Clinical Evaluation of the StablePoint Catheter and Force-Sensing System for Paroxysmal Atrial Fibrillation (NEwTON AF)

NEwTON AF

PC053

Master Informed Consent Form

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Sponsored By
Boston Scientific Corporation
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And

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Study Sponsor: Boston Scientific	**Study:** Clinical Evaluation of the IntellaNav StablePoint™ Catheter and Force-Sensing System™ for Paroxysmal Atrial Fibrillation (NEwTON AF)
	Study site: <insert name of **Study site** where Study procedure will take place>
	Study Doctor: <insert Study Doctor name>

Introduction

We are asking you to be in a research study for the treatment of Paroxysmal Atrial Fibrillation (PAF) using the IntellaNav StablePoint™ Catheter and Force-Sensing System™. This consent form provides information on the procedures and risks involved in this study. The study doctor or his/her representative will also talk to you about the study. Please read this form carefully so you can decide if you want to take part in the study and ask the study doctor or his/her representative any questions that you may have about this study. You do not have to be in the study. If you agree to participate in the study you can still leave the study at any time without having to provide a reason. Your medical care will not change in any way if you say no or decide to leave the study at a later date. Please take as much time as you need to make your decision.

Study Information

You are being asked to participate in this study because you have a condition where your heart beats rapidly or irregularly. This type of heart condition is called an arrhythmia. The name of the arrythmia is Paroxysmal Atrial Fibrillation (PAF). Your doctor has advised you that you should have a procedure to try and restore normal heart rhythm. This procedure is called an ablation. Ablation procedures use either heat or cold to destroy abnormal tissues inside the heart that cause atrial fibrillation. This study will use heat to destroy the abnormal tissues in the heart that cause your irregular heart rhythm.

This study will research the safety of the IntellaNav StablePoint™ Catheter and Force-Sensing System™ and also study how well it works for the treatment of PAF. The system is made by Boston Scientific Corporation, who is also the Sponsor of this research.

The IntellaNav StablePoint™ Catheter and Force-Sensing System™ are considered “investigational” in the United States because they are not approved by the Food and Drug Administration (FDA) for the treatment of atrial fibrillation.

Due to your arrhythmia your doctor plans to perform an ablation procedure. If you choose not to participate in this study, your doctor will use a different system for the ablation procedure.

Device Information

The IntellaNav StablePoint™ catheters are thin tubes that are placed inside your heart during the ablation procedure. The tubes are used to apply heat to the heart muscle in areas known to cause atrial fibrillation. The heat causes tiny scars which can help stop the atrial fibrillation.

The Force-Sensing System™ is a combination of many different parts, which you can see in the picture below. In basic terms, the IntellaNav StablePoint™ Catheter is used with a computer that helps guide your doctor during the ablation procedure, which includes the force being applied by the catheter. The computer is called the Rhythmia HDx™ Mapping System and is used to collect information about the shape and the electrical activity of your heart. The information collected helps your doctor perform the ablation procedure.

Figure 1: Rhythmia HDx™ Mapping System with the IntellaNav StablePoint™ Catheter

Study Description

The number of patients expected to join this study will be approximately 299 at up to 50 centers in North America, Europe and Asia.

If you decide to participate in this study, you will be asked to sign and date this consent form. If you sign this consent form, information about you and your health will be collected before, during and after your ablation procedure. You will be asked to come back to the hospital or clinic for some tests at different times at 1 month, 3 months, 6 months and 12 months after the ablation procedure. Your participation in the study will be complete after you have completed all the tests for the 12-month visit.

Study Visits

Please find below a list of all tests and when they will happen during the study. The listing below has more detailed explanations of the tests that may be performed and the activity you may be asked to do.

