

R. Randolph Waterford, MD, FACS, RVT, RPVI Sclerotherapy Consent Form

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Varicose Veins and Spider Veins are chronic and recurrent conditions. The varieties of treatments available do not offer a cure, but rather a control of the condition. Successfully treated veins cannot come back. However, your inborn tendency to develop new veins will not be cured by this or any other form of treatment.

INJECTION SCLEROTHERAPY

This is the most popular method of eliminating superficial telangiectasias ("spider veins") and small varicose veins. A solution called a sclerosing agent, either Polidocanol or Sotradecol, is injected into the veins with a very small needle. The majority of patients who have sclerotherapy performed will achieve a vast improvement.

<u>Sclerotherapy never leads to one hundred percent perfection</u>. Unfortunately, there is no guarantee that sclerotherapy will be effective. Less than 10% of patients who undergo sclerotherapy have fair to poor results. In rare instances, the patient's condition may become worse after sclerotherapy treatments.

The number of treatments will vary from person to person and Dr. Waterford has discussed with me the minimum number of treatments that I will most likely require. In addition, although the treatments are carried out meticulously and with the assistance of the highest quality imaging techniques, under magnification, there will undoubtedly be veins that are missed or overlooked. Also, some veins may not be completely eradicated the first time they are treated. Hence, the importance of at least 2-3 treatments per leg. This way we can achieve close to 100% coverage of the treated leg.

ULTRASOUND GUIDED INJECTION SCLEROTHERAPY

This is used to treat varicose veins, which are not visible on the surface of the leg. Imaging modalities are used to guide needle placement and monitor the injection of the sclerosing agent.

RISKS/SIDE EFFECTS OF SCLEROTHERAPY

The most common side effects experienced with sclerotherapy treatment include but are not limited to:

- 1. <u>TRANSIENT HYPERPIGMENTATION</u>: Approximately 10% of patients who undergo sclerotherapy notice a discoloration (light brown streaks) after treatment. This usually fades in 4 to 6 months. In rare instances, this darkening of the skin may persist for years. We have some treatment alternatives should this occur that might lessen the discoloration. Patience is usually the best approach.
- 2. <u>ULCERATIONS</u>: This occurs in less than 1% of patients who receive sclerotherapy. Ulceration near the injection site can occur and may take a few months to heal. A blister may form, break open, and become ulcerated which may or may not leave a scar. Antibiotic therapy may be indicated. This is problem is minimized through meticulous techniques that we use here at the vein center.
- 3. <u>ALLERGIC REACTIONS</u>: Very rarely a patient may have an allergic reaction to the sclerosing agent. The most common allergic reaction is hives, usually occurring during the treatment session, although a life threatening reaction can always occur. This is usually fairly easy to treat with Epinephrine, Benadryl and/or topical lotions that we keep here at the Center.
- 4. <u>PAIN</u>: A few patients may experience moderate pain usually at the site of the injection. The veins may be tender to the touch after treatment, and an uncomfortable sensation may run along the vein route. This discomfort is temporary and is best treated by our compression stockings. If this does not subside you can alert the physician.
- 5. <u>TELANGIECTATIC MATTING</u>: This refers to the development of new very fine blood vessels in the area of the treated vein. This phenomenon occurs 2 to 4 weeks after treatment and usually resolves within 4 to 6 months. It occurs in up to 20% of women receiving estrogen therapy and in 2% to 4% of all patients. Again, patience is usually the best remedy.
- 6. <u>ANKLE/LEG SWELLING</u>: This may occur after treating veins in the lower leg. It usually resolves in a few days but may last a few weeks, especially after treatment of larger varicose veins. Wearing the prescribed support/compression stockings lessens ankle swelling.
- 7. <u>DEEP VEIN PHLEBITIS</u>: This is a <u>very rare</u> complication seen in approximately 1 out of 10,000 patients treated in the U.S. The dangers of phlebitis include the possibility of pulmonary embolus (a blood clot carried to the lungs) and post phlebitic syndrome (a permanent swelling of the leg). In most cases eliminating varicose veins actually decreases the risk for deep vein phlebitis.



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8. <u>ARTERIAL INJECTION</u>: This is also a <u>very rare</u> complication seen in approximately 1 out of every 100,000 patients treated across the U.S. The dangers of injecting into an artery are severe tissue loss and ischemia of the limb or foot.

ALTERNATIVE TREATMENTS (OTHER OPTIONS)

- 1. I understand that other treatments for varicose and spider veins exist.
- 2. Because varicose veins and spider veins are not life-threatening conditions, treatment is not mandatory.
- 3. SUPPORT/COMPRESSION HOSE: Many patients get adequate relief of venous symptoms from wearing support stockings. This is a conservative way to manage venous symptoms but does nothing to get rid of varicose veins or spider veins.
- 4. ANOTHER OPTION IS TO RECEIVE NO TREATMENT AT ALL.

PROPOSED TREATMENT RESULTS

The practice of medicine is not an exact science, and therefore, reputable practitioners cannot guarantee results. While an overwhelming number of patients have gratifying symptomatic and cosmetic improvement, the Waterford Vein Institute of Hawaii cannot promise or guarantee any specific result and does not attempt to do so. I understand that sclerotherapy treats only those veins that are currently visible and it does not prevent new veins form surfacing in the future. I also recognize the need to keep the Waterford Vein Institute of Hawaii office informed of any changes in my medical condition and cooperate with them in my after-care, including any changes in my address and phone number. (Note: smokers have more side effects and poorer results than non-smokers)

INFORMED CONSENT

Understanding all of the above, I hereby provide informed consent to the Waterford Vein Institute of Hawaii physician and/or assistants to perform sclerotherapy upon me. I confirm with my signature below that my physician has discussed all the above information with me, that I have had the chance to ask questions, and that all my questions have been answered to my satisfaction, and that I have been given a copy of this Sclerotherapy Consent Form.

In addition, I have been given a copy of the Waterford Vein Institute of Hawaii's sclerotherapy policy. This discusses, in detail, our policy with regards to insurance reimbursement and payments for sclerotherapy. We want our patients to be familiar with our office's specific policies regarding payment for cosmetic spider veins. Please sign below after all of your questions have been fully answered and you have been given a separate copy of our sclerotherapy policy form.

Patient's Signature	Date	
Witness	 Date	
	NING CONSENT to the patient. In my judgment, the patient has been provided with sufficient efits involved in order to make an informed decision and I was given a copy of	:
Physician	Date	