WIRB-APPROVED CONSENT TEMPLATE TO PARTICIPATE IN A RESEARCH STUDY

TITLE: Feasibility Clinical Trial of the Cardio Flow FreedomFlow™ Atherectomy System to Treat Peripheral Artery Disease (FAST Trial)

PROTOCOL NO.: 010-031
WIRB® Protocol #20172653
Approved December 05, 2017

SPONSOR: Cardio Flow, Inc.

ClinicalTrials.gov **NCT03365154**

Cardio Flow

Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
Dec 05, 2017
WIRB®

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

PLEASE READ THIS INFORMATION CAREFULLY AND MAKE SURE THAT YOU UNDERSTAND IT BEFORE SIGNING YOUR NAME TO THE FINAL PAGE

TITLE:	Feasibility Clinical Trial of the Cardio Flow FreedomFlow™ Atherectomy System to Treat Peripheral Artery Disease (FAST Trial)
PROTOCOL NO.:	010-031 WIRB® Protocol #20172653
SPONSOR:	Cardio Flow, Inc.
INVESTIGATOR:	Name Address City, State, Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name Number (24-hour number required)

Introduction

You are being invited to participate in a research study to test an investigational treatment for peripheral artery disease (PAD). The doctor in charge of this study at this site is [Principal Investigator]. Before you decide if you want to participate in this study, we want you to know the purpose of the study, how it may help you, any risks to you, what other choices you may have, and what is expected of you.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. This form may contain words that you do not understand. Please ask the study doctor to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this form to think about or discuss with family and friends before making your decision. If you agree to take part in this study, you will be asked to sign this consent form. You should not sign this form if you have any questions that have not been answered. After you sign the form, you will be given a copy. An additional copy will remain in your medical chart.

Before you learn about the study, it is important that you know the following:

- Your participation is entirely your choice (voluntary).
- You may or may not benefit from taking part in this study, but knowledge gained from your participation may help others.

- You may decide not to take part or to stop being in the study at any time without losing the benefits of your usual medical care.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include summary of the results. You can search this Web site at any time.

This study is sponsored by Cardio Flow, Inc. (referred to in this document as "Cardio Flow"), a company that is testing a new investigational device for Peripheral Artery Disease (PAD). If you have any questions, please ask the study staff.

Study Purpose

The purpose of this research study is to test the safety and effectiveness of the Cardio Flow FreedomFlow™ Atherectomy Device to remove the plaque deposits in your leg.

This study will provide information that will determine whether the device is safe and effective to treat PAD.

The FreedomFlow™ Atherectomy Device consists of a user handle with a thin shaft that the doctor will insert into your blocked artery, a control module that controls the speed of the rotating shaft, and a cable set that allows fluids to be administered and a wire to monitor speed of the device.

This is an experimental device. This means that the FreedomFlow™ Atherectomy Device has not been approved by the U.S. Food and Drug Administration (FDA). People volunteering to participate in this study will be the first people treated with this device. The device is made by Cardio Flow, Inc.

Size of Study

A total of ten subjects at two institutions in the United States will be asked to participate in this study. If you decide to participate, you will be one of five subjects asked to participate at this location.

Study Procedures

Visit 1: Screening/Baseline

After signing this consent form, you will be asked questions about your medical history and medications you are taking. You will also be asked to report demographic information such as your race, age, height and weight. Your physician will record your heart rate and blood pressure at your ankle or toe and arm. You will be asked to complete a questionnaire to see how your peripheral vascular disease symptoms affect your quality of life – this is the same questionnaire that some physicians use in their routine practice.

You will have an angiogram (inject dye into the artery to take a picture) and a duplex ultrasound (which uses sound waves to produce a picture of the structures inside your artery).

You will have blood tests taken within a month and/or on the day of the procedure. If you are female and are able to become pregnant, you will also have a pregnancy blood test within 7 days of the procedure.

Some of these procedures and tests are the same you would have if you were not in the study – your physician can tell you which ones he/she does as part of their routine practice.

Depending on the results of the screening / baseline tests, you may be eligible to participate in this study. If you are not eligible based on the results, you will not participate in this study and will not qualify to have the procedure performed with the FreedomFlow™ Atherectomy Device.

