



INFORMED CONSENT FOR VARITHENA TREATMENT

This document is intended to supplement the information already provided to you during your physician consultation. This information should enable you to make an informed decision prior to undergoing treatment for your varicose veins.

COMMON OCCURRENCES WITH TREATMENT OF VARICOSE VEINS:

- 1. BRUISING:** Bruising is an expected effect and occurs with needle, incision, or catheter insertion. Bruises generally will fade over a few weeks.
- 2. TRAPPED BLOOD** - is also a normal occurrence associated with sclerotherapy treatment. It is temporary and will diminish with flushing or evacuation. It may be limited by leg positioning, and weeks of compression therapy over the treated veins immediately following injection sessions.
- 3. DISCOLORATION TO THE SKIN (BROWN SPOTS):** Some patients may experience areas of skin discoloration, pigmentation or even skin breakdown. Darkened areas may persist from two to twelve months. In rare instances, pigmentation may become permanent. Change of pigmentation is more likely in patients who have darker skin. Should this occur, additional treatment may be required. The potential for skin damage depends on the health of the skin, the size, location, and amount of abnormal veins.
- 4. YOU MAY DEVELOP OR FIND MORE VEINS DURING OR AFTER TREATMENT.** These will require more treatment.
- 5. TELANGIECTATIC MATTING:** (smaller than spider veins) may occur in some areas as a result of treatment. It is unpredictable and unavoidable in some patients. These tend to resolve spontaneously within three to twelve months, but occasionally, additional treatment may be required, or, in rare cases, the telangiectatic matting may be permanent.
- 6. Patients with swollen legs, or leg ulcers, or who require external compression bandages, tapes or compression pads, may experience blisters, irritation, rash, abrasions, local tenderness and/or swollen toes.** Every effort will be made to prevent these from occurring. Early notification by the patient to the medical staff is required to reduce the incidence and severity.
- 7. TEMPORARY SWELLING:** especially of the foot and ankle areas, is common early in treatment. Proper use of compression stockings combined with walking can greatly reduce swelling in the near term.
- 8. PAIN/DISCOMFORT:** Some element of discomfort is expected given the inflammatory response to injection therapy, and simply needle punctures. This discomfort is typically mild and your provider team will guide you in how to best manage any discomfort that arises.

RARE SIDE-EFFECTS ASSOCIATED WITH VARICOSE VEIN TREATMENT:

- 1. ALLERGIC REACTIONS:** A patient may experience an allergic reaction to the sclerosing agent, compression wraps, anesthetic agent, preservative, cleansing agent, stockings or tapes. All medications, including sclerosing agents and anesthetics, have the risk of causing varying degrees of allergic reaction. Allergic reactions can result in hives, fever, headache, itching, vertigo, nausea, hospitalization, breathing

problems, and anaphylactic shock. Should an allergic reaction occur, it would be recognized and treated immediately.

2. DEEP VENOUS THROMBOPHLEBITIS: A very rare occurrence of a blood clot forming in the deep veins. This may be associated with permanent leg swelling and may progress to a clot in the lungs, (pulmonary embolus). Superficial thrombophlebitis may also occur, but is generally not serious, responding well to outpatient treatment consisting of evacuation, compression, and walking.

3. INTRA-ARTERIAL INJECTION: A very unusual complication, which can occur if the agent is inadvertently injected into an artery. This may result in a skin ulceration, tissue destruction and/or loss of limb.

4. NERVE IRRITATION/DAMAGE: Partial or complete nerve damage from injection, thermal injury, or compression may cause numbness and/or pain or difficulty in walking which could last for months.

5. ULCERATION: Skin ulceration may occur without venous treatment. Open sores may occur in some cases following sclerotherapy and a dramatic inflammatory response. It has been reported to occur from thermal injury, but is exceedingly rare. The healing process takes approximately four to eight weeks, and permanent scars may occur.

6. INFECTION: Although extremely rare, the possibility of infection exists whenever a break in the skin occurs (such as a needle puncture or small incision).

7. BLEEDING: Bleeding may occur through incision sites or puncture sites after surgery or trapped blood removal. It is advised that you call for any major hemorrhage, and to keep your dressings and compression in place for the recommended period of time to minimize this risk.

8. VISUAL DISTURBANCE/MIGRAINE HEADACHES/STROKE: Rare neurologic events have been reported in the medical literature following sclerotherapy using foam or liquid sclerosants. Patients with history of migraine are at greater risk of neurologic disturbances despite the extremely rare frequency.

CONSENT

By signing this form, I attest that I have read and understand the procedure and its risks, and that it has been explained to my satisfaction. I agree to proceed with the treatment today.

Photographs: I consent to the taking of photographs while I am undergoing treatment and the use of those photos for scientific, educational or research purposes. I understand that I will never be identified personally with the photos.

Signature

Date

Print Name

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