STUDIO MD

INFORMED CONSENT FOR SCLEROTHERAPY TREATMENT

This form is designed to provide you with the information you will need to make an informed decision about whether to have treatment performed. If you have any questions or do not understand any potential risks, please ask for an explanation.

Note: Varicose Veins and Spider Veins are chronic and recurrent conditions. The variety of treatments available will not offer a cure, but rather a control of the condition. Surgically removed veins cannot come back, veins which are successfully closed with chemical will not return. However, your tendency, inborn in the majority of cases, of developing new veins will not necessarily be relived by this or any other form of treatment.

The treatment of large surface varicose veins is usually done with a minor surgical procedure. Hidden large varicose veins can be treated with special injections guided by ultrasound. Medium to small varicosities and spider veins are treated with sclerotherapy, laser or Phototherapy. Your particular condition may require a combination of any or all of these treatments.

AUTHORIZATION FOR VEIN SURGERY
(Only applicable if a surgical candidate)

ANESTHESIA (Only applicable if surgical candidate)

I consent to the anesthesia to be administered by StudioMD doctors or under their direction. I am aware that risks are involved with the administration of local anesthesia and sedation such as allergic or toxic reactions to the anesthetic which could under extreme circumstances lead to cardiac arrest. (Extremely rare)

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. The majority of persons who have sclerotherapy performed will be cleared or at the least see a good improvement (85% improvement is generally felt to be the “industry Standard”). Sclerotherapy never achieves one hundred percent perfection. Unfortunately there is no guarantee that sclerotherapy has fair to poor results. In rare instances the patient’s condition may become worse after sclerotherapy treatment. The number of treatments needed differs from patient to patient, depending on the extent of the problem. You will be given an estimate of the number of treatments when you are examined.

RISKS
The nature of the procedure(s) to be preformed has been explained to me, and I understand that among the known risks are bruising, swelling of the leg, transitory pigmentation, scarring, keloid formation, and secondary telangiectasias (spider veins). See further explanations below.

I am aware that in addition to the minor risk, there are the other risks that may accompany any surgical procedure, such as blood loss, infection, inflammation in the venous system with formation of the thrombus (clot), postoperative bleeding, and nerve trauma that may lead to temporary or permanent numbness.

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RISKS – SIDE EFFECTS

The most common side effects and risks of treatment associated with treatment using sclerotherapy included: (**NOTE: Smokers can have more side effects and less optimal results than non-smokers**

1. TRANSIENT HYPERPIGMENTATION: Approximately 20% of patients who undergo sclerotherapy notice a discoloration (light brown streaks) after treatment. This is generally only in a small portion of the areas treated and usually fades in 4 to 12 months. In rare instances this darkening of the skin may persist for years.
2. SLOUGHING: This occurs in less that 1% of patients who receive sclerotherapy. Sloughing consists of a ulceration near the injection site that heals slowly over a few months. A blister may form, open, and become ulcerated. After healing, they usually leave a scar. (This occurrence represents injection into or near a small artery and is not preventable)
3. ALLERGIC REACTIONS: 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.
4. PAIN: A few patients may experience moderate to severe 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 usually temporary.
5. TELANGIECTATIC MATTING: This refers to the development of new tiny 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 2% to 4% of all patients and can be difficult to treat if it persists.
6. ANKLE SWELLING: 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 large varicose veins. Ankle swelling is lessened by wearing the prescribed support/compression stockings.

OTHER SIDE EFFECTS

Deep vein phlebitis is a VERY RARE complication, seen in approximately 1 out of every 100,000 patients treated. The danger of phlebitis include the possibility of pulmonary embolus (a blood clot carried into the lungs) and post phlebitic syndrome resulting in a permanent swelling of the leg.

POSSIBLE COMPLICATIONS OF NOT RECEIVING TREATMENT

In cases of large varicose veins, spontaneous phlebitis and/or thrombosis (blood clot) may occur with the associated risk of possible pulmonary embolus. Additionally skin ulceration may develop around the ankles of patients with long-standing varicose veins and underlying venous insufficiency.

ALTERNATIVE TREATMENTS

Aside from ambulatory phlebectomy and sclerotherapy, I understand that alternative treatments for varicose veins exist. Because varicose veins and spider veins are not life-threatening conditions, treatment is not mandatory in every patient. Some patients get adequate relief of symptoms from wearing graduated support stockings.

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Surgical stripping may also be used to treat varicose veins. This usually requires a hospital stay and is performed while the patient is under general anesthesia. Risks of vein stripping are similar to sclerotherapy with the additional risk of the general anesthetic. General anesthesia has some associated serious serious risks, including the possibility of paralysis, brain damage, and death.

The other option is to receive no treatment at all.

PROPOSED TREATMENT RESULTS

I know the practice of medicine and surgery is not an exact science, and therefore, the reputable practitioner cannot guarantee results. While the overwhelming number of patients have noted gratifying symptomatic and cosmetic improvement, StudioMD's doctors and staff cannot promise or guarantee and specific results and do not attempt to do so. I understand it is important to, and agree to, keep doctor and staff informed of any changes in my medical condition and cooperate with them in my after-care, including informing the office of changes in my permanent address and phone number. I understand that I need to be accessible for follow up visits for expected or unexpected problems so that the performing doctor and staff can adequately follow up and provide treatment as necessary.

