MEDICAL AESTHETICS

HINGHAM | EASTON | MILTON

SCLEROTHERAPY ASCLERA® CONSENT FORM

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INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about ASCLERA® (polidocanol) injections, its risks, as well as alternative treatment(s). It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent as proposed by your provider and agreed upon by you.

ASCLERA® (polidocanol) Injection is a prescription medicine that is used in a procedure called sclerotherapy to remove unwanted veins on your legs. It is administered by a healthcare provider to treat two types of veins:

- Uncomplicated spider veins (very small varicose veins ≤ 1 mm in diameter)
- Uncomplicated small varicose veins (1 to 3 mm in diameter) known as reticular veins

ASCLERA® has not been studied in varicose veins more than 3 mm in diameter.

GENERAL INFORMATION

Procedure: Sclerotherapy is the injection of medication ASCLERA®(polidocanol) via a needle into unwanted veins. The goal is to irritate and scar the veins from the inside such that these abnormal veins close and no longer fill with blood. Several treatments are usually required to obtain maximum improvement.

TREATMENT OPTIONS:

There are generally no major risks if I elect not to have treatment. I am aware that alternative treatments exist and can include no treatment, compression therapy, surgery to excise the veins, and ablation with laser or radiofrequency.

INHERENT RISKS OF ASCLERA® INJECTIONS

There are risks and hazards related to the performance of sclerotherapy planned for me. I realize that complications can occur and include but are not limited to these listed below:

- Brownish discoloration. This is not uncommon but is usually temporary. It could take several months or longer to resolve. It is uncommon for discoloration to be permanent.
- Clusters of spider veins (telangiectatic mattes). These small veins often resolve spontaneously, may need treatment in an attempt to clear them, and could be permanent even with treatment.
- Bruising is common and typically resolves over a few days to weeks.
- Blistering, redness, itching, irritation, swelling or pain can occur but are usually temporary.
- Infection is very rare
- Ulceration and scarring occur rarely.
- Allergic reactions are rare. They range in severity from mild to life threatening reactions.
- Inflammation around a vein can occur. This may be tender but generally resolves with treatment Tenderness, bruising or firmness in the treated area can occur and may be long lasting but rarely permanent.
- Deep vein thrombosis (blood clots) and pulmonary embolism (clot in the lungs) are rare.
- Injury to a nerve, causing either prolonged or permanent discomfort, numbness or difficulty walking is very rare.

- An arterial injection can occur very rarely. Consequences range from discomfort, scarring of the skin, injury to muscle or nerves or other tissue, or loss of limb.
- Other side effects are possible although uncommon.

ADDITIONAL ADVISORIES

MEDICATIONS AND HERBAL DIETARY SUPPLEMENTS:

There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with forming blood clots, and therefore may contribute to more bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, blood vessels with blockages, or blood clots) and are taking medications to thin your blood and prevent clotting such as Plavix, Warfarin, Coumadin, Xarelto, Effient or Pradaxa, discuss management of these medications around the time of treatment with your provider. If you have an adverse reaction, stop the drugs immediately and call your provider for further instructions. If the reaction is severe, go immediately to the nearest emergency room.

SUN EXPOSURE – DIRECT OR TANNING SALON:

The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their provider and either delay treatment, or avoid tanning until the provider says it is safe to resume. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

IMPORTANT COMMITMENTS / TRAVEL PLANS:

Any treatment holds the risk of complications that may delay healing and your return to normal life. Please let the provider know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of treatment can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

FEMALE PATIENT INFORMATION:

It is important to inform your provider if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant.

MENTAL HEALTH DISORDERS AND ELECTIVE TREATMENT:

It is important that all patients seeking to undergo elective treatment have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional treatment and often are stressful. Please openly discuss with your provider, prior to treatment, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective treatment, effects on mental health cannot be accurately predicted.

PATIENT COMPLIANCE:

Follow all physician instructions carefully; this is essential for the success of your outcome. Personal and vocational activity may need to be restricted.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including a decision not to proceed with treatment. This document is based on a thorough evaluation of scientific literature and relevant clinical practices to describe a range of generally acceptable risks and alternative forms of management of a particular disease or condition. The informed consent

process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed-consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your provider may provide you with additional or different information which is based on all the facts in your particular case and the current state of medical knowledge. Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individualcase and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

AUTHORIZATION (S):

_____ (Patient Initials) I acknowledge that I have been informed about the Off-Label FDA status of ASCLERA® (polidocanol) and I understand it is not experimental and accept its use.

_____ (Patient Initials) For women: I confirm that I am not pregnant or breastfeeding and do not intend to become pregnant anytime during the course of treatment.

_____ (Patient Initials) Before and after treatment instructions have been discussed with me. The procedure, potential benefits and risks, and alternative treatment options have been explained to my satisfaction.

_____ (Patient Initials) I understand that the procedure is purely elective, that the results may vary with each individual, and multiple treatments may be necessary.

_____ (Patient Initials) I have read and understand all information presented to me before consenting to treatment.

_____ (Patient Initials) I have had all my questions answered. I freely consent to the proposed treatment.

_____ (Patient Initials) Photographic documentation will be taken for teaching and before/after purposes. I hereby □ do □ do not authorize the use of my photographs and understand that all attempts will be made to conceal my identity.

I, _____ hereby authorize _____ to perform ASCLERA® (polidocanol) injection on me. I understand that I am a patient of Medical Aesthetics MA, a medical practice led by a Harvard trained Board Certified Plastic Surgeon with over two decades of medical aesthetic experience, and that my licensed provider is an employee of the practice.

PATIENT SIGNATURE DATE TIME

and/or

RESPONSIBLE RELATIVE OR GUARDIAN RELATIONSHIP

PROVIDER'S NAME PROVIDER'S SIGNATURE