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SCLEROTHERAPY INFORMED CONSENT

This consent form is designed to provide the information you need to make an informed decision on whether or not to have sclerotherapy. If you have questions, please ask. ***Please read this over carefully.***

WHAT IS SCLEROTHERAPY?

Sclerotherapy is an injection treatment used to eliminate small to medium size varicose veins and superficial telangiectasis called "spider" veins. It is the treatment of choice. A tiny needle is used to inject a sclerosing solution into the vein, which causes the vein to close off and eventually disappear. Once injected, the cells that line the vein wall (endothelium) become irritated, inflamed and damaged. The vein walls seal together with the help of wearing compression hose and eventually your body resorbs the damaged vein.

DOES SCLEROTHERAPY WORK FOR EVERYONE?

The majority of people who have sclerotherapy will see improvement. Unfortunately, it is not guaranteed to be effective in every case. ***Approximately, 10% of veins treated do not disappear after five treatments. You can expect resolution of 50% - 90% of your veins with multiple treatments.*** The number of treatments necessary to clear or improve the condition differs with each patient and depends on the extent of the varicose and spider veins. ***One to five treatments may be needed, but the average is two to three. It is best to wait 6-8 weeks between treatments.***

WHO SHOULD NOT BE TREATED?

Patients with active thrombophlebitis, infection, bleeding and/or clotting disorders, poor circulation, diabetes, patent foramen ovale, people confined to bed rest, a history of pulmonary embolus, clots in the legs or a history of extreme swelling of the feet and legs should not be treated. If you are currently taking Tamoxifen, you should not be treated. Please let us know if you have any of the above conditions or are taking blood thinners such as heparin or coumadin, so we can evaluate you prior to treatment.

WHAT ARE THE MOST COMMON SIDE EFFECTS?

Itching: You may experience mild itching along the injected vein. It usually lasts for one to two days.

Transient Hyperpigmentation: Approximately 90% of patients who undergo sclerotherapy notice a discoloration (light brown/yellow) in the areas treated. In almost every case the veins become darker immediately after the procedure. This usually fades in a couple of weeks, but in 10% to 20% of cases this darkening may persist for 4-12 months. There is a 1% to 2% chance of this continuing after 1 year.

Telangiectatic Matting: The formation of new, fine "spider" veins in the area injected can occur. This is usually a temporary phenomenon and occurs 2-4 weeks after treatment and usually resolves within 4 to 6 months. It occurs in approximately 20% of women taking estrogen and 2% - 4% of all patients. The exact reason that this occurs is unknown. If it does not fade, the area can be re-injected.

PAIN: It is common to have some tenderness at the injection site. Injection of the sclerosing agent can be uncomfortable, but is usually well tolerated. The veins may be tender to touch after treatment. The discomfort is temporary lasting 1 to at most 7 days. Ibuprofen is recommended for discomfort.

BRUISING: This may occur at the injection sites.

TRAPPED BLOOD: Some of the larger veins that we inject (reticular veins) can result in the collection of trapped blood. This consists of old, clotted, semi-liquid blood. It is not dangerous and does not move to other parts of the body. It can delay healing and increase the chance of brown skin discoloration. If you develop a raised or tender area within a treated vein, with or without visible dark blood, notify us and we will evaluate the area. Sometimes we drain the blood using a small needle. This will improve the tenderness and will decrease the likelihood of skin discoloration.

WHAT ARE RARE SIDE EFFECTS?

SLOUGHING: This is a small ulceration at the injection site that heals slowly over 2 to 3 months. This occurs in less than 1% of patients. A blister may form, open and become ulcerated. The scars that follow should return to normal color over the course of about 12 months.

ALLERGIC REACTIONS: Very rarely a patient may have an allergic reaction to the sclerosing agent used. The risk of an allergic reaction is greater if you have a history of allergies or asthma.

PHLEBITIS: This is inflammation of the vein which can cause pain, discoloration and swelling. It develops in approximately 1% to 5% of people following treatment. It occurs more frequently in the treatment of larger veins which have been treated with a "foam" sclerosing agent. Treatment of phlebitis includes wearing compression hose, applying moist heat packs, NSAIDS and frequent ambulation.