When		Tests and Evaluations to be Conducted
Prior to the Procedure	During a study visit after consent	Demographic data (such as age and gender), medical history, physical exam, blood tests, health status, medications, ECG, imaging of your heart (if needed), quality of life (QOL) questionnaire, stroke questionnaire
During the Procedure	At the hospital, during the ablation procedure	Imaging of your heart, information on the ablation procedure, health status, ECG, medications

When		Tests and Evaluations to be Conducted
After the Procedure / at Discharge	After the ablation procedure, but before leaving the hospital	Physical assessment including examination of your heart and lungs, health status, medications, ECG, imaging of your heart (if needed), stroke questionnaire, event monitor
1 Month after the procedure	During a study visit	Physical assessment, health status, medications, ECG, imaging of your heart (if needed), event monitor
3 Months after the procedure	During a study visit	Physical assessment, health status, medications, QOL Questionnaire, ECG, imaging of your heart (if needed), event monitor
6 Months after the procedure	During a study visit	Physical assessment, health status, medications, QOL Questionnaires, ECG, imaging of your heart (if needed), 24-hour heart monitor, event monitor
12 Months after the procedure	During a study visit	Physical assessment, health status, medications, QOL Questionnaires, stroke questionnaire, ECG, imaging of your heart (if needed), 24-hour heart monitor, event monitor
Repeat Procedure for PAF	At the hospital, during the ablation procedure	Imaging of your heart, information on the ablation procedure, health status, ECG, medications, stroke questionnaire
Unscheduled Visits	During a study visit	Physical assessment, health status, medications, ECG, imaging of your heart (if needed), event monitor

To find out more about what will happen at each visit, please read the information below.

Enrollment

Your doctor, or a member of his/her team, will collect your information. You will also have a basic physical examination. Your doctor, or a member of his/her team, will ask you to fill out 2 surveys which will look at your quality of life and check your overall health to see if you are able to participate in the study.

You may need to have some tests to find out if you can participate in the study. Your doctor will also check if it is safe for you to have the procedure by looking at your heart and nearby blood vessels. These tests are part of normal care and may be done even if you do not join the study. These tests will be done at various times throughout the study and at the end of the study. If you have had some of them recently, they may not need to be done again.

- **Transthoracic echocardiogram (TTE)** is a type of image of your heart. A probe that looks like a microphone is placed on the skin of your chest or abdomen and uses sound waves to get various views of the heart. The test takes about 45 minutes.
- **12-lead Electrocardiogram (ECG)** gives us a measure of the heart's electrical activity. You will be asked to lie flat on a table and several stickers attached to wires will be placed on the body. This test takes about 10 minutes.
- **Pregnancy test** is a blood or urine test that is only done if applicable.

You might need to have some extra tests to look at your heart and to check for a blood clot. The types of test that could be used are described below. You will not need to have all of them. Your doctor will decide which test is best for you based upon what he/she may need for the ablation procedure. If a test is needed, your doctor will provide you with instructions prior to having the test.

- **Cardiac Magnetic Resonance imaging (MRI)** is a procedure which uses a big magnet, radio waves and a computer to produce images of the inside of your heart.
- **Cardiac Computed Tomography (CT)** scan allows doctors to see inside your body, using a combination of X-rays and a computer to create pictures of each part of your heart. It shows more details than a regular X-ray.
- **Transesophageal Echocardiography (TEE)** is a test which provides a more detailed evaluation than is possible with a different type of echocardiogram. The test uses sound waves to evaluate your heart function by inserting a small tube down your throat.
- **Intra Cardiac Echocardiography (ICE)** is a test that takes a picture of your heart using sound waves. A sensor at the end of a long catheter is inserted into your body via a vein in your groin. This test can only take place during the procedure.
- **Pulmonary Venogram** during this test, a special dye will be injected into your veins and x-rays will be used to take pictures of your heart.

Ablation Procedure

The ablation procedure used is basically the same as the procedure you would have if you choose not to participate in this study. Your doctor will perform an ablation in the top left part of your heart. This part of your heart is called the left atrium and is the area that doctors target when treating atrial fibrillation. If you have a history of another type of arrythmia called atrial flutter or develop one during your procedure, the doctor may decide to ablate the top right part of your heart. Your doctor will use the IntellaNav StablePoint™ Catheter to deliver electrical energy (heat) around the blood vessels that bring the blood to the heart from the lungs. These vessels are the common source for atrial fibrillation activity. The heat delivered with the catheter causes scarring of the tissue to stop the electrical signals causing the atrial fibrillation.The procedures of using the IntellaNav StablePoint™ Catheter to deliver energy to the heart are experimental.

