a local anesthetic agent. During the second stage of the treatment, the catheter will be slowly retrieved. As it is removed, it seals the affected vein closed. This will relieve the backflow pressure, which is causing your varicose veins. Following the procedure, we will put you in a compression dressing, which you will sleep in for one night. You should then wear your compression garment for the next seven days (or as instructed).

Few weeks following your ablation we will evaluate your results using Ultrasound. If we find any branches that need to be further addressed, we may recommend treating them with a procedure called Ultrasound-guided sclerotherapy or microphlebectomy. Utilizing Ultrasound, the varicose vein is visualized on a screen. The physician uses this technology to guide the placement of a needle directly into the abnormal vein. A sclerosing agent is injected directly into the vein(s). This causes an irritation to the inner lining of the vein, resulting in closure of the vein(s).

Varicose Veins and Spider Veins are chronic and recurrent conditions. The variety of treatments available will not offer a cure, but rather a control of the condition. Surgically removed veins cannot come back; veins that are sclerosed generally will not return. However, your tendency towards developing new veins will not be relieved by this or any other form of treatment.

Contraindications for EVLT/EVLA Treatment

Contraindications include but are not limited to the following:

- Patients with thrombus in the vein segment to be treated;
- Patients who are pregnant or breast feeding;
- Other complications may be raised by the individual physician at the time of consultation or treatment;

Note extremely tortuous vein segments may require treatment by alternative techniques (phlebectomy, sclerotherapy).

Potential Risks and Side Effects

All surgical interventions carry an inherent risk of infection, allergic reaction, bleeding and anesthetic complications including cardiopulmonary complications. Below are possible risks and side effects that are specific to endovenous laser ablation.

Allergic reaction: While extremely rare, allergic reactions to the anaesthetic agent can occur. The risk of this is greater in patients who have a history of allergies.

Pain: Patients may experience moderate to severe pain following the procedure. The leg may be tender to the touch after treatment and/or an uncomfortable sensation may run along the vein route. This discomfort is usually temporary.

Swelling: Usually occurs after treating veins in the leg. It usually resolves in a few days but may last a few weeks, especially after treatment of large varicose veins. Wearing the prescribed compression hose lessens leg swelling.

Thrombophlebitis- The EVLT works by producing inflammation of the veins-(called thrombophlebitis). For some people, this reaction can be exaggerated to produce lumpy veins. All the reactions and lumpiness will disappear in due course.

Skin Burns: Utilizing ablative therapy carries a risk of skin burns; this may require further surgical treatment.

Damage to the eyes: Laser therapy carries a risk of damage to the unprotected eye. You will be provided with safety goggles to protect your eyes (EVLT only).

Vessel perforation: Vessel perforation can occur with ablative therapy. This is a small hole in your vein and will usually heal completely on its own.

Hematoma: Bruising is very common around the injection site and can last several days or weeks. Trapped blood may cause discolouration, which may need additional treatment.

Infection: As with any surgical procedure there is a risk of infection. We use the sterile technique with all procedures to reduce this risk.

Nerve trauma: Tiny sensory nerves run alongside your veins. Occasionally, there can be trauma to these surrounding nerves, which can result in altered sensation. This may be described as burning, tingling, or pinpricks. These usually resolve with time. In rare instances, the localized sensation may be permanent.

Neovascularization: The development of new, tiny blood vessels may occur at the site of sclerotherapy treatment. These tiny veins can appear days or weeks after the procedure. They often fade within three to twelve months without further treatment.

Haemorrhage: Bruising is very common after ablative therapy, specifically around the treated area. It can last several days or weeks.

Pulmonary embolism/ Deep Vein Thrombosis: This is an unusual complication; the dangers of phlebitis (vein inflammation) include the possibility of pulmonary embolus (a blood clot carried to the lungs) and post-phlebitic syndrome, resulting in a permanent swelling of the leg.

Transient hyperpigmentation: Some discolouration after treatment is common. This discolouration is usually transient and will resolve in about three months. In some cases, this darkening of the skin may persist up to a year or longer.

Nodularity: Nodularity at the site of vein treatment may persist for up to a year or longer. This occurs when there are pieces of the vein that remain in the body and have scarred down and become hard. With time, the body will absorb and soften these areas.

Skin ulceration: Skin ulceration can occur at the site of injection. This is an uncommon complication. In the event of a skin ulcer it may take months for the area to heal.

Reoccurrence of new veins: When a patient has varicose veins, it is usually an ongoing problem. Several years after the vein has been treated the body will attempt to repair itself by taking veins that were insignificant and make them significant.

Spider Veins: Occasionally occur along the path of the treated areas.

Recurrence of veins- There is a small chance of recurrence of varicose veins. It may take few years for the recurrence to establish. EVLT is known to be successful in 97% of the patients.

I am aware that in addition to the risks listed above, there are other risks that may accompany any surgical procedure, such as loss of blood, infection, and inflammation in the venous system with the formation of a thrombus (clot), postoperative bleeding, and nerve trauma that may lead to temporary or permanent numbness. I consent to the local anaesthesia to be administered. I am aware that risks are involved with the administration of local anaesthesia such as allergic or toxic reactions to the anaesthetic and cardiac arrest.

Potential Benefits of EVLT/EVLA

Endovenous laser treatment causes closure of 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 an improvement in varicose vein-related symptoms. Most patients have additional venous diseases requiring additional treatment such as sclerotherapy in order to treat all of the patients' venous diseases 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.

Evidence suggests that EVLT achieves vein closure in 97-98% of patients for 5 to 10 years.

Alternative Treatments

Since varicose veins are only life-threatening if they cause spontaneous severe hemorrhage or clot formation very close to a junction, endovenous laser therapy or phlebectomy are not mandatory. Some patients may get adequate symptomatic relief by wearing graduated compression stockings. Stocking however is not a treatment for varicose veins. 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 of varicose veins as having the least potential side effects, and the lowest risk for recurrence within 5 years. I have been made aware of these alternatives.

The other option is to receive no treatment at all.

Effect 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. The condition can transfer from a stage of reversible changes to a stage of irreversible changes like skin pigmentation. 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- irreversible), and if severe venous insufficiency, non-healing skin ulcers can develop and become infected.

Informed Consent

By signing below, I acknowledge that I have read the foregoing information and understand the risks and possible side effects, alternative methods, and potential benefits of treatment, and I hereby consent to the treatment.

I know the practice of medicine and surgery is not an exact science, and therefore, reputable practitioners cannot guarantee results. While the overwhelming numbers of patients have noted gratifying symptomatic and cosmetic improvement, we cannot promise or guarantee any specific result.

Patient Signature: _____ Date:_____

Print Patient name:_____

Physician's Signature: _____ Date:_____

Print Physicians name:_____

Witness Chaperone Signature:_____ Date:_____