

**Gilvydis Vein Clinic**  
**Informed consent for “EndoVenous Laser Ablation (EVLA)”**

“**EndoVenous Laser Ablation**” is a minimally invasive option for greater saphenous vein incompetence (leaky valves). The first stage of your procedure will involve inserting a catheter fiber into the leg vein, advancing it up the greater saphenous vein (the root of your problem) under ultrasound guidance. Your leg will then be anesthetized with a local anesthetic agent. During the second stage of the treatment, the laser, while firing, is removed slowly; as it is removed it destroys the greater saphenous vein. This will relieve the back flow pressure, which is causing your varicose veins. If the doctor deems it necessary, foam sclerotherapy, the injection of a foamed sclerosing agent into the vein, may be incorporated into your laser procedure. Following the procedure we will put you in a compression stocking which you will sleep in for two nights, and then wear for the next ten days.

After your laser procedure we will continue to evaluate your results using ultrasound. If we find anymore diseased veins remaining we will destroy them with a procedure called “**Ultrasound Guided Foam Sclerotherapy**”. Using ultrasound, the Physician guides a needle directly into the diseased vein. He then injects a foamed sclerosing agent directly into the vein. This causes an irritation to the inner lining of the vein resulting in closure of the vein.

Varicose 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 or lasered will not return. However, your tendency towards developing new veins will not be relieved by this or any other form of treatment.

**Potential Risks and Side Effects:** All invasive procedures carry inherent risks. Below are possible risks and side effects that are specific to EndoVenous Laser Ablation.

- **Allergic reaction:** Very rarely, a patient may have an allergic reaction to the anesthetic agent. The risk 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 an uncomfortable sensation may run along the vein route. This discomfort may last up to 4 weeks.
- **Swelling:** This may occur after treating veins in the leg. It usually resolves in a few days but may last a few weeks, especially after

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treatment of large varicose veins. Wearing the prescribed compression hose lessens swelling.

- Skin Burns: Laser therapy carries a risk of skin burns requiring further 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.
- Deep Vein Thrombosis: A very rare complication, the dangers of thrombosis include the possibility of pulmonary embolus (a blood clot carried to the lungs) and post thrombotic syndrome, resulting in a permanent swelling of the leg.
- Transient Hyperpigmentation: Patients who have had EndoVenous Laser Therapy may notice some discoloration after treatment. This discoloration is almost always transient and will resolve in about three months. In rare cases this darkening of the skin may persist up to a year.
- Nodularity: Nodularity at the site of vein removal may persist for up to a year. 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 but some may persist.
- Skin Ulceration: This is a rare complication. In the event of a skin ulcer it may take months for the area to heal.
- Nerve Trauma: Occasionally there can be trauma to surrounding nerves, which can result in a transient numbness that will resolve on its own with time. In rare instances the localized numbness may be permanent.
- Reoccurrences 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. We recommend a yearly follow up with ultrasound so that we can detect any new problems and treat them accordingly as they arise.

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- Rare Side Effects: Arterial injection which can cause discomfort, scarring of the skin, injury to muscle or nerves or other tissues, or loss of limb. Neurological events can also occur more commonly in individuals with a history of migraine headaches or a known symptomatic right-to-left heart shunt (patent foramen ovale). Neurological side effects may include temporary visual and speech disturbances, headaches and transient ischemic attack (TIA). There have been rare cases of a cerebrovascular accident (CVA) reported in the literature.

I am aware that in addition to risks listed above, there are other risks that may accompany any invasive procedure, such as but limited to loss of blood, infection, inflammation in the venous system with formation of a thrombus (clot), postoperative bleeding, nerve trauma that may lead to temporary or permanent numbness, allergic reaction and anesthetic complications including cardiopulmonary complications.

#### **Alternative Treatments:**

-Because varicose veins and spider veins are not life threatening conditions, surgical treatment is not mandatory in every patient. Some patients get adequate relief of symptoms from wearing graduated support stockings.

-Surgical stripping may also be used to treat large varicose veins. This usually requires a hospital stay and usually is performed while the patient is under anesthesia. Risks of vein stripping are similar with the additional risk of the general anesthetic.

-The other option is to receive no treatment at all.

#### **Photographs:**

I do \_\_\_\_\_ or do not \_\_\_\_\_ (please initial) consent to photographs and other audio-visual and graphic materials before, during, and after the course of my treatment to be used for medical, marketing, and education purposes.

Although the photographs or accompanying material will not contain my name or any other identifying information, I am aware that I may or may not be identified by the photos.

#### **Informed Consent:**

-I authorize the physician to perform a Stab Phlebectomy of my right/left leg varicose vein if deemed necessary. I understand this means that the physician will introduce small incisions above the veins to remove the vein segments. The physician will give local anesthetic at each incision site.

-I consent to the local anesthesia to be administered. I am aware that risks are involved with the administration of local anesthesia such as allergic or toxic reactions to the anesthetic and cardiac arrest.

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-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.

-By signing below, I acknowledge that I have read the foregoing information and understand the risks of Endovenous Laser Ablation (EVLA) alternative methods of treatment, and the risks of not treating my condition. I have been given the opportunity to ask questions and I believe I have sufficient information to consent to treatment.

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Patient Printed Name: \_\_\_\_\_

Physicians Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_