Pre-discharge and Follow-up visits

Before you leave the hospital, information about your health will be collected along with a physical examination. A 12-lead ECG will be performed. Your doctor might decide to perform imaging of your heart and x-rays of the muscle that controls your breathing. The x-rays take pictures while you breath in and out.

Before leaving the hospital, you will be provided with a device called an event monitor and a cell phone along with a quick reference guide on how to use the event monitor. An event monitor is about the size of a USB stick and records your heart rhythm.

The recording is sent directly by you to a lab that reviews it and then provides it to your doctor. This information will be sent using a cellphone.

You will be given instructions on how to use the event monitor by the study team. You will be asked to make a recording any time you begin to feel your heart beating rapidly. You will be asked to record any abnormal heart rhythms you feel any time after your ablation procedure until the end of the study at 12 months.

After your 3-month visit, you will be asked to record your heart rhythm a minimum of 2 times per month including whenever you have symptoms. You should discuss with your doctor whether and under what circumstances he/she would like you to call him/her when you have such episodes. You will be paid $25 for submitting 2 records of your heart rhythm monthly between 3 and 12-months. This means that you will be paid $25 for submitting 2 records of your heart rhythm at months 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12. You will not get paid if you submit less than 2 records of your hearth rhythm and you will not get paid for submitting more records than what is required. If you submit 2 records of your heart rhythm each month, you may be eligible to receive up to $250. You should practice submitting your heart rhythms after your ablation procedure is complete. If you have any problems with submitting your heart rhythm, please contact a study team member right away.

You will be asked to come back to the hospital or clinic for follow-up visits. These visits will take place at 1 month, 3 months, 6 months and 12 months after the ablation procedure. During each of these visits your health status will be checked, your heart medications will be documented and you will be asked to have a 12-lead ECG test. If deemed necessary by your study doctor, imaging of your heart and x-rays of the muscle that controls your breathing may be performed.

At the 6 and 12-month visits, you will be asked to wear a Holter monitor for 24 hours and submit your heart rhythms. If you complete the 24 hour Holter monitor after your 12-month visit, you may need to return to the hospital or clinic to return the event monitor. The Holter is a small box, worn on your chest, which continually measures your heart rate. In the hospital or clinic, you will be shown how to wear and use the device. While you are wearing the Holter monitor (24 hours), you cannot shower because the device may not be waterproof.

What is expected from you?

If you agree to be in this study, you will be expected to visit your study hospital or clinic for all required examinations, study procedures and follow-up tests as indicated in the table above. In the event that COVID-19 prevents you from going to the clinic or the hospital, the study doctor may require you to complete your visit or other study assessments/testing remotely or at another clinical location. You will be contacted by your study doctor or a member of the study team to discuss this with you first.

You are expected to tell your study doctor about all other medical treatments and any medical problems or concerns that you have, including any new or changed symptoms you experience, admissions to hospital, changes made to your heart medications or any heart related events during your participation in the study.

Potential Risks from Your Participation

If you take part in this study, you will be subject to similar risks shared by all patients outside of the study who have a paroxysmal atrial fibrillation ablation procedure conducted per standard of care . There may also be additional risks or side effects which are unknown at this time.

Please refer to the Appendix at the end of this form for a list of known risks.

Please talk to your doctor if you have any questions.

Risks of Being Pregnant in This Study

Pregnant women and women who plan to become pregnant during this study may not participate in this study. Notify your doctor immediately if you become pregnant while taking part in this study as there may be risks to you or your fetus that are currently unknown. If you are a woman of child bearing potential

your study doctor will ask you to take a pregnancy test to confirm you are not pregnant, unless you have already completed one with a negative result within 7 days prior to enrollment.

Potential Benefits from Your Participation

You may or may not receive any benefit from participating in this study. However, medical science and future subjects may benefit from your participation.

Alternative Devices/Treatments

You do not have to participate in this study. You may still undergo an ablation procedure for the treatment of atrial fibrillation using a commercially available ablation system. You also have the choice to take medication or have surgery to control your irregular heart rate or heart rhythm. Device implantation may also be a treatment option. The study doctor will review the potential risks and benefits of these alternatives with you.

What happens at the end of the study?