PULMONARY EMBOLISM AND DEEP VEIN THROMBOSIS (DVT):

This is the formation of a blood clot that occurs in the deep veins (DVT) which has the potential to travel to the lungs (pulmonary embolism). This usually happens when a large amount of foam is injected into a single vein that is connected to the deep venous system. Taking high doses of hormone replacement and oral contraceptives may also increase the risk of DVT. This is very rare and occurs in approximately 1 out of every 100,000 patients.

AIR EMBOLISM, STROKE, MIGRAINE AND VISUAL DISTURBANCES:

This can occur when a patient has a patent foramen ovale (PFO). It is estimated that approximately 25% of people have a PFO. With the use of foamed sclerosing agents, there is an increased risk of an air embolism going into the cerebral arterial circulation causing minor stroke, migraine and/or visual disturbances. This is very rare occurring in less than 1% of patients.

ANKLE SWELLING:

This may occur after treatment. It usually resolves in a few days and is lessened by wearing your support hose.

INFECTION:

This is rare, but can occur. If it does, we will prescribe an antibiotic.

NORMAL OCCURRENCES AFTER TREATMENT AND NORMAL EXPECTATIONS:

It is important to understand that after treatment it is normal for the treated areas to look worse. Bruising is a normal occurrence and happens almost all of the time. Most people see the bruising go away after 2 weeks, but this can be variable. The treated veins will likely still be present when the bruising goes away. It often takes 4 to 6 weeks for the veins to fade completely. Remember, the area will look **worse before it looks better** and this is perfectly normal.

WHAT ARE POSSIBLE COMPLICATIONS OF NOT RECEIVING TREATMENT:

Because varicose and telangiectatic leg veins are not life threatening conditions, treatment is not mandatory in every patient. In large varicose veins greater than 3 to 4 mm in diameter, spontaneous phlebitis/thrombosis may occur. Additionally, skin ulcerations may develop in the ankle region in people with longstanding varicose veins and underlying venous insufficiency. Small spider veins generally are considered cosmetic and don't cause problems.

WHAT ARE SOME ALTERNATIVE OPTIONS FOR TREATMENT?

Some patients may get adequate relief of symptoms from wearing graduated support stockings. Smaller spider veins can often be treated with lasers with with low risk and shorter recovery, however, pigmentation, recurrence and "skin burning" can be a complication. Ohmic therapy can also be used as an adjunct for treatment of spider veins which we use here at the clinic when appropriate. The other option is to receive no treatment at all.

PROPOSED TREATMENT RESULTS

The practice of medicine and surgery is not an exact science, and therefore, reputable practitioners cannot guarantee results. While the overwhelming number of patients have noted gratifying results, we cannot promise or guarantee any specific result and do not attempt to do so. It is important to keep *You're So Vein* informed of any changes in your medical condition.

RISK OF RECURRENCE

Most patients are pleased with the difference sclerotherapy makes. The skin of your legs will appear younger, clearer and more healthy looking. Often, patients are surprised at the dramatic difference appearance between a treated leg and an untreated one. Although sclerotherapy will obliterate the treated veins for good, it will not prevent new spider veins from developing in the future. You may find that you need minimal "touch-ups" or full treatments for new veins that surface. There is no permanent cure for spider veins.

FEES

It is important to understand that payment for sclerotherapy is your own responsibility and will not be billed to your insurance company. Most insurance companies consider treatment for spider veins cosmetic and will not pay.

BY MY SIGNATURE BELOW, I ACKNOWLEDGE THAT I HAVE READ AND RECEIVED A COPY OF THE YOU'RE SO VEIN AESTHETIC CENTER INFORMED CONSENT. I UNDERSTAND THE RISKS OF SCLEROTHERAPY AND AM AWARE OF ALTERNATIVE METHODS OF TREATMENT AND THE RISKS OF NOT TREATING MY CONDITION.

I HEREBY CONSENT TO PROCEED WITH SCLEROTHERAPY TREATMENT.

WE ARE SCHEDULING A SPECIFIC TIME FOR YOUR APPOINTMENT TO MEET YOUR NEEDS. WE ARE REQUESTING A DEPOSIT OF \$50 TO SCHEDULE YOUR APPOINTMENT. WE REQUIRE 48 HOUR NOTICE OF ALL CANCELED APPOINTMENTS. THIS DEPOSIT WILL BE FORFEITED FOR FAILURE TO DO SO.

Patient Signature

Date

Witness

Date