INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

TITLE: Investigator Initiated Safety Study Using the Venclose Vestico (commercial name TBD) Radiofrequency (RF) Ablation System for the Treatment of Incompetent Perforator Veins (IPVs)

PROTOCOL NO.: CL-VAV-001
WIRB® Protocol #20200683

PROTOCOL DATE: 14-April-2020

SPONSOR: Venclose, Inc.

INVESTIGATOR: Jeffrey G. Carr, MD, FACC
1783 Troup Highway
Tyler, Texas 75701
United States

STUDY-RELATED PHONE NUMBER: 903.595.2283 (24 Hours)

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand.

INTRODUCTION

The following information describes the study and your role as a participant. This document is intended to inform you about the nature and risks of the research study in which you have been asked to participate. The study doctor or his staff will answer any questions you may have about this consent form and about the study. Please read this consent form carefully and do not hesitate to ask any questions you may have about the information provided below. Your participation in this study is entirely voluntary. If you choose to participate, you have the right to withdraw from the study at any time. You will receive a copy of this consent form after you have signed and dated it.

DESCRIPTION AND PURPOSE OF THE STUDY

Venclose Inc. is conducting a study to see if their medical product is useful in the treatment of varicose veins, specifically, incompetent perforator veins (IPVs). Many people get these veins on their legs. There may be more than one IPV. The veins are not malignant and do not become malignant over time. They do not have to be removed. Many people choose to have them treated for aesthetic reasons.

You are being asked to participate in this study because you have decided that you want your IPVs closed, and Dr. Carr has determined that you are a good candidate for this [21]procedure. Dr. Carr is the Principal Investigator for this study. The study team working with Dr. Carr will include Amy Solis, Research Coordinator, and John Carlow, EdD, MPH, Study Coordinator.

[22]Twenty (20) volunteers will participate in this study. If you choose to volunteer for the study, you will be asked to come into Dr. Carr's office a total of 5 times. The first time will be to look at the IPVs on your leg(s) to see if they fit the study criteria. On that same day, the IPVs may be treated with the Vestico System or you may come back for the treatment. There is only one

treatment session. Over the next month, you will return to the office 3 times to have the treated location checked.

The Vestico treatment will be applied to 1-2 IPVs on your leg(s). Following the treatment, a small bandage will be applied and you will go home. The treated area may become slightly red or raised and a small scab may appear. A mild ointment and a bandage should relieve any minor discomfort. The Treatment visit may take up to 1 hour. Each of the three follow up visits, [21]including the duplex ultrasound imaging procedure, should be completed in about 30 minutes. The entire study will be conducted in Dr. Carr's location in Tyler Texas. The study team will work with you to schedule the appointments well in advance to make them as convenient as possible for you.

VESTICO SYSTEM DESCRIPTION

The Venclose® Vestico System uses radiofrequency ablation (RA) via energy delivered to heat the wall of an incompetent vein with temperature-controlled energy. This is a common procedure to cause irreversible vessel occlusion. This vessel occlusion is followed by fibrosis (scarring) and ultimately resorption of the vessel tissue. The Venclose® Vestico System is not approved by the FDA and considered investigational in this study.

STUDY PROCEDURE

The following is an example of the activities that will take place: The exact order may slightly differ depending on schedules and preferences for you and the study team. The first contact day and the first study day may be at the same visit depending on schedules for all concerned.

- The Vestico device will be put into the vein lumen using ultrasound imaging guidance.
- The target treatment position is confirmed.
- Local anesthesia is applied to the vein and surrounding tissues.
- The Vestico device will be turned on to deliver the thermal ablation energy to the vessel.
- Once the treatment cycle has been completed, the device will be taken out and closure of the vessel confirmed with duplex ultrasound.
- A bandage and compression hose will be applied.
- You will then immediately be able to walk.

POTENTIAL RISKS AND DISCOMFORTS

Numbing medicine will be applied to the area to be treated with the Vestico System to manage discomfort. After the numbing wears off, you may see minor redness and/or swelling, blistering, bruising, crusting, itching, oozing, pin-point bleeding or swelling. These side effects may be part of the normal healing process and will gradually diminish. This may be readily managed with a mild ointment and bandage that Dr. Carr or his assistant can discuss with you. Although it is not anticipated, it is possible that the spot may not be partially or completely removed. The other potential risks include:

- Edema
- Skin changes
- Venous ulcers
- Deep vein thrombosis (blood clot within a blood vessel)
- Superficial vein thrombosis
- Pulmonary embolism (arteries in the lungs become blocked by a blood clot)
- Venous thromboembolism
- Skin burn
- Thermal injury of adjacent tissues
- Paresthesia

- Infection/cellulitis
- AV Fistula (abnormal connection between an artery and a vein)
- Need for re-operation
- Death

In addition to these risks, taking part in this research may harm you in unknown ways.

If you have any injury, bad effect or any other unusual health experience that you think may be related to this study, you should contact Dr. Carr or the study staff immediately at (903) 595-2283. You can call at any time, day or night, to tell them about your health experiences. Dr Carr or the study staff will treat you or will refer you for treatment.

COMPENSATION
You will be compensated for any inconvenience that study participation may represent. Specifically, you will make 5 total visits to the surgeon's office (approximately 4 hrs. total time).

In return for this time commitment, you will receive $75 each for the Screening/Planning Visit and the Treatment Visit, as well as for each of the two follow-up visits out to 15 days after treatment. For the Final Follow-up Visit at 30 days after treatment, you will receive $150. The total you will receive if you attend all study visits is $450. There will be no cost to subjects as a result of participating in this study.

BENEFITS
There may be no benefit to you as a result of your participation in this study. There may be shrinking or disappearance of the IPVs. If the Vestico System proves to be successful in building a product that safely and effectively changes tissue your participation may be beneficial to patients in the future. Information obtained from this study will benefit the sponsor of the study, Venclose, Inc.

NEW FINDINGS
You will be told of any significant new findings that develop prior to or during the course of this study that may affect your willingness to continue participating in this study.

ALTERNATIVES TO STUDY PARTICIPATION
IPVs may be treated using other surgical or electrical-thermal products such as a scalpel (stripping) or ultrasound guided sclerotherapy (USGS) and endovascular thermal ablation (EVTA) with either laser or radiofrequency energy sources. Dr. Carr can tell you more about these options. Another alternative is to not participate.

INVESTIGATOR PAYMENT AND RECRUITMENT BONUS
Dr. Carr and the study staff will be compensated for their participation in this study. Dr. Carr owns shares in the company that makes the device. Study team members may receive a payment for recruiting subjects. Feel free to ask them any questions you have about this.

RESEARCH-RELATED INJURIES
In the event of an illness or injury that is determined to be directly related to the Vestico System or the study process, Venclose agrees to pay all reasonable and necessary medical expenses to treat such injury provided that you have followed all of Dr. Carr's directions.

Financial compensation for such things as lost wages disability, or discomfort due to any research-related injury is not routinely available. Further information regarding medical treatment for research-related injuries can be obtained from Dr. Carr or the study team. You

must notify Dr. Carr or other members of the study team of any research related injury. If research related injury occurs, in signing this form, you have not waived any of your legal rights to pursue a claim through the legal system.

PARTICIPATION INFORMATION
Your participation in this study is completely voluntary. You can choose not to take part in the study or you can quit at any time. In either case, you will not be penalized, nor will you lose any benefits to which you are otherwise entitled. If you decide to end your participation in the study, please contact Dr. Carr or the study team immediately.

You will not be prevented from participating in future studies. If you decide to stop your participation in the study, it is important that you report any problems that might have occurred during your participation in the study . Additionally, Dr. Carr may end your participation in this study with or without your consent. Venclose, Inc. or the FDA may stop the study at any time.

CONFIDENTIALITY
Every reasonable effort will be made to keep your study records confidential. The medical information gathered in this study will be submitted to Venclose, Inc., its representatives and perhaps to the U.S. Food and Drug Administration (FDA). This information may also be submitted to governmental agencies in other countries where the Vestico System may be considered for commercialization.

Any records that identify you and the consent form signed by you will be inspected by the sponsor and its representatives and may be inspected and/or copied by the FDA, other regulatory agencies, and the Western Institutional Review Board (WIRB). An IRB is a group of independent scientific and non-scientific people who are not affiliated with the sponsor.