Once you complete the study assessments as part of the 12-month follow-up visit, your participation in the study will end. You will also need to return the 24-hour Holter Monitor and event monitor. Your doctor may follow your health status according to the standard practice of the hospital or clinic.

Voluntary Participation

Your participation is voluntary. You may choose not to be in the study, and you may withdraw from the study at any time without providing a reason. If you do not sign this form you will not be in the study. There will not be any penalty, any negative impact to the care or treatment you receive or any loss of benefits to you to which you are otherwise entitled if you decide not to be in the study or stop being in the study at any time.

Your study doctor may decide to stop your participation in the study if it is necessary for your safety or if you do not follow their instructions. This may occur with or without your consent. The entire study may also be stopped by a regulatory authority such as the U.S. Food and Drug Administration (FDA), Ethics Committee (EC) or Institutional Review Board (IRB), or the Study Sponsor. If your study doctor stops your participation in the study or if the entire study is stopped, you will be notified.

New information may come up during the study and it will be given to you in writing in a timely manner. The new information may affect your decision to continue to be part of the study. Depending on the new information, you may be asked to read and sign a new updated consent form for the study.

Financial Statement

The Study Sponsor is paying <Center Name> for their work on this study. This payment is compensation for the time and resources required for study administration and execution.

Compensation and Costs

The Study Sponsor will pay for the special tests and examinations that are required by this study and not otherwise part of your standard medical care. However, many of the tests, procedures, and exams you will receive are believed to be part of standard medical care, and may or may not be covered by your medical insurance. If your medical insurance does not pay for your care that is considered part of standard medical care, you will be responsible for the cost of the medical care related to your condition including but not limited to: laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures You should consult with your insurance plan if you would like to get more detail about what your costs might be if you participate in this study.

In case of Injuries

In the unlikely event that you are injured or experience discomfort as a result of participating in this study, you may contact your study <doctor or contact> at <insert phone number> who will provide or arrange medical treatment. No special arrangements have been made for payment to you for additional treatment resulting solely because of injuries from your participation in this study. No payment will be made by the Study Sponsor or <Study site's Name> for lost wages, expenses, compensation for pain and suffering, discomfort or disability.

However, the Study Sponsor or <Study site's Name> may be responsible if any injury or illness is caused by negligence (mistake) on the part of them, their employees or agents. Your study <doctor or contact> can provide you with information about the general liability policies of <Study Site's Name>, to determine if compensation may be available from that source.

Study Insurance

The laws governing medical devices may require that an insurance policy is subscribed by the sponsor to cover subjects participating in a clinical study. Insurance has been subscribed for this study. For more information about the policy and contact details you can reach out to your study doctor. You can get further information concerning insurance through your study doctor.

Legal Rights

By signing this form, you are not giving up any of your legal rights or releasing the Study Doctor, study staff, Study Sponsor, hospital or their agents from liability for negligence.

Medical Records Recovery

The study staff will need access to your medical records to monitor your overall health. These medical records will be shared with the study sponsor. In the unlikely event of your death while you are participating in the study, your study doctor will seek copies of your medical records regarding your death. This may include emergency room records and hospital records. This information will be used for research purposes and will be kept confidential.

Identification and the Advice of the <Ethics Committee or Institutional Review Board>

This clinical investigation and Patient Information and Consent Form has been reviewed and approved by the following Ethics Committee: <Insert name of EC/IRB>.

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 a summary of the results. You can search this Web site at any time.

Role of the Boston Scientific Representative/s

In this study, and at the request of your doctor, a representative of Boston Scientific, who is obligated to maintain your privacy, may:

- provide technical expertise on the Rhythmia HDx™ mapping system during the preparation and execution of ablation procedure, including preparing, setting or adjusting the device parameters under the direction of your doctor;
- be present and have some direct contact with you at the ablation procedure and other study related visits at your doctor's request;

- assist and review the collection of information about your procedure and study documents for completeness and accuracy. Be aware of the outcome of your ablation procedure and other study information;

Please talk to your doctor if you have any questions.

Privacy

Your privacy is important and your participation in this study will be kept confidential per relevant laws.

How will data be collected and processed?