Visit 2: Device Treatment
While under local pain medicine, the physician inserts a thin, flexible tube (catheter) into the artery in your leg located near your groin. Using an X-ray camera, the physician guides the catheter to the site of the narrowed artery. The physician then injects a dye into the artery, and takes an angiogram, or picture of the artery. This helps the physician see the exact size and place of the blockage. The physician will make a final decision whether you meet all criteria for participating in the study. If the diseased area(s) is not suitable for using the FreedomFlow™ Atherectomy Device, you will not participate in the study. You will receive any commercially available treatment method(s) best suited to you per the physician's discretion. If the diseased area(s) is deemed to meet all criteria, the physician will thread the FreedomFlow™ Atherectomy Driveshaft to the site of the blockage and perform the procedure to remove the plaque. In some cases, the physician may also perform balloon angioplasty (inflating a balloon in the artery to press plaque against the artery wall) to further open up the artery. After the artery is open, the physician may place a narrow metal tube (stent) inside to help hold it open.

Your treatment after the procedure will be the standard of care at this hospital / clinic, which means, you will receive the same care as patients who are not participating in this study.

Visits 3 and 4: Follow up
You will be asked to schedule follow-up visits at the clinic at 30 days and 6 months after your procedure to see how you are doing. At each visit, your physician will record your heart rate and blood pressure at your ankle or toe and arm and ask what medications you are taking. You will be asked to complete the same questionnaire to see how your peripheral vascular disease symptoms affect your quality of life after treatment. You will also have a duplex ultrasound which is a procedure to image your artery from the outside. If you are having symptoms and your physician thinks your condition might require another intervention, you will have an angiogram and additional treatment.

Your participation in this study will end after your visit at 6 months.

Duration of Study (Length of Time)
You will be in the study for about six months.

Your study doctor or Cardio Flow may stop the research study or may stop your participation at any time and this does not require your agreement. This may be done for any reason such as if

you have an unrelated illness or complication, if you do not follow the study instructions, if your medical condition changes and he/she feels it is in your best interest to stop the study, if you cannot tolerate the device or for administrative reasons.

If you choose to discontinue or are withdrawn from the study, or your study doctor decides that you should discontinue the therapy, the study staff will discuss options with you.

End of Study

At the end of the study, data collected from all ten patients will be submitted to the FDA and a larger trial will be designed to enroll additional patients with the intent of gaining FDA approval for the Cardio Flow FreedomFlow™ Atherectomy Device.

Risks and Side Effects of Study

Every medical procedure carries risks. It is not possible to list all the risks, to predict with certainty the likelihood of side effects or problems occurring, or predict the types of side effects or problems which may occur. The Cardio Flow FreedomFlow™ Atherectomy Device has not been used in humans, so the specific risks of using this device are unknown. However, there are some risks which are known from experience with other similar treatments for PAD. These risks include, but are not limited to:

Anticipated Risks (Side Effects) of Atherectomy Procedure (listed in alphabetical order, not the frequency of occurrence)

- Allergic reaction to medication/media/device components
- Amputation (cutting off a limb)
- Anemia (low red blood cell count)
- Aneurysm (part of the artery wall weakens, allowing it to widen abnormally or balloon out)
- Bleeding complications which may require transfusion
- Cerebrovascular accident (CVA) (a stroke - blood flow to a part of your brain is stopped either by a blockage or the rupture of a blood vessel.)
- Death
- Distal embolization (a small particle like a blot clot travel through the blood vessels until it reaches a vessel that is too small to let it pass. When this happens, the blood flow is stopped.)
- Entry site complications
- Hemolysis (rupture or destruction of red blood cells)
- Hypotension/hypertension (low/high blood pressure)
- Infection
- Myocardial infarction (heart attack)
- Pain
- Pseudoaneurysm (a blood vessel wall is injured, and the blood is contained by the two outer layers of the blood vessel)
- Restenosis (re-narrowing) of treated segment that may require revascularization (restoration of the blood circulation)

- Renal (kidney) insufficiency/failure
- Slow flow or no reflow phenomenon
- Thrombus (blot clot)
- Vessel closure, abrupt (sudden)
- Vessel injury, including dissection and perforation (tears or punctures) that may require surgical repair
- Vessel spasm (brief tightening or constricting of a blood vessel)
- Vessel occlusion (blockage of a blood vessel)

Participation in this study may cause some or all of the side effects listed above. In addition, there is always the risk of developing previously unknown side effects. Some side effects stated in this consent document, if severe, may cause death. You should ask your physician any questions you might have about the severity, frequency, and duration of these risks.

Participation in this study may cause some inconveniences to you such as having to come back to the physician's office for the required study follow-up visits, duplex ultrasounds, angiograms (if needed), ankle-brachial index, and questionnaires.

