SCLEROTHERAPY INFORMED CONSENT
FOR TREATMENT

I understand that medicine is not an exact science, and that though the vast majority of patients are satisfied with their results, there is no guarantee that I myself will be satisfied with the improvement of my veins after treatment. I acknowledge that the following topics have been fully explained to me, and that I understand the explanations I was given. I have had the opportunity to ask questions. I will be undergoing a vein removal procedure that involves the use of either laser application and or sclerotherapy. This consent form is provided as a means of education between the provider and the patient as to the methods and risks involved in vein removal. I understand that laser application and or sclerotherapy treatments may be repeated several times.

Methods/Options:

1. Prior to any procedure the physician will consult the patient.
2. The consultation time will allow for assessment of the problem, determination of a diagnosis and development of a treatment plan and what my options are if I chose to do nothing about my vein problem.
3. Diagnostic evaluations utilizing Doppler and or ultrasound may be required.
4. Treatments may include both Laser and or Sclerotherapy, using physician-determined appropriate energy levels and dosages.
5. The sclerosing agent, Asclera™ (Polidocanol), may be used in my procedure. Polidocanol is approved by the FDA and is widely used by many vein specialists in the United States and is considered by many specialists to be the safest sclerosing agent with the least amount of side effects
6. Photographs of the treatment area may be taken for the chart and for future comparison.

Risks:

1. Pain, burning, blister formation, and stinging sensation at the treatment site.
2. Infection associated with the treatment site.
3. Pigment(color) changes at the treatment site, including hyperpigmentation (increase in skin color or darkening).
4. Scar formation at the treatment site.
5. Poor cosmetic outcome.
6. Reoccurrence of vessels at the treated site.
7. Allergic reaction possibly severe or life-threatening.
8. Superficial or deep clot formation (deep vein thrombosis).
9. Bleeding and or bruising at the treatment site.
10. Ulcer formation at site of treatment.
11. Temporary phlebitis at the treatment site.
12. Matting (bruised appearance that is often temporary, but sometimes permanent)

Benefits:

1. Lightening of the veins in the treatment site.
1. Complete removal of the veins in the treatment area.

I recognize that even though any particular problem may be extremely rare, it is always possible that any patient may have one of these problems. I accept that possibility for my own treatment. I understand that I am responsible for my own medical bills. I realize that most insurance companies do not cover treatment of spider veins and that I must pay for my treatment today. I authorize this practice to submit my bill to my insurance company and to receive reimbursement. If my insurance company reimburses this practice for the services in which I am paying for today I will receive a refund of payment from this practice.

Patient: _____ Date: _____

Witness: _____ Date: _____

I have discussed the above with the patient and have answered their questions.

Physician: _____ Date: _____

Asclera© (polidocanol) Injection Informed Consent

I, _____ understand that I will be injected with Asclera® (polidocanol) in the following areas:

_____

Asclera® (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.

Do not have Asclera® (polidocanol) Injection if you have a known allergy to Asclera® (polidocanol) or have an acute thromboembolic disease.

Risks and complications that may be associated with Asclera® (polidocanol) Injection procedure 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. Accidental Intra-arterial Injection: I understand that Asclera® (polidocanol) can be accidentally injected into an artery, which may cause severe necrosis, ischemia, or gangrene.

3. Inadvertent Perivascular Injection: I understand that Asclera® (polidocanol) can be inadvertently injected near or around a vessel, which may cause pain.

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 Thrombosis: I understand that there is a risk of blood clot formation at the site of Asclera® (polidocanol) Injection.

6. Injection site Neovascularization: I understand that new blood cells may develop due to the trauma at the Asclera® (polidocanol) Injection site.

7. Injection site Scar: I understand that the Asclera® (polidocanol) Injection may cause a scar at the injection site.

8. 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.

9. 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.

10. Pregnancy: Asclera® (polidocanol) should not be injected in pregnant women. There are no adequate and well controlled studies in pregnant women. The effects of Asclera® (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, Asclera® should not be used in nursing women. The safety and effectiveness of Asclera® in pediatric patients have not been established.

Clinical studies of Asclera® 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.

- **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 Asclera® (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 Asclera® (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 Asclera® (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 Asclera® (polidocanol) Injection and the facility from liability associated with this procedure.

_____		_____	
Patient Signature	Date	Witness Print Name	
_____		_____	
Witness Signature	Date	Witness Address Line 1	