During this study, your personal data (such as age, gender, date of birth or other information that could identify you) and medical information will be collected by the study team and processed for the purpose of the study. Your personal data will be recorded in your paper or electronic medical record and stored at the study site.

The information will be collected, transferred/sent to the sponsor and analyzed in coded form, which means that your name will be replaced by a code. All this information will be protected against unauthorized access. The connection between your code and your name, will be kept secured at the study site.

If the results of this study are published your identity will remain confidential.

Use and Disclosure Covered by this Authorization

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your special authorization before we may use or disclose your protected health information (PHI) for the research purposes described in the Informed Consent Form for this study. This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed. Please read the information below carefully before signing this form.

Who will disclose, receive, and/or use your information?

The following person(s), class(es) of persons, and/or organization(s) may disclose, use, and/or receive your protected health information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as otherwise permitted or required by law:

- ☒ Boston Scientific Corporation and its affiliated corporations and their respective employees, contractors and other agents (“Sponsor”)
- ☒ Every health care provider who provides services to you in connection with this study
- ☒ Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study’s protocol
- ☒ The United States Food and Drug Administration, Medicare, Medicaid, Notified Bodies, Competent Authorities and other regulatory agencies from countries where data from this study may be submitted
- ☒ The members and staff of the Institution’s affiliated Institutional Review Board, Ethics Committee(s), Privacy Board, and all other institutional review boards or persons who watch over how the research is performed and/or monitor the safety and success of the research, including the Institution that approves this study
- ☒ Study Doctor
- ☒ Study Coordinator
- ☒ Members of the Research Team

- ☒ Members of the Institution's administrative staff responsible for administering clinical studies and other research activities
- ☒ Data Monitoring Committee/Clinical Events Committee members

What information will be used or disclosed?

The entire research record and any original medical records held by the Institution and any health care provider authorized to disclose, use or receive the information may be used and disclosed.

What could happen if you agree to this use or disclosure of your health information?

There is the possibility that information disclosed under this authorization for the use of your protected health information may be re-disclosed and that the Federal privacy laws (laws that protect the privacy to your protected health information) may no longer protect it from being given to another person, class of persons, and/or company.

Once information that could be used to identify you has been removed and your information is no longer identifiable (connected to your identity), the information that remains is no longer protected by this Authorization (agreement) and may be used and given by the Members of the Research Team and Sponsor to others, including for other research reasons.

The Researchers and Sponsor have agreed that no publication or presentation of the research will reveal your identity without your separate specific written permission and authorization (agreement) (even if you revoke (take back) this Authorization (agreement)).

What rights do you have?

You have a right to refuse to sign this authorization. Your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form. You will not be able to participate in the research described in the informed consent form and will not receive treatment as a study participant if you do not sign this form.

You may change your mind and cancel your authorization at any time. To cancel your authorization, you must write to: <insert name of Study Coordinator, Principal Investigator, or other responsible person or department, with full Institution Name and Address>. However, if you cancel your authorization, you may no longer be allowed to participate in the research study and may no longer receive research-related treatment. Also, even if you cancel your authorization, the information already obtained may remain a part of the research as necessary to preserve the integrity of the research study.

When does this Authorization expire?

This authorization will never expire unless you revoke it.

California: This authorization expires when the research ends and all required study monitoring is over.

Specific Understandings

By signing this consent form, you authorize the use and/or disclosure of your protected health information (PHI) described above. The purpose for the uses and disclosures you are authorizing is to conduct the research project explained to you during the informed consent process and to ensure that the information relating to that research is available to all parties who may need it for research purposes. Your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable), and to run the normal business operations of the Institution or other providers providing services in connection with this study.

What happens if you withdraw from the study?

Your participation in the study is voluntary. You may choose not to be in the study. If you choose not to be in the study there will not be any negative impact to the care or treatment you receive or any loss of benefits to you.

In addition, if you withdraw from the study it may be necessary for the study sponsor to continue using the information collected about you up to the point of your withdrawal as allowed by this consent form.

