

**Informed Consent**

**Microfoam Venous Ablation (Varithena)**

**Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of Birth\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Leg and Vein(s) to be Treated:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Dr. James St.George has explained to me that I suffer from chronic venous insufficiency of the lower extremity superficial vein(s.) This is the result of abnormal valves within the vein(s) that allow pooling of blood in the legs. This may cause some or all of the following symptoms: leg heaviness, aching, cramping, swelling, restless legs, sensory skin symptoms and prominent visible veins.

**Procedure:**

Varithena microfoam is a minimally invasive option for treating greater saphenous vein and tributary vein incompetence (leaky valves). The first stage of your procedure will involve inserting a catheter or needle into the vein under ultrasound guidance. Your leg may be anesthetized with a local anesthetic agent, lidocaine. During the second stage of the treatment, the Varithena microfoam is inject thru the catheter or needle under ultrasound guidance. This will cause the vein to spasm and ultimately close decreasing the venous insufficiency within the leg. Following the procedure we will put you in a compression wrap, which you will wear constantly for 2 days, and then wear only during the day for the subsequent 12 days.

I understand that closure of the saphenous vein(s) treats the underlying cause of your symptoms and visible veins, but will not remove or eliminate the visible surface veins. The latter require treatment by other techniques such as phelbectomy and/or additional sclerotherapy.

Varicose Veins and Spider Veins are chronic and recurrent conditions. The variety of treatments available

will not offer a cure, but rather a control the condition. *However, your tendency towards developing new veins will not be relieved by this or any other form of treatment.* We recommend yearly ultrasound exams to follow yourprogress.

**Potential Risks and Side Effects:** All surgical interventions carry an inherent risks. of infection, allergic

reaction, bleeding and anesthetic complications. While unusual, the following are possible risks and side effects that are specific to Radiofrequency Vein Closure:

* **Allergic reaction:** Very rarely, a patient may have an allergic reaction to the anesthetic agent or the microfoam. The risk of this is greater in patients who have a history of severe allergies.
* **Pain:** Whilemost patients have only minimal to mild tenderness or discomfort after the procedure. Occasionally some patients may experience moderate to severe pain following the procedure. The leg may be tender to the touch after treatment, and an uncomfortable or pulling sensation may run along the vein route. This discomfort is usually temporary.
* **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 treatment of large varicose veins. Wearing the prescribed compression hose lessens ankle swelling.

**Deep Vein Thrombosis** is a very rare complication (<0.2%.) The large majority of these are minor and many do not require further treatment. However, while very rare, a large blood clot has the possibility of pulmonary embolus (a blood clot carried to the lungs) and post-phlebotic Syndrome which could result in permanent pain and swelling of the leg.

* **Transient hyperpigmentation:** Some patients may notice some red or brown discoloration of the skin along the course of the vein after treatment. This is usually due to the treated vein being located very close to the skin surface. This discoloration is almost always transient and will resolve. In rare cases this darkening of the skin may persist up to a year.
* **Nodularity:** Nodularity at the site of vein closure 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.

* **Nerve trauma:** Occasionally there can be trauma or irritation to surrounding nerves, which can result in a local numbness that will often resolve over the course of many months. In rare instances the localized numbness may be permanent.

I am aware that in addition to 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 formation of a

thrombus (clot), postoperative bleeding, and nerve trauma that may lead to temporary or permanent

numbness.

**Benefits:** The benefits of the procedure have been explained to me. Specifically, these are to eliminate some or all of the symptoms associated with chronic venous insufficiency. I understand that similar symptoms may also be caused by other medical conditions. There is no guarantee of either the results of the procedure or the freedom from potential complications.

**Alternative Treatments:**

Because varicose veins and spider veins are not life-threatening conditions, treatment is not

mandatory. 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 is usually performed while the patient is under general 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.

**Informed Consent:**

By signing below, I acknowledge that I have read the foregoing information and understand the risks and

possible side effects, alternative methods of treatment and I hereby consent to the treatment. I have had sufficiency opportunity to discuss my condition and proposed treatment and all my questions have been answered.

I consent to the local anesthesia to be administered. I am aware that risks are involved with the

administration of any local anesthesia such as allergic or toxic reactions to the anesthetic and cardiac arrest. While the overwhelming number of patients have gratifying symptomatic and cosmetic improvement, I understand that the practice of medicine and surgery is not an exact science, and therefore, reputable practitioners cannot guarantee results.

Patient Name (printed):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Provider Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_