Houston Heart Health
Advanced Vein & Vascular Center

INFORMED CONSENT FOR VENASEAL PROCEDURE

PATIENT: _____ DOB: _____

PHYSICIAN NAME: ANIL KUMAR, M.D.

DATE OF PROCEDURE: _____

SIDE: ☐ Left Leg ☐ Right Leg VESSEL: ☐ GSV ☐ SSV ☐ ASV

Probable Diagnosis: Chronic Venous Insufficiency

Procedure Details: Vena Seal is an FDA-approved product used specifically for this purpose. The Venaseal procedure delivers a small amount of a specially formulated medical adhesive (N Butyl Cyanoacrylate) to seal — or close — the diseased vein, rerouting blood to nearby healthy veins and providing symptom relief. I understand that alternative treatments for obliterating the function of the vein(s) include ligation (cutting or tying the vein in the groin or behind the knee), stripping the vein (surgical removal of a long segment), thermal ablation techniques (that require local or tumescent anesthesia injections prior to burning or cauterizing the vein), or compression sclerotherapy (injecting a chemical into the vein).
The doctor has explained that common symptoms of Chronic Venous Insufficiency (CVI), include varicose veins, leg heaviness and pain, leg edema, skin color changes and discoloration, and venous stasis ulcers. As explained to me, these symptoms arise from malfunctioning valves in the vein(s) resulting in venous reflux (reverse/backward blood flow) which has been identified by a diagnostic Duplex Ultrasound Study performed by a skilled Sonographer. Satisfactory treatment of CVI symptoms is usually achieved by permanent closure of the diseased vein(s). Although closure of the vein(s) should reduce the pressure and pain in my legs and thus relieve my symptoms, I understand this procedure for treatment of my vein(s) does not include actual removal of the varicose veins, which may still be visible and may require adjunctive treatments.

RISKS: The Venaseal closure system is a safe and effective treatment, offering improvement in quality of life. Following possible risks and side effects that are specific to VENASEAL therapy, have been explained to me in a language I understand: **Failure to close the vein** (or reopening), **Bruising, Phlebitis** (pain, tenderness, redness of the treated vein), **Paresthesia** (i.e., tingling, numbness and burning), **Superficial thrombophlebitis** (i.e., inflammation of a superficial vein caused by blood clot), **Skin burn, permanent/temporary skin discoloration, very rarely AV Fistula** (i.e., an abnormal connection between an artery and a vein), **bleeding from the access site, Deep Venous thrombosis** (i.e., blood clot in the deep vein), **Edema** (i.e., swelling) **in the treated leg,** Embolization (i.e., blockage of a vein or artery), **including Pulmonary Embolism** (i.e., blockage of an artery in the lungs), **Hematoma** (i.e., collection of blood outside the vessel), **Infection or ulceration at the Access Site, Cellulitis, Visible Scarring, Early or delayed Hypersensitivity or allergic reaction to cyanoacrylates causing skin redness, tender lumps, itching, urticaria, shortness of breath and anaphylactic shock, requiring hospitalization, steroids or even surgical removal of the treated vein. Additionally, there is a risk of allergic reaction to the local anesthesia, Chlorhexidine or betadine.**

I further understand that it is imperative for me to follow up with the treating doctor for any signs or symptoms of complications for they are better managed if addressed early.

Alternative Treatments: Because varicose veins and spider veins are not life-threatening conditions, Venaseal treatment is not mandatory. Some patients get adequate relief of symptoms from wearing graduated support stockings/wraps. Surgical stripping, Endovenous chemical ablations (Sclerotherapy) and Thermal ablation may also be used to treat large varicose veins. The other option is to receive no treatment at all.

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AUTHORIZATION

1. **Operation/Procedure**: I authorize the performance of the above Operation/Procedure by or under the direction of the Physician, and his/her assistant surgeon/associate or other individuals as necessary. Physician has explained to me the nature and purpose of the Operation/Procedure, the alternative treatment to the Operation/Procedure, and the possible complications.

2. **Additional Operation/Procedures**: I authorize the performance of such additional operation/procedure that the above-named Physician may deem necessary to adequately treat the above Probable Diagnosis.

3. **Operation/Procedure Complications**: I understand that, there is no operation/ procedure in which complications have not been reported. Most complications are of a minor nature and respond to treatment. Serious complications can occur in any operation/procedure including death of the patient, excessive bleeding, nerve and blood vessel injury, infection, heart attack or stroke.

4. **Results Not Guaranteed**: I understand that no guarantee or assurance has been made as to the results of the Operation/ Procedure and that it may not cure the condition.

5. **Photography/Videotape**: I consent to photographing/ videotaping of operations or procedures showing portions of my body for medical, scientific or educational, promotional advertisements purposes providing that my identity is not revealed. I acknowledge that I will not receive any compensation for this. I hereby release Houston Heart Health Team/Agents from any claims which arise out of such use.

6. **Residual Symptoms:** I attest that I currently have leg symptoms despite use of conservative therapy.

7. **Allergy/Anaphylaxis Education:** I have received education about anaphylaxis reaction that can rarely happen after VENASEAL therapy.

I, further, attest that I do not have any known allergies or unwanted reactions to: Lidocaine, Latex, Band-Aid, surgical tape, glues, fake nails, fake eye lashes, Dermabond or cyanoacrylates, or Iodine/Betadine, Chlorhexidine.

Initial _____

☐ I HAVE READ AND UNDERSTAND THE ABOVE AUTHORIZATION

PATIENT OR PERSON WITH AUTORITY TO CONSENT/DECLINE FOR THE PATEINT SIGNATURE	DATE	TIME
WITNESS SIGNATIURE		

PHYSICIAN DECLARATION: I have explained the contents of this document to the patient and answered all the patient's questions, and to the best of my knowledge, the patient has been adequately informed. The patient has consented.

PHYSICAN SIGNATURE