For example, the study staff, IRB, Boston Scientific or its representatives, and applicable regulatory authorities will continue to have access to your original medical records to confirm your data collected during your time in the study is accurate. This information is important for study sponsors and regulatory authorities to identify potential patient and device safety issues. Finally, in order to confirm the safety of the device, regulatory authorities may request confirmation of your health status, including information about device clinical performance, effectiveness or safety, even if you have withdrawn from the trial or you do not continue to follow up with your study doctor as required in this form. By signing this consent form you agree to be contacted and/or to have your original medical records and public records accessed to confirm your health status.

Anonymization and Future Use of Data

Data obtained from this study may be used in future related research. Before use in future related research, your data will be anonymized. Anonymized means the data cannot be connected to you in any way, not even by a code. Your consent and authorization to participate in this study represents your consent and authorization to the use of your anonymized data in future related research. The results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor, people who work with the Study Sponsor, as well as others who request access to the results, may use the results of this study for other research purposes, in particular:

- evaluating other products or therapies for patients
- developing a better understanding of disease
- improving the design of future clinical trials

I understand that my general practitioner may be informed about my participation in this study.

Contact Information

If you have questions or would like more information about this study, contact:

<Study Doctor or other title/role>	< insert name >	< insert phone number >

If you are injured or hospitalized for any reason during the study, contact

<Study Doctor or other title/role>	< insert name >	< insert phone number >

If you have questions about your rights as a study subject, contact:

<Institutional Review Board (IRB) / Ethic Committee (EC)>	< insert IRB/EC name >	< insert phone number >

Subject Consent Declaration

My signature below means that:

1. I have read this consent form, or it has been read to me, and I acknowledge the information provided.
2. I have been given time to consider the study-related procedure(s) and risks, as well as the alternatives. All my questions were answered to my satisfaction.

3. I understand that my participation in the study is voluntary and my refusal to participate will not result in any penalty and will not compromise my medical treatment. I can withdraw my consent at any time without providing a reason prior to and during the study, without any legal consequences and without any penalty or loss of benefits to which I am entitled. I know who to contact in the future if I decide to withdraw or if I require additional information.
4. I agree to comply with the requirements of the study, follow the study doctor's instructions, and to inform the study doctor about my medical background, medication or other medical matters and about all medical events that occur during the course of this study.
5. My consent does not release the Study Sponsor from its obligations, and my legal rights will not be affected.
6. I agree that the Study Sponsor's representatives, regulatory authorities and IRB/Ethics Committee representatives will be granted direct access to my original medical records.
7. I will be given a signed and dated copy of this document for my records.
8. By signing this form I agree that my general practitioner may be notified about my participation in this study.

Region/country-specific requirement (e.g. Regulation 2016/679/EU) include the *following 5 paragraphs, if applicable to the region or country where the study will be conducted*

9. I am aware of my right to have access to and to correct any data relating to me that will be subjected to computerized data processing.
10. I am aware and agree that my relevant personal data will be processed for the purpose of this study.
11. I am aware that for the purposes of analysis and publication it may be necessary to send data to countries where the <European or other applicable region> legislation on data protection does not apply (for example the United States of America).
12. I agree to the transmission of my personal data, as long as it is encrypted (coded) as required per the <European or other applicable region> legislation on data protection.
13. I agree to the use of my anonymized data for future research.

Signatures

Subject:

Printed name _____

Signature _____ Date and Time _____

Witness: (if applicable)

Witness printed name _____

Witness signature _____ Date and Time _____

Person conducting informed consent discussion:

Printed name _____

Signature _____ Date and Time _____

By signing below I agree to record my heart rhythm a minimum of 2 times per month, whenever I have symptoms and submit those recordings so they may be evaluated. If I am not submitting my heart rhythms a minimum of 2 times per month, I agree that a site coordinator or designee may contact me. I also agree that the company that provides the event monitor may contact me to troubleshoot any issues I have with submitting my heart rhythm recordings.

Subject:

Printed name _____

Signature _____ Date _____

Appendix – Table of Known Risks

The following risks would be the same for the ablation procedure if you decide not to join this study.