The IRB reviews research studies involving people by following the Food and Drug Administration (FDA) rules. This group is also required by the FDA to do periodic review of ongoing research studies. The primary purpose of such review is to ensure the protection of the rights and welfare of the human subjects.

Due to the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, your identity will not be disclosed. Your permission for review of confidential information is granted by signing this form. You acknowledge that your medical information may be held and processed on a computer.

PERMISSION TO USE AND SHARE PERSONAL HEALTH INFORMATION FOR RESEARCH

INTRODUCTION
This section may contain words that you do not understand. Please ask the study investigator or staff to explain any words or information that you do not understand. By signing this form, you allow the study investigator to use and share your personal health information during the course of this study.

INFORMATION THAT MAY BE USED AND GIVEN TO OTHERS
Information that may be used and given to others may include past, present and future health information collected during this study. Your personal information includes, but is not limited to your name, date of birth, and results of study related procedures as described in the informed consent e.g. name, medical history, photographs etc.

Your personal health information will be used to carry out the research, to review records on the information collected in this study, to check how the study was carried out, or for other uses permitted by law.

INFORMATION MAY BE SEEN BY:

- The study investigator and staff,
- The study sponsor,
- The Food and Drug Administration ,
- The Department of Health and Human Services,
- Government agencies that require reporting of reportable diseases , Governmental agencies in other countries,
- Western IRB.

It is advised that you discuss this with the study investigator or a member of the staff and ask any questions that you may have about the sharing of your health information.

OTHER INFORMATION

If you decide that you no longer wish to have your personal health information shared.

- You must provide a written request to the study investigator and tell him or her that you no longer want to share your information.
- You will no longer be a part of this research study.
- The study investigator and staff can continue to share any of the information that they already have.
- Your health information may still be shared if you have a bad reaction from the study drug or device.

Once the information has been shared by the study investigator to someone outside this study, it may no longer be protected. There is a chance that your information will be shared with others in ways that are not listed here and released without your permission. You have a right to see and copy your information, however; not while the research study is going on.

This permission expires at the end of the research or 50 years from the date you signed.

AUTHORIZATION

I agree to share my information as described in this form and I have received a copy for my records.

Printed Name of Study Participant	Signature of Study Participant	Date

PERSONS TO CONTACT

You have the right to ask any questions concerning the potential and/or unknown hazards of this study at any time. If you have any questions,[21]complaints or concerns about your participation in this study, or if at any time you feel you have experienced a research -related injury or reaction, contact Dr. Carr or Amy Solis at 903.595.2283, 24- hours a day.

If you have questions about your rights as a research subject, or questions, concerns or complaints about the study, you may contact the WIRB for this study at: Western Institutional Review Board. 1019 39th Avenue SE suite 120 | Puyallup, WA 98374-2115 or call toll free, (800)

562-4789 [21]or email help@wirb.com. Do not sign this form unless you have had a chance to ask questions and have received satisfactory answers to all your questions.

CONSENT

I have read this informed consent. I have discussed and understand the purpose and procedures of this study, which have been explained to me. I have been given the chance to ask any questions that I have about the study, and all my questions have been answered to my satisfaction. I understand that I am free to withdraw from the study at any time. I will notify Dr. Carr if I decide to withdraw so that my participation can be ended in an orderly manner. I acknowledge that I will be given a signed copy of this consent form.

I acknowledge that the sponsor of the study, Venclose, Inc., its representatives, regulatory authorities including the FDA, and the IRB will have direct access to my original study records for verification of clinical trial procedures and/or data, without violating my confidentiality, to the extent permitted by applicable laws and regulations.

I voluntarily agree to participate in this research study. I understand that I have not given up any of my legal rights by signing this informed consent.

_____
Participant's Name (Print)

_____ _____ _____
Participant's Signature Date Time

The information contained in this document was fully and carefully explained to the study participant. The study participant understands the nature, risks, and benefits of his/her participation in this research study.

_____
Printed Name of Individual Conducting Informed Consent Discussion

_____ _____ _____
Signature of Individual Conducting Informed Consent Discussion Date Time

_____
Printed Name of Investigator

_____ _____ _____
Signature of Investigator Date Time