

VISUAL GUIDED SCLEROTHERAPY

This document is intended to supplement the information already discussed with you during your meetings with Dr. Ragu Murthy and the clinical care team. It applies to the treatment plan that has been reviewed with you and encompasses multiple treatment sessions. This information should enable you to make an informed decision prior to undergoing your treatment.

At the beginning and/or during the course of your treatment, photographs of the area being treated might be taken in order to document the results and effectiveness of treatment. If taken, these will be maintained in your medical record. These photographs might also be used for educational, demonstration, information or research purposes. In this event, there will be no compensation and all personally identifiable information will be removed to protect your identity unless photos are required for health insurance reimbursement purposes or release of this information is as required by law.

Visually Guided Sclerotherapy involves the treatment of veins that are visible at the skin's surface and are readily seen without the use of ultrasound. This procedure involves the injection of a sclerosing agent, or sclerosant, into abnormal veins through a series of treatment sessions. A single treatment session will include multiple injections into affected veins using very small needles. The injected sclerosant produces an inflammatory reaction in the vein wall, causing fibrosis (scarring) and closing of the vein. Over time the vein shrinks to an imperceptible size and is absorbed by the body.

The sclerosants used are Polidocanol and/or Glycerin. Polidocanol and Glycerin are approved by the U.S. Food and Drug Administration (FDA) in certain concentrations. I understand the concentrations of Polidocanol and Glycerin used during treatments at Well & You Vein and Vascular are considered to be "off label", but are considered to be within the standard of care in current national and international medical literature for their ability to close certain veins. I consent to the use of Polidocanol and/or Glycerin for treatments.

It is important to remember that varicose veins and spider veins are part of a chronic, recurrent and progressive condition. Although there are a variety of treatments available for vein disease, no single treatment offers a cure. The goal is to manage the vein disease process by gaining control of the condition. However, it is important to remember that it can be possible to develop new visible veins or abnormality in existing veins. This can occur in treated and untreated areas and your tendency to do so is not relieved by this or any other form of treatment.

It is important to let the healthcare staff know, before each sclerotherapy treatment:

- **If you are pregnant or breast feeding.** The effects of sclerosants during pregnancy and/or while breast feeding are not clear. As a result, they are routinely not recommended for use during pregnancy and/or while breast feeding unless the benefits of treatment clearly outweigh any potential risks.
- **If you are on Birth Control Pills or Hormone Replacement Medications** and have had a recent change in medication (new medication, change in dose, stopped taking). This could put you at increased risk for a DVT, and the physician will need to discuss your situation with you.

Potential Risks and Side Effects

Below are *possible* risks and side effects that relate to Visually Guided Sclerotherapy. Not all risks are significant; not all risks can be foreseen. This is not meant to be an exhaustive listing.

Most Common

- **Bruising:** This is common and an expected side effect. This is always temporary and generally resolves over several weeks.
- **Trapped Blood:** A common occurrence associated with treatment and healing. This can cause hard, tender, and sometimes lumpy areas that either self-absorb or which can be removed during an office visit.

- **Pain:** Patients can experience discomfort with the needle injections. There can also be discomfort associated with bruising. Any pain is temporary. **Appearance of new veins:** When a patient has varicose veins, it is an ongoing problem. At some point in time, spider veins or larger veins can appear along the path of the veins treated with laser or sclerotherapy. Generally, a yearly follow-up with ultrasound is recommended so that new vein abnormalities can be detected and treated accordingly, as they arise.
- **Nodularity:** A hardness or firmness at the sites of vein treatment that can persist for up to a year or longer. With time, the body will soften and absorb these areas, but some can persist for longer periods of time.

Less Common

- **Matting:** Refers to the appearance of tiny spider veins that can occur in association with treatment. Although uncommon, its occurrence is unpredictable and unavoidable when it happens. These miniscule spider veins tend to resolve spontaneously over the course of a few months but can require additional treatment. They are rarely permanent.
- **Bandage or Hose Chafing:** Depending on the location of the vein treatment, the area may be bandaged, or you may be asked to wear compression stockings. Both bandages and compression stockings can dry and/or irritate the skin.
- **Hyperpigmentation:** After treatment, some skin discoloration over the treated vein can remain. This discoloration is almost always temporary and tends to resolve with time. In rare cases this darkening of the skin can persist up to a year, or longer, or can become permanent.

Rare

- **Swelling:** Rarely occurs after treating veins in the leg with Visually Guided Sclerotherapy. Swelling usually resolves in a few days but can last from a few weeks to a year or more.
- **Skin ulceration:** A skin ulcer can develop after Visually Guided Sclerotherapy, but this is a rare occurrence. In the very unlikely event of a skin ulcer development, it can take months for the area to heal, and a small scar will likely form.
- **Allergic reaction:** Very rarely, a patient can have an allergic reaction to the local anesthetic and/or the sclerosants used. The allergic reaction can be mild, such as developing a rash with itching, or more significant, with nausea, vomiting, and/or difficulty breathing. Most allergic reactions can be treated in the office; however, on rare occasions, hospitalization might be necessary.
- **Infection:** While precautions are taken to provide a clean treatment environment, any puncture of the skin carries the risk of infection.
- **Intra-arterial injection:** Intra-arterial injection occurs when the sclerosant is introduced into a superficial artery that might be in close proximity to the vein being treated. This is a very rare complication with Visually Guided Sclerotherapy and can result in a skin ulceration, tissue destruction, and/or even loss of limb.
- **Deep Vein Thrombosis:** A deep vein thrombosis (DVT) is a blood clot that forms in a deep vein and is a very rare complication of any form of vein treatment. A DVT can lead to a pulmonary embolus (PE), which is a blood clot that is carried to the lungs. This is a life-threatening condition that requires hospitalization. In patients having a diagnosed or undiagnosed heart defect, called a patent foramen ovale (PFO), there is the chance a DVT could travel to the brain causing a stroke. A DVT can also lead to post-thrombotic syndrome, which could result in permanent pain, discoloration, and swelling of the affected leg.
- **Localized numbness:** On rare occasion, a nerve near or in the area being treated can be irritated

by an injection. This can result in a temporary numbness that will resolve on its own with time. In extremely rare instances the localized numbness can be permanent.

- **Visual disturbance / Migraine:** In patients with a history of migraine and/or an undiagnosed heart defect, called a PFO, the risk of having a temporary visual disturbance and/or migraine is remotely possible.
- **Blood in the urine:** On extremely rare occasion, Visually Guided Sclerotherapy with Glycerin can cause blood to appear in the urine. This is a benign condition and always goes away after treatment is finished. It is never permanent.

Alternative Treatments

Some patients get adequate relief of their symptoms that arise from their varicose and spider veins by wearing graduated compression vascular support stockings. Superficial laser treatment is also frequently utilized in the treatment of spider and/or reticular veins. The other option is to receive no treatment at all, which can lead to progression of venous disease and attendant complications.