Risk Technical Term	Risk Simple Term
Pain or discomfort, for example:	
• Angina	Pain or discomfort in the chest or neck
• Chest pain	Uncomfortable feeling in chest
• Non-cardiovascular pain	Pain in the body not related to the heart
Cardiac / Respiratory arrest	Heart or breathing stops
Death	Death
Hypertension	High blood pressure
Hypotension	Low blood pressure
Infection/inflammation/exposure to biohazardous material	Infection/Swelling or redness/coming into contact with blood or body fluids
Edema	A collection of fluid in part of the body
Heart Failure	When your heart doesn't pump as well as it should
Pleural Effusion	A collection of fluid around the lungs
Procedural related side effects, for example:	
• Allergic reaction (including anaphylaxis)	Allergic reaction
• Genitourinary complication	Complication of genitourinary system
• Side effects related to medication or anesthesia	Feeling unwell or unwanted symptoms
• Radiation injury/tissue burn	Damage or burns due to xrays
• Renal failure/insufficiency	The kidneys stop working/do not work well
• Vasovagal response	Fainting due to drop in blood pressure
Respiratory distress/insufficiency/dyspnea	Slow and/or ineffective breathing
Arrhythmia (new or exacerbated)	Abnormal heart rhythm (new or worsened)
Conduction pathway injury (Complete heart block (transient or permanent), nodal injury, etc.)	Injury to the electrical system of the heart (permanent or temporary)
Nerve injury, for example:	
• Phrenic nerve injury	Damage to nerve that controls breathing
• Vagal nerve injury	Damage to nerve that controls the heart, lungs, and digestive tract.
Gastrointestinal disorders	Stomach or bowel problems
Vessel trauma, including:	
• Perforation	A hole in an artery or vein
• Dissection	Tear in an artery or vein
• Coronary artery injury	Damage to the arteries that supply the heart
• Vasospasm	Temporary tightening of an artery or vein
• Occlusion	Blockage of an artery or vein
• Hemothorax	Blood in the space between the chest wall and the lung
Cardiac trauma, for example:	
• Cardiac perforation/cardiac tamponade/pericardial effusion	A hole in the wall of the heart or blood in the sac surrounding the heart
• Valvular damage	Damage to heart valves

Risk Technical Term	Risk Simple Term
• Stiff left atrial syndrome	Top left heart chamber does not pump blood as well as it should
Injury related to tissue damage and/or adjacent structures, for example:	
• Esophageal injury	Injury to the tube that connects the throat to the stomach
• Pulmonary injury	Injury to the lungs
• Catheter Entrapment	Catheter getting stuck on tissue in or around the heart or vessels
• Physical trauma	Any other damage to surrounding areas
Fistula, for example:	
• Atrio-esophageal fistula	Abnormal connection between the tube that connects your throat to your stomach and the heart
• Bronchopericardial fistula	Abnormal connection between the lungs and the sac around the heart
PV stenosis and its symptoms, for example:	Narrowing of the vessels that drain blood from the lungs to the heart
• Cough	Cough
• Shortness of breath, fatigue	Difficulty breathing, feeling tired
• Hemoptysis	Coughing up blood
Surgical and access complications, for example:	Unable to gain access to a vein or other body part
• Hematoma/seroma	Leaking of blood from vessels
• AV fistula	Abnormal connection between the artery and the vein
• Bleeding	Loss of blood
• Pseudoaneurysm	Leaking of blood into vessel walls
• Pneumothorax	Collapsed lung
• Residual atrial septal defect	Hole remaining between the right and left upper chambers of the heart
Injury due to embolism/thromboembolism/air embolism/foreign body embolism	Problems due to clots, air bubbles or something entering the body blocking an artery or vein
• Cerebrovascular Accident (CVA)/stroke	Blood clot or bleed in the brain
• Transient Ischemia Attack (TIA)	Temporary blockage of blood flow to a part of the brain
• Myocardial infarction	Heart Attack
• Neurological impairment and its symptoms, for example:	Problems with the nervous system
○ Cognitive changes, visual disturbances, headache, motor impairment, sensory impairment, and speech impairment	Difficulty thinking, blurred or tunnel vision, headache, difficulty moving, difficulty feeling, smelling or tasting, difficulty talking
• Pulmonary embolism	Air bubbles or clot in your lungs
• Asymptomatic cerebral embolism	A loss of blood supply to a part of the brain that is due to the blockage of the flow of blood in an artery that does not cause a patient to have symptoms.