

INFORMED CONSENT FOR SCLEROTHERAPY

This Informed Consent Form is designed to provide you with the information you will need to make an informed decision about whether or not to have SCLEROTHERAPY performed. If you have any questions or do not understand any potential risks, please do not hesitate to ask for help.

WHAT IS SCLEROTHERAPY?

Sclerotherapy is a popular method of eliminating varicose veins and superficial telangiectasias (“spider veins”) in which a solution, called a sclerosing agent is injected into the veins and/or a laser is used to help eliminate the veins. Sclerotherapy has been safely and effectively performed for over 50 years. Multiple solutions have been used over the years. Currently, Polidocanol and Sotradecol are commonly used throughout the world. At this time, neither are FDA approved.

DOES SCLEROTHERAPY WORK FOR EVERYONE?

The majority of persons who have sclerotherapy performed show improvement of their varicosities, or at least see some improvement. Unfortunately, there is no guarantee that sclerotherapy will be effective in every case. Approximately 10% of patients who undergo sclerotherapy have fair to poor results. (Poor results mean that the veins will not disappear and rarely even worsen.)

HOW MANY TREATMENTS WILL I NEED?

The number of treatments needed to clear or improve a condition differs from patient to patient, depending on the extent of varicose or spider veins present. One to six or more treatments may be needed; the average is three or four.

WHAT ARE THE MOST COMMON SIDE EFFECTS?

The most common side effects experienced with sclerotherapy are:

1. **TRANSIENT HYPERPIGMENTATION:** Approximately 5-10% of patients who undergo sclerotherapy notice a discoloration of light brown streaks after treatment. This usually fades in two to twelve months.
2. **SLOUGHING:** This occurs in less than 3% of patients who receive sclerotherapy. Sloughing consists of a small ulceration at the injection site that heals slowly. A blister may form, open, and become ulcerated. After healing, the skin should return to a normal color. You may have what looks like a chicken pox or vaccination scar.
3. **ALLERGIC REACTIONS:** Very rarely, a patient may have an allergic reaction to the sclerosing agent used. This risk of allergic reaction is greater in patients who have a history of allergies.
4. **PAIN:** A few patients may experience moderate pain and bruising, usually at the site of injection. The veins may be tender to touch after treatment and an uncomfortable sensation may run along the vein route. This discomfort is temporary, in most cases lasting one to seven days.

WHAT ARE THE OTHER SIDE EFFECTS?

Other side effects include a burning sensation during injection of some solutions, development of new tiny blood vessels (“matting”), transient swelling of the vein which could cause the ankles to swell, temporary superficial blebs or wheals (similar to hives), and very rarely, wound infection, poor healing or scarring.

Deep vein thrombosis is a very rare complication, seen in approximately 1 out of every 1,000 patients treated. The dangers of thrombosis include the possibility of pulmonary embolus (a blood clot carried to the lungs) and post phlebitis syndrome, resulting in permanent swelling of the leg. Inadvertent arterial injection and possible severe tissue damage are other rare complications.

WHAT ARE THE POSSIBLE COMPLICATIONS IF I DO NOT HAVE TREATMENT?

In cases of large varicose veins, spontaneous phlebitis and/or thrombosis (blood clot) may occur with the associated risk of possible embolus. Additionally, large skin ulcerations may develop around the ankles with permanent pigmentation (staining) of the skin.

ARE THERE OTHER TYPES OF PROCEDURES TO TREAT VARICOSE VEINS?

Surgical stripping and/or ligation may also be used to treat large varicose veins. This generally requires a hospital stay and is performed while the patient is under general anesthesia. Surgery and general anesthesia have some associated risks. The other option is to receive no treatment at all.

By signing below, I acknowledge that I have read the foregoing Informed Consent Form and that I understand the risks of sclerotherapy treatment, alternative methods of treatment, and the risks of not treating my condition, and I hereby consent to sclerotherapy treatment.

Patients Signature

Date

Witness

Date

Signature of physician providing explanation

Date