INFORMED CONSENT

By signing below, I acknowledge that I have read the foregoing informed consent form and that I understand the risk of surgical and/or sclerotherapy treatment, alternative methods of treatment, and the risks of not treating my condition, and I hereby consent to vein treatment.

_____ _____

Patient's Signature Date

_____

Physician's Signature

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Polidocanol Injection Informed Consent

I, _____understand that I will be injected with polidocanol in the following areas:

Polidocanol is a sclerosing agent indicated to treat uncomplicated spider veins (varicose veins = 1 mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremity. It has not been studied in larger varicose veins > 3 mm in diameter.

Risks and complications that may be associated with polidocanol injection include, but are not limited to:

1. Anaphylaxis: Severe allergic reactions have been reported following polidocanol use, including anaphylactic reactions, some of them fatal. Severe reactions are more frequent with use of larger volumes (>3 mL). The dose of polidocanol should therefore be minimized. Be prepared to treat anaphylaxis appropriately.

2. Bruising, Redness, Swelling, Itching, Pain, Warming, and Discoloration at injection site: I understand that there is a risk of bruising, redness, swelling, itching and pain associated with the procedure. These symptoms are usually mild and last less than a week but can last longer.

3. Injection site Irritation: I understand that there is a risk of irritation associated with this procedure. As with any transcutaneous procedure, there may be the possibility of swelling or other local reactions.

4. Injection site Necrosis: I understand that there is a risk of necrosis at injection site. Severe adverse local effects, including tissue necrosis, may occur following extravasation.

5. Injection site Neovascularization: I understand that new blood cells may develop due to the trauma at the polidocanol injection site.

6. Injection site Scar: I understand that the polidocanol injection may cause a scar at the injection site.

7. Accidental Intra-arterial Injection: I understand that polidocanol can be accidentally injected into an artery, which may cause severe
necrosis, ischemia, or gangrene.

8. Inadvertent Perivascular Injection: I understand that polidocanol can be inadvertently injected near or around a vessel, which may cause pain.

9. Injection site Thrombosis: I understand that there is a risk of blood clot formation at the site of polidocanol injection.

10. Pregnancy: polidocanol should not be injected in pregnant women. There are no adequate and well controlled studies in pregnant women.

The effects of polidocanol injection on labor and delivery in pregnant women are unknown. It is not known whether polidocanol is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, polidocanol should not be used in nursing women.

The safety and effectiveness of polidocanol in pediatric patients have not been established.

Clinical studies of polidocanol did not include sufficient number of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Overdose may result in higher incidence of localized reactions such as necrosis.

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Post Market Safety Experience: The following adverse reactions have been reported during use of polidocanol in world-wide experience; in some of these cases adverse events have been serious of troublesome. Because these reactions are reported voluntarily from a population of uncertain size and without a control group, it is not possible to estimate their frequency reliably or to establish a casual relationship to drug exposure.

Immune system disorders: anaphylactic shock, angioedema, urticaria generalized, asthma

Nervous system disorders: Cerebrovascular accident, migraine, parasthesia (local), loss of consciousness, confusional state, dizziness

Cardiac disorders: Cardiac arrest, palpitations

Vascular disorders: Deep vein thrombosis, pulmonary embolism, syncope vasovagal, circulatory collapse, vasculitis

Respiratory, thoracic and mediastinal disorders: Dyspnea

Skin and subcutaneous tissue disorders: Skin hyperpigmentation, dermatitis allergic, hypertrichosis (in area of sclerotherapy)

General disorders and injection site conditions: Injection site necrosis, pyrexia, hot flush

Injury, poisoning and procedural complications: Nerve injury

No studies of interactions of polidocanol injection with drugs or other substances or implants have been conducted.

This above list is not meant to be inclusive of all possible risks associated with polidocanol injection or sclerosing agents in general, as there are both known and unknown side effects and complications associated with any medication or sclerotherapy injection procedure. I understand that medical attention may be required to resolve complications associated with my injection.

I have discussed the potential risks and benefits of polidocanol injection with my doctor. I understand that there is no guarantee of any particular results of any treatment.

I understand and agree that all services rendered will be charged directly to me, and I am personally responsible for payment. I further agree, in the event of non-payment, to bear the cost of collection, and/or court costs and reasonable legal fees, should they be required.

By signing below, I acknowledge that I have read the foregoing informed consent, have had the opportunity to discuss any questions that I have with my doctor to my satisfaction, and consent to the treatment described above with its associated risks. I understand that I have the right not to consent to this treatment and that my consent is voluntary.

I hereby release the doctor, the person performing the polidocanol injection and the facility from liability associated with this procedure.

_____ _____

Patient's Signature Date

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Progress Notes

Date: _____ Name: _____

Follow-up date

Signature of consultant