Cardiovascular Medicine
Equbal Kalani, MD, FACC
Board Certified in Cardiology and Internal Medicine

ICANL Nuclear Cardiology Accredited Nuclear Cardiology Laboratory

International Board of Heart Rhythm Examiners
Certified Cardiac Device Specialist
Physician

1501 South Pinellas Ave, Suite S, Tarpon Springs, FL 34689. Ph: 727-943-2880. Fax: 727-943-2878

INFORMED CONSENT FOR VENASEAL CLOSURE PROCEDURE

Treatment of Chronic Venous Insufficiency / Superficial Venous Reflux

Patient Name | Date of Birth | Date

Treatment Leg: ☐ Right ☐ Left ☐ Bilateral

Vein(s) to be Treated: ☐ Great Saphenous Vein (GSV) ☐ Small Saphenous Vein (SSV)
☐ Accessory Saphenous Vein ☐ Other:

DIAGNOSIS AND PURPOSE

I have been diagnosed with chronic venous insufficiency/venous reflux. Abnormal valves in superficial veins can allow blood to flow backward and pool in the leg, contributing to pain, aching, heaviness, swelling, fatigue, varicose veins, skin changes, inflammation, and/or venous ulceration.

My physician has recommended the VenaSeal Closure System, a minimally invasive, nonthermal procedure intended to permanently close an incompetent superficial truncal vein.

DESCRIPTION OF PROCEDURE

Under ultrasound guidance, a catheter is introduced into the abnormal vein through a small skin puncture. Small amounts of medical-grade cyanoacrylate adhesive are delivered through the catheter while external pressure is applied. The treated vein is closed and blood is redirected through other functioning veins. The adhesive remains within the treated vein. VenaSeal does not use thermal energy and generally does not require tumescent anesthesia along the length of the vein.

EXPECTED BENEFITS

Potential benefits include improvement in venous reflux and associated symptoms. Successful treatment is not guaranteed. The vein may fail to close completely, reopen, or require additional treatment.

RISKS AND POSSIBLE COMPLICATIONS

- Pain, tenderness, bruising, swelling, bleeding, hematoma, or access-site problems.
- Phlebitis, superficial thrombophlebitis, local inflammation, foreign-body reaction, redness, itching, hives, skin irritation, pigmentation changes, or ulceration.
- Allergic or hypersensitivity reaction to cyanoacrylate adhesive, potentially including a severe reaction or anaphylaxis.
- Infection; numbness, tingling, or other sensory disturbance.
- Deep vein thrombosis (DVT), extension of thrombus and/or adhesive into the deep venous system, embolization, or pulmonary embolism (PE).
- Edema, vascular injury, perforation, rupture, arteriovenous fistula, or visible scarring.
- Failure to close the vein, reopening of the vein, persistent/recurrent symptoms or varicose veins, and need for additional treatment, imaging, medication, hospitalization, or another procedure.

CONTRAINDICATIONS / ALLERGY DISCLOSURE

I understand that VenaSeal is contraindicated in patients with previous hypersensitivity to VenaSeal adhesive/cyanoacrylates, acute superficial thrombophlebitis, thrombophlebitis migrans, or acute sepsis. I have informed my physician of all known allergies and prior reactions to medical glues or adhesives.

☐ No known cyanoacrylate/adhesive allergy

☐ History of adhesive/cyanoacrylate reaction:

ALTERNATIVES

Alternatives may include conservative management (compression, exercise, leg elevation, and medications when appropriate), radiofrequency ablation, endovenous laser ablation, ultrasound-guided foam or liquid sclerotherapy, surgical ligation/stripping, phlebectomy or other varicose-vein treatment, or no procedure at this time.

PATIENT ACKNOWLEDGMENT AND CONSENT

I have had the nature and purpose of the proposed VenaSeal procedure, expected benefits, risks, possible complications, alternatives, and consequences of declining treatment explained to me. I understand that medicine is not an exact science and no guarantee has been made regarding the outcome. I have had the opportunity to ask questions, and my questions have been answered to my satisfaction. I voluntarily authorize my physician and appropriate clinical personnel to perform the procedure described above.

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SIGNATURES

Patient / Authorized Representative Signature (type name if electronically signing)

Date / Time

Printed Name

Relationship to Patient (if applicable)

Physician Signature (type name if electronically signing)

Date / Time

Witness Signature (type name if electronically signing)

Date / Time

Practice template: Review and adapt this form to applicable law, institutional policy, current manufacturer labeling, and the patient's individual circumstances before clinical use.