

SCLEROTHERAPY CONSENT FORM

You have the right to be informed about your treatment so that you will make the decision whether or not to undergo the procedure after knowing the risks involved. Disclosure is not meant to scare or alarm you; it is simply an effort to better inform you so that you may give or withhold your consent for the treatment. Please initial each section to indicate that you understand each topic.



A) PROPOSED TREATMENT

I have requested that Dr. _____ attempt to eliminate my spider veins using sclerotherapy. A solution, called a sclerosing solution, is injected into small and medium sized veins, which causes an irritation to the inner lining of the vein and causes it to close off. A fine needle is used to perform the injections and most patients relate the discomfort to a barely noticeable pinprick feel. Initials: _____

There are two FDA approved sclerosing agents for the treatment of leg veins—Sotradecol and Polidocanol. Both solutions are comfortable to use, effective, and have very low incidence of allergies or side effects. A foam sclerosant is sometimes created using these solutions to enhance the effectiveness when treating larger veins. This is a well reported technique in the literature and widely performed by physicians, but the FDA has not approved those uses. Hypertonic saline (salt solution), though not approved specifically for treatment of leg veins, has been widely used for this purpose, especially in patients with moderately serious history of allergies and asthma. Initials: _____

B) ANTICIPATED BENEFITS

The majority of persons who have Sclerotherapy performed have satisfying results. Unfortunately no medical technique is perfect and no two patients are alike. Accordingly, there is no guarantee that Sclerotherapy will be effective for you. Approximately 10% of patients who undergo sclerotherapy have fair to poor results. Others may see new veins develop in the areas of treatment. Initials: _____

Fading of the vessels occurs gradually, over a period of months. Initials: _____

The number of treatments needed differs from patient to patient, depending on the extent of the problem. A single blood vessel may have to be injected more than once, usually 1-2 months apart, depending on its size. After several treatments (3-5 on average), most patients can expect 70-90% improvement. Initials: _____

I understand that several sessions may be needed to complete the injection series. I understand that there is a separate charge for any subsequent treatment. Initials: _____

C) RISKS AND COMPLICATIONS

As the vessels close up, they go through the inflammation process. This takes several weeks to resolve, and it is common for the veins to look worse immediately after the procedure. Initials: _____

Side effects that may occur with Sclerotherapy include:

- **Brown lines or spots on the skin.** Approximately 20% of patients who undergo sclerotherapy notice a discoloration (light brown streaks) after treatment. This usually fades in 4-12 months. In rare instances this darkening of the skin may persist for years.
- **Matting** refers to the development of tiny blood vessels that looks like blush areas. These may develop in the treated areas, occurring in 2-4% of all patients treated and up to 18% of women taking estrogen. This temporary phenomenon occurs 2 to 4 weeks after treatment and usually resolves within 4 to 6 months. Rarely, these can be persistent and, in some cases, permanent. These are usually, but not always, more attractive than the vessels that were originally treated.
- **Skin Sloughing** associated with sclerotherapy is very rare complication. A blister may form and create an open sore. Healing occurs slowly over a few months. After healing, this may leave a lightened scar.
- **Superficial thrombophlebitis** is an irritation or inflammation of the treated vessel. This rare complication shows up as a local area of redness along the treated vein that is tender to touch. It is usually treated with anti-inflammatory or antibiotics and is not necessarily dangerous but mostly annoying. These areas may sometimes require a small nick to the skin to drain.
- **Allergic Reaction** Very rarely, a patient may have an allergic reaction to the sclerosing agent. The risk of this is greater in patients who have a history of allergies.
- **Deep Vein Thrombosis** is a very rare complication in approximately 1 out of 1000 patients treated for large varicose veins. The risk of this in treatment of spider veins is extremely low. The dangers of phlebitis include the possibility of pulmonary embolus (a blood clot carried to the lungs) and post phlebitic syndrome, resulting in a permanent swelling of the leg.
- **Pulmonary embolus and neurological symptoms/damage** (migrane, headache, vision change) have been rarely reported. Initials: _____

- **Most Common Side Effects** The veins may be tender to the touch after treatment, and feel lumpy and hard under the skin along the vein route. This discomfort is usually temporary. Temporary bruising and mild swelling are common and should be expected. It is also common to get red, raised areas at the sites of injections. These should disappear within a day or so. Some patients complain of an itchy sensation after treatment for 1-2 days, which is also very normal. Trapped blood may cause a discoloration, which can be flushed out, although this may leave hyperpigmentation up to one year.
- **Temporary bruising** is common and should be expected. Substances that increases the risk of bruising including Vitamin E, Aspirin, Motrin, Advil, Aleve, Plavix, Coumadin, and other non-steroid anti-inflammatory drugs. I understand If I have taken any of the above within the past 7 days, I have an increased risk of bruising. Initials: _____

This procedure is not recommended for pregnant women or nursing mothers. I am not pregnant or nursing. Initials: _____

Please also complete reverse side.

C) RISKS AND COMPLICATIONS (cont.)

Dr. _____ has explained to me the importance of **wearing compression stockings for 2-3 weeks** after treatment to reduce the risk of bruising and swelling or other complications. This may help seal the treated vessels, keep the blood from collecting under the skin, and reduce the development of dark spots. It may also reduce the number of treatments necessary, and the possibility of recurrence. I have been given preop and post op instructions. I understand that there may be a higher possibility of side effects if I do not adhere to the preop and post op instructions.

Initials: _____

D) LIMITATIONS AND ALTERNATIVES

A treatment may be effective for variable lengths of time with subsequent treatments, may not work as well as expected, or may not work at all. Alternatives to Sclerotherapy for spider veins include laser treatment and no treatment at all.

Initials: _____

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.

Initials: _____

It is very important to realize that Sclerotherapy and Laser do not prevent the development of new spider veins and varicosities later in life. Many people require treatments from time to time to keep their legs clear.

Initials: _____

E) PHOTOGRAPHY

Before and After photographs are an important part of your medical records to document your progress with treatment. I understand and agree to use of my photographs in my patient record and decision making.

Initials: _____

I understand and agree to use of my before and after treatment photographs for use in medical education and research.

Initials: _____

I will allow use of my pre/post op photos for media relations including advertisements, television, or film.

Initials: _____

F) INFORMED CONSENT

By signing below, I acknowledge that I have read the above information and fully understand the above paragraphs and that I have had sufficient opportunity for discussion and to ask questions.

| 1st Procedure | 2nd Procedure | 3rd Procedure | 4th Procedure |
|---------------------|---------------------|---------------------|---------------------|
| _____ | _____ | _____ | _____ |
| Patient Signature | Patient Signature | Patient Signature | Patient Signature |
| _____ | _____ | _____ | _____ |
| Staff Signature | Staff Signature | Staff Signature | Staff Signature |
| _____ | _____ | _____ | _____ |
| Physician Signature | Physician Signature | Physician Signature | Physician Signature |
| _____ | _____ | _____ | _____ |
| Date | Date | Date | Date |