



### INFORMED CONSENT FOR VEIN SCLEROTHERAPY/VARITHENA PROCEDURE

PATIENT: \_\_\_\_\_ DOB: \_\_\_\_\_

PHYSICIAN NAME: ANIL KUMAR, M.D.

DATE OF PROCEDURE: \_\_\_\_\_

SIDE:  Left Leg  Right Leg

VESSEL:  GSV  SSV  ASV

**Procedure Details:** Sclerotherapy is the injection of the medication (Sclerosant) via needle into an unwanted vein. The goal is to irritate and scar the vein from the inside such that these abnormal veins close and no longer fill with blood. Several treatments are usually required to obtain maximum improvement. The two types of chemical injectable medications are Polidocanol, and Sotradecol

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.

**Potential Risks and Side Effects:** Following possible risks and side effects that are specific to Sclerotherapy/Varithena Vein procedure, have been explained to me in a language I understand:

1. **Firmness or Lumps** under the skin in the vein with or without local tenderness or dark streak like discoloration at the area of the injected veins are common. This bruising or collection of blood in the vein is an expected part of the treatment process. Needle aspiration is done to hasten dissolution. Expected clearance may take months.
2. **Inflammatory Reaction** or chemical phlebitis following sclerotherapy develops in 1-3% of cases and only with patients with varicose veins. It may sometimes be painful to the touch; however, the reaction is temporary, and easily treated with anti-inflammatory medication.
3. **Bruising and Discoloration** at the area of treatment, compressed veins are common; but will resolve spontaneously based on your individual healing process.
4. **Ulceration or Skin Sore** may occur at the site of injection due to infiltration of the solution into the tissues around the vein, this may leave a scar. This is an extremely rare occurrence, however is a possibility.
5. **Brown Pigmentation** at the treated site that occurs approximately 10-15% of the time. This may increase in patients with dark complexions. The pigmentation fades over time, sometimes lasting 12-24 months. Rarely is the pigmentation permanent.
6. **Blushing** may occur when the body responds to the injection of veins by making fine red capillaries. When this occurs, the area will become pink, red, or purple and may appear bruised. The following options will be reviewed and the provider will make recommendations: (a) Allow time for the area to clear on its own, usually 3-6 months. (b) Further injections and treatments with stronger solutions. (c) Laser and/or intense pulsed light.
7. **Accidental Injection into the Artery** instead of vein is possible although very rare. This could cause extensive damage to the skin, soft tissue, and/or muscle.
8. **Visual Changes** or scotomas can occur with injection of sclerosant agents. This is experienced as a flashing of lights or blotching in the visual field, usually on a transient and temporary basis.

9. **Neurological Deficits;** Headache, Dizziness, Blurry Vision, Transient Ischemic Attacks, Stroke have been reported rarely.
10. **Allergic reaction** is a possibility, although quite rare. It usually manifests itself by hives, although respiratory problems have been reported.
11. An even more rare complication is **Embolia cutis medicamentosa syndrome**, a painful discoloration that can result in skin loss.
12. **Deep Vein Thrombosis** (blood clot) and/or pulmonary embolism can occur in an extremely rare circumstance with sclerotherapy. Postthrombotic syndrome may develop and could result in permanent pain and swelling of the leg.
13. **Failure to close the vein** (or reopening) occurs in ~15%.
14. Very rarely AV Fistula (i.e., an abnormal connection between an artery and a vein), bleeding from the access site, Hematoma (i.e., collection of blood outside the vessel), Infection or ulceration at the Access Site, Cellulitis, Visible Scarring, Paresthesia (i.e., tingling, numbness and burning).

I further understand that it is imperative for me to follow up with the treating doctor for any signs or symptoms of complications for they are better managed if addressed early.

**Alternative Treatments:** Because varicose veins and spider veins are not life-threatening conditions, Endovenous sclerotherapy vein treatment is not mandatory. Some patients get adequate relief of symptoms from wearing graduated support stockings/wraps. Surgical stripping, Endovenous thermal ablations, & Venaseal may also be used to treat large varicose veins. The other option is to receive no treatment at all.

### AUTHORIZATION

1. **Operation/Procedure:** I authorize the performance of the above Operation/Procedure by or under the direction of the Physician, and his/her assistant surgeon/associate or other individuals as necessary. I understand and agree that under the supervision of my Physician, allied health professionals (MA, RN, Technicians), Other physicians, residents/fellows, may participate in my care. Physician has explained to me the nature and purpose of the Operation/Procedure, the alternative treatment to the Operation/Procedure, and the possible complications.
2. **Additional Operation/Procedures:** I also authorize the performance of additional operation/procedures that the above-named Physician may deem necessary to adequately treat the above probable diagnosis.
3. **Operation/Procedure Complications:** I understand that, there is no operation/ procedure in which complications have not been reported. Most complications are of a minor nature and respond to treatment. Serious complications can occur in any operation/procedure including death of the patient, excessive bleeding, nerve and blood vessel injury, infection, allergic reaction, complications due to anesthetics, heart attack or stroke.
4. **Results Not Guaranteed:** I understand that no guarantee or assurance has been made as to the results of the Operation/ Procedure and that it may not cure the condition.
5. **Follow up Care:** Varicose Veins and Spider Veins are chronic and recurrent conditions. I am informed that, the variety of treatments available will not offer a cure, but rather control the condition. I am aware that new veins may form in future and may require further treatments. Veins once treated are not available as a conduit for future bypass surgery.  
I understand and agree that the recommend continuation of conservative therapy (Avoidance of immobilization, Periodic Leg elevation, Feet exercises, Compression therapy) and a regular follow up to monitor progress is a must for long term optimal venous health.

6. **Photography/Videotape:** I consent to photographing/ videotaping of operations or procedures showing portions of my body for medical, scientific or educational, promotional advertisements purposes providing that my identity is not revealed. I acknowledge that I will not receive any compensation for this. I hereby release Houston Heart Health Team/Agents from any claims which arise out of such use.

6. **Allergy/Anaphylaxis Education:** I have received education about anaphylaxis reaction that can rarely happen after Vein Ablation/Sclerotherapy.

7. **Residual Symptoms:** I further attest that I currently have leg symptoms despite use of conservative therapy.

I HAVE READ AND UNDERSTAND THE ABOVE AUTHORIZATION

PATIENT OR PERSON WITH AUTHORITY TO CONSENT/DECLINE FOR THE PATIENT SIGNATURE	DATE	TIME
WITNESS SIGNATURE		

**PHYSICIAN DECLARATION:** I have explained the contents of this document to the patient and answered all the patient's questions, and to the best of my knowledge, the patient has been adequately informed. The patient has consented.

PHYSICIAN SIGNATURE

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