ASCLERA® (polidocanol) Injection Informed Consent

1. 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.

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. 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 Asclera® (polidocanol) injection site.

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

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

8. Inadvertent Perivascular Injection: I understand that Asclera® (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 Asclera® (polidocanol) injection.

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, paraphasia (local), loss of consciousness, confusional state, dizziness
- Cardiac disorders: Cardiac arrest, palpitations
- Vascular disorders: Deep vein thrombosis, pulmonary embolism, syncope vsavoglal, 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.

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