For Women of child-bearing potential:

It is not known if the treatment might harm an unborn child; therefore you may not take part in this study if you are pregnant, or you intend to become pregnant within the next six months. If you are a woman who is of child bearing potential, you will be asked to have a pregnancy test (urine or blood) before taking part to confirm that you are not pregnant. You must agree to use a reliable form of contraception through the duration of your participation in the study. Examples of acceptable forms of highly effective contraception include:

- Established use of oral, injected or implanted hormonal methods of contraception.
- Placement of an intrauterine device (IUD) or intrauterine system (IUS).
- Sterilized male partner (with the appropriate post-vasectomy documentation of the absence of sperm in the ejaculate).

If you become pregnant, you should notify your study doctor immediately.

Benefits of Study

You may or may not get any benefit from participating in this study. By participating in this study you will contribute to providing valuable information for medical science, which could lead to future treatments for other people who have the same condition as you.

Alternative Treatments

You do not have to participate in this research study to be treated for PAD. You can continue with available standard treatments. Some of the other possible treatments include other atherectomy devices, balloon angioplasty, placement of stents to prop open your artery, and bypass surgery. Your study doctor will explain in more detail the various alternative procedures or therapies available and the risks and benefits of these alternatives. Your future care and your relationship with your doctor will not be affected if you decide not to be in this study.

Role of Cardio Flow Representative

In this study and at the request of the study doctor, a representative of Cardio Flow may:

- Provide technical expertise on the study device you will receive
- Be present at treatment (operating room) and follow up visits and procedures
- Have some direct contact with you

The study doctor or their designee will always be present or nearby. Please talk to the study doctor if you have any questions.

Your Rights as a Research Subject

Your participation in this study is voluntary. You may decide not to take part or to stop being in the study at any time without penalty or losing the benefits of your routine medical care. If you withdraw from the study, you are asked to notify the investigator or study staff so that your future care can be discussed and your participation can be stopped in an orderly manner. You will be asked to return to your study doctor to complete all of the procedures that would have been required in the final study visit. It is important for your health and safety to have this last visit. Your study doctor will discuss your treatment options.

You will be told about any significant new findings about the device or this study, or if any changes are made to the study plan that may make you change your mind about staying in the study.

Responsibility for Costs

You will not be charged for the study device, tests, or procedures required for the study that are not considered standard of care. This includes any special blood tests or x-ray or ultrasound images. Cardio Flow will reimburse the medical center and/or doctors their fair costs for these tests and procedures and you will not be charged.

There may be certain treatments, tests and examinations that will happen during the study that are part of the normal standard of care for people who have PAD. These may include, but are not limited to medications, office visits, hospitalizations, and physical therapy or other procedures. Cardio Flow has not agreed to pay for standard of care procedures. The costs for standard of care items will be billed to you or your insurance company, as usual.

Cardio Flow has not agreed to pay you or anyone else for any other medical costs related to your peripheral artery disease that aren't part of the study. This includes, but is not limited to any prescriptions you may take, physical therapy, medical equipment, etc., and all tests or procedures not required for the study.

Please ask the study doctor or study staff if you are unsure about whether a specific test or procedure is required for the study.

No Payment to You as Research Subject

You will not be paid for being in the study.

Treatment and Compensation for Injury/Illness

If you get hurt or sick during the study, please contact the study doctor. He/she will arrange for your treatment. Cardio Flow, will reimburse the research center for the reasonable and necessary costs of the short-term treatment of an injury that is directly caused only by the research device or by properly performed research procedures or testing required only for the study.

Cardio Flow has no plans to make any payments directly to you. Cardio Flow has no plans to pay for any injury or illness that occurs as a result of negligence, malpractice or other wrongful acts on the part of the study doctor or the study staff. Cardio Flow has no plans to pay for injuries or illnesses that are the result of a pre-existing condition or the normal progression of your disease, treatment rendered to you prior to the study, standard of care medical procedures or medications performed or delivered during the study, or any other reason. Cardio Flow has no plans to pay you for any pain, worry, lost income, or non-medical care costs that occur from taking part in the study. You are not giving up any of your legal rights by signing this consent form.

Commercial Interests

This clinical research study is paid for by Cardio Flow, who makes the device being tested. Research money from Cardio Flow may help support the activities of the research center, including partial salaries of the doctors and nurses who conduct the study.

Cardio Flow and other researchers may patent or sell discoveries based on their research, including any information or blood or tissue samples you provide. Cardio Flow and other researchers may receive money from these activities. There are no plans to pay you or give you a personal economic interest in any products that may be developed from your procedure or information or tissue samples you provide. There are no plans for you to obtain or acquire any financial interest in the research.

Confidentiality & Authorization to Disclose Personal Information

As part of this study, the study doctor and hospital will keep records of your participation in the study. This section of the consent form describes how your personal information may be used and disclosed as part of the study. Under federal law, your personal information cannot be used or shared for the study unless you sign this form. You do not have to sign this form. If you do not sign it, you will not be able to be in the study, but it will have no other effect on the medical care you receive.

