Consent for VenaSeal™ – Cyanoacrylate Adhesive Closure of Superficial Veins

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.

I hereby authorize Dr. Matthew Wise and his/her associates/assistants and other healthcare providers he/she deems necessary, to close my: Right ☐ Left ☐ Great ☐ Small ☐ Accessory ☐ saphenous vein(s) using VenaSeal™, which is a cyanoacrylate adhesive (glue) closure procedure.

It has been explained to me that I suffer from chronic venous insufficiency (CVI). CVI of the superficial veins is largely the result of abnormal vein valve function which results in the leg veins failing to efficiently drain the blood from the legs. The accumulation of extra blood in the legs leads to vein distension and the leakage of fluid from the veins into the surrounding tissue. This leads to symptoms and signs of CVI which include, in part, the following: 1) leg heaviness or calf ache after standing or sitting for prolonged periods, 2) swelling of the ankle and/or calf, 3) varicose veins which are large, visible veins under the skin, 4) venous ulcers, and 5) bleeding veins in the legs. It has been explained to me that the superficial vein ablation technique closes the great/small/accessory saphenous veins so that the leaking valves no longer exist. This should reduce the pressure in my lower veins and thus relieve many of my symptoms. The blood from the closed vein is rerouted to the deep veins. I understand the VenaSeal™ procedure does not include the actual removal of the varicose veins, which may still be visible and may need further treatment.

Procedure: The VenaSeal™ technique involves placing a needle and a catheter into the superficial vein under sterile conditions. Local anesthesia is used to numb the skin so that placement of the catheter does not hurt. The catheter is positioned near to where the superficial vein empties into the deep veins. A small amount of cyanoacrylate adhesive is injected into the vein under ultrasound guidance thus closing the vein.

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, surgery to ligate and/or remove the veins, thermal (laser/radiofrequency) endovenous ablation, and sclerotherapy (chemical ablation).

Risks: I have also been advised of the risks of this procedure which may include, but are not limited to:

1. failure to access/close the vein or the vein later reopening
2. inflammation of the treated vein with resulting pain, tenderness and redness (phlebitis)
3. deep vein thrombosis and/or pulmonary embolism (clot in a deep vein and/or lungs)
4. bleeding / infection / scar formation at the puncture site
5. infection requiring additional procedures
6. allergic reaction to anesthetics
7. allergy or sensitivity to the cyanoacrylate adhesive that might result in a rash, hives, or rarely anaphylaxis

Benefits: The benefits of this treatment, namely improvement or resolution of the signs and symptoms listed above, have been explained to me. It has also been explained that if I choose to not treat my condition, I may or may not have progression of symptoms and tissue damage in my leg(s) and that the condition has the potential to make my leg(s) worse over time.

Freedom from potential complications of this procedure are not guaranteed. I have had sufficient opportunity to discuss my condition and proposed treatment, and all my questions have been answered to my satisfaction. I believe that I have adequate knowledge on which to base an informed consent for treatment.

I do ◯ do not ◯ consent to taking photographs/videos for use regarding my care and for educational, scientific or marketing purposes.

I do ◯ do not ◯ consent to having device representatives (medical equipment company personnel) present during the procedure to assist with any technical questions regarding the device being used.

PATIENT SIGNATURE _____ WITNESS _____

I have informed the patient of the available alternatives for treatment of the superficial leg or saphenous veins, and of the potential risks, complications and results that may occur.

PHYSICIAN SIGNATURE _____ DATE _____