In the event of your death, the study staff will seek copies of your medical records regarding your death. This information will be used for research purposes and will be kept confidential.

Type of information that may be used or disclosed (shared)
The personal information that may be used or shared is:

- All information collected during the study, including your name, address, phone number, birth date, treatment dates, device identifiers, social security number, health insurance claim number and other details about you.

- Information in your medical records that is relevant to the study, including past medical records and the results obtained during the study.
- Records relating to your medical charges (your medical bills) regarding your treatment that are relevant to the study.
- Videotapes, films or photographs of the procedure or follow up (Note: any photographic or video recording will not contain any images that would allow you to be identified)
- If Cardio Flow pays for treatment of a research related injury or complication, you may be required to provide additional personal identification information (such as your social security number or health insurance claim number) and some of your personal health information to Cardio Flow for the purposes of reporting such compensation to the Centers for Medicare & Medicaid Services.

People who may disclose or receive your information

As part of the study, your personal information may be kept by the [relevant hospital/research center/practice group/investigator name(s)], and the people who work for them. The people who work with them include the Institutional Review Board, which is a group of people who watch over the study for the hospital or practice. It also includes other employees and contractors who need to see your personal information to help with the study or make sure it is being run right. Any of these people or groups of people may disclose your information. These people and groups are called the "Researchers" in this form.

People working with any of the following groups might receive your information:

- Cardio Flow (the sponsor of the study), including its employees, contractors and representatives;
- The Western Institutional Review Board;
- Other institutions and laboratories that are participating in the study and their Institutional Review Boards;
- Government organizations such as the Food and Drug Administration (FDA), Office for Human Research Protections and similar agencies in other countries and other persons have the right to see your information required to watch over the safety, effectiveness, and conduct of research.

Ways in which your personal information may be used

Information about you can be used and disclosed (shared) by the Researchers and Cardio Flow for any of the following reasons:

- To conduct monitor and/or audit the study and to confirm the research results;
- To prepare publications or presentations (but no publication about the study will reveal your identity without a different specific, written permission from you);
- For regulatory purposes, such as meeting the reporting requirements of government agencies and getting the approval of government agencies to sell products made by Cardio Flow;
- To create a data set from which all personal information that could be used to identify subjects has been removed;
- To support the marketing, distribution, sale and use of the research device;

- To conduct new medical research and other activities related to research and development of new medical products or therapies;
- For reimbursement advocacy purposes, that is to decide how the procedure that is the subject of the study will be paid for by Medicare, Medicaid, or insurance companies in the future;
- As required by applicable laws.

Revoking authorization
You can change your mind about allowing your personal information to be used or shared at any time by sending a written notice to the study doctor. If you do so, you will be taken out of the study and no personal information about you will be gathered for the study after that date, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of the research. If you think it is likely that you will change your mind, please do not sign this form.

Protection of information after disclosure
After the Researchers have shared your personal information with third parties, including Cardio Flow, federal laws may not protect it from being further shared.

Access to your personal information
You will not have access to personal information related to this research study until the study is completed. This information is available to your doctor in the case of an emergency. At the end of the study, you will again have access to personal information that is normally within your medical records. However, some research records will not be part of your medical record and you may not be allowed to see those research records. There may be other limitations on access to medical information unrelated to this study.

Duration of authorization
The Researchers may use and share your information until the study and any necessary follow-up activities for the study have been finished. There is no end date for when Cardio Flow can use your personal information, unless you withdraw your authorization.

Contact Information for Questions or Problems

If you have questions, concerns, or complaints at any time about this research study, the investigational device or the procedure, or the use of your personal information, or if you believe you have been injured as a result of being in this study, please ask. You should contact:

Principal Investigator: [Name]
Phone: [Phone] (24 hours)

If you have any questions, concerns, complaints about the research, or about your rights as a research participant, you should contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Consent

My signature on this consent form and authorization to use and disclose health information means that I have read this form, or had read it read to me, and understand the information in this form about the research study. My signature also means that my doctor or a nurse has talked with me about the study and I have had a chance to ask questions, and all of my questions have been answered. I know that taking part in this research study is my choice and that I can quit at any time. If I decide not to take part in the study, it will not affect my medical care in any way. I agree to be in this study, and to the use and disclosure of my personal information as described in this form.

I understand that I will receive a signed and dated copy of this informed consent form for my records. By signing this consent form I have not waived any legal rights.

_____ _____
Signature of Subject Date

_____ _____
Printed Name of Subject Date

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent