AtriCure	Subject Informed Consent Form	
	Protocol #: CP2015-4	**Study Title:** **FROST - Cryoablation**
	Site #:	**PI Name:**

Protocol Title: The *cryo*ICE™ CryoAnalgesia study **F**or pain management in post tho**R**acic procedures via interc**OST**al cryoanalgesia (FROST)

This consent form contains important information to help you decide whether to participate in a research study. Being in a study is voluntary – it is your choice whether or not to participate.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

1.0 INVITATION TO PARTICIPATE

You are being invited to participate in a clinical research study because you are having a minimally invasive surgical procedure on your heart and your study doctor has determined that you may also benefit from a technique to assist with post-operative pain control. This is called Cryoanalgesia. This is done at the same time as your other surgical procedure(s).

The information in this document contains details about the study procedures and the device that will be used during the research study. It also describes possible risks and benefits so that you will be able to make an informed decision about your potential participation in this research study. This consent form also describes the privacy protection rules and who will have access to your medical and study records.

This is a randomized study. That means not everyone will have cryoanalgesia. Agreeing to participate does not guarantee you will have cryoanalgesia. Your care will not be affected in any way if you choose not to take part in this study.

2.0 INTRODUCTION

Based on your medical condition, the surgery on your heart will be done using a minimally invasive approach called a thoracotomy. This is an incision made in the side of the chest between the ribs. Minithoracotomy is another approach that can be used in some instances – a small incision is made to decrease pain and scarring, and improve recovery time.

Pain control is very important when recovering from this type of surgical procedure. Although there are a number of ways to manage post-operative pain, IV medications containing opiates are most commonly used. All opiates have side effects that include changes in mental status and respiratory depression.

Cryoanalgesia is a pain-relieving technique which uses cold to treat nerve pain. It's been around for centuries. Very simply it uses ice to numb nerves. The more sophisticated, current type of cryoanalgesia uses a needle-like probe to deliver very cold sensation and thereby incapacitate nerves.

If you choose to participate in this study and are randomized to receive cryoanalgesia, your doctor will treat your surgical area with a session of cryoanalgesia during your surgery. This study will examine the effect that cryoanalgesia may have on post-operative pain control.

3.0 DESCRIPTION OF DEVICE - THE ATRICURE® cryoICE™ cryo-ablation system

The cryoICE™ cryo-ablation probes are intended for use in the cryosurgical treatment by freezing target tissues that blocks the electrical conduction pathway. The probe is also intended for use in blocking pain by temporarily freezing peripheral nerves. This device is approved for use to temporary block pain of peripheral nerves.

4.0 DURATION OF STUDY INVOLVEMENT

Up to 100 subjects are expected to take part in the research study at up to 5 hospitals across the United States. Your participation in this clinical study will last for approximately 180 days from the date of your heart surgery.

5.0 STUDY PROCEDURES

There are two groups in this study. If you agree to take part in this research, sign this Informed Consent, and meet all of the other study requirements you will be enrolled and then during your surgery, you will be "randomized". One group will receive the cryoanalgesia and the other group will not.

You doctor will be allowed to open a sealed envelope only after all of the necessary evaluations have been made. You will not be told if you received cryoanalgesia. Knowing if you received the cryoanalgesia could have an impact on evaluating your pain after surgery.

Randomization is 3:1. That means for every four subjects in the study, three (3) will get the cryoanalgesia and one (1) will not.

To further evaluate the effect of the surgical procedure, you will be asked to return to your doctor at 30 days after surgery at which time you will be asked about your recovery, medications, and any new problems. A follow up phone call will be scheduled at 90 days and 180 days after surgery. During the phone call, you will be asked about your recovery, medications, and any new problems. If the questions elicit a positive response you will be asked to make an office visit for more thorough allodynia assessment.

What you will be asked to do for this study

Visit 1: This is a baseline evaluation

You will be asked a number of questions that evaluate if you are a good candidate for this study.
Your chart will be reviewed to insure you meet all of the inclusion criteria of the study

You will be given a simple breathing test using a hand held spirometer, asked about any current pain, and evaluated how easily you can walk.
Your vital signs and review of medications will be done at every visit.
You will be asked about new or existing problems at each visit.

Visit 2: This is your surgical procedure
Before your surgery, your vital signs, review of medications and a physical exam will be done.
You will be asked about your current pain again.
You will be asked about new or existing problems.
You will have your surgical procedure which may or may not include cryoanalgesia
Your post-operative pain will be controlled using standard of care regardless if you receive cryoanalgesia or do not receive cryoanalgesia.

Visit 3: 24 hours after your surgery
Your vital signs and review of medications will be done.
You will be asked about new or existing problems.

Visits: 4, 5, 6, 7 48, 72, 96, and 120 hours after your surgery
Your vital signs and review of medications will be done.
You will be asked about new or existing problems at each visit.
You will be given a simple breathing test using a hand held spirometer and asked about any current pain.
You will be given an ambulatory movement test.

Visit 8: The day you go home from the hospital
Your vital signs and review of medications will be done.
You will be asked about new or existing problems.
You will be given a simple breathing test using a hand held spirometer and asked about any current pain.
You will be given an ambulatory movement test.

Visit 9: 30 days after your surgical procedure, Office Visit
Your vital signs and review of medications will be done.
You will be given a simple breathing test using a hand held spirometer.
You will be asked about new or existing problems.

Visit 10: 90 days after your surgical procedure, Phone call
Your medications will be reviewed.
You will be asked about new or existing problems.
Your incision pain will be evaluated using a series of questions.
Based on your responses, you may need to go into the physician's office for further evaluation.

If you go to the office, you will be given an allodynia test. This involves using a cotton swab on your incision to see how sensitive it is.

Visit 11: 180 days after your surgical procedure, Phone call

Your medications will be reviewed.
You will be asked about new or existing problems.
Your incision pain will be evaluated using a series of questions.
Based on your responses, you may need to go into the physician's office for further evaluation.
If you go to the office, you will be given an allodynia test. This involves using a cotton swab on your incision to see how sensitive it is.

6.0 COSTS AND PAYMENTS

The cost associated with your heart operation and your hospitalization will be your responsibility or that of your insurance carrier. There are no study related costs to you in this clinical study. You might have unexpected expenses from being in this study. Ask your study doctor, this discussion should include who will pay the costs of treating possible side effects.

Compensation for research related injury:

If you are injured as a result of this study, the study doctor will arrange medical treatment for your injury. The sponsor of this study, AtriCure, Inc. will pay reasonable medical expenses not covered by your health insurance or third party payer, for the treatment of an injury that in the reasonable judgment of an independent physician reviewer assigned to the study, was the direct result of your study devices. Medical expenses will be paid only to the extent that the expenses are not due to a pre-existing medical condition of yours or your underlying disease, or to the negligence or misconduct of the study doctor, the research site, or one of its employees or agents.

The sponsor, AtriCure, Inc. does not have any plans to pay for lost wages, disability, pain and suffering, or other costs other than reasonable medical expenses.

No compensation is routinely available from [redacted] does not intend to provide free medical care for any sickness or injury resulting from being in this study.

Payment:

[redacted]

Funding for this research study is provided by AtriCure, Inc. The study doctor is being paid by the sponsor to conduct this research and/or to recruit participants.

7.0 POSSIBLE RISKS AND DISCOMFORTS:

This consent covers the risks associated with having cryoanalgesia and does not address the risks and discomforts associated with your cardiac surgery.

Your doctor should advise you on the risks specific to your surgery. The possible risks and discomforts that may be associated specifically with the use of the cryoICE Probe during a procedure are identified below.

- Skin injury due to cryoablation of the skin
- Intercostal muscle injury
- Permanent peripheral nerve damage
- Device breakage
- Tissue perforation
- Tissue freezing
- Failure to ablate peripheral nerve may require additional pain medication

These risks could lead to symptoms that include:

- Numbness around the incision lasting from 1 to 6 months
- Neuralgia (intense localized pain) occurring 6 weeks after cryoanalgesia lasting up to 2 months.
- Hyperesthesia (excessive skin sensitivity)

POTENTIAL RISKS

Complications may occur at any time during the procedure, post procedure or follow-up period. There also may be risks unknown at this time. Your study team will want to know about any adverse events but are specifically interested in an event that could have occurred from the cryoanalgesia. These are called adverse events.

There are also complications that could rarely occur:

- Injury to user
- Nitrous gas exposure
- There may be other risks that are not known at this time

8.0 POSSIBLE BENEFITS

There may be no direct benefits to you as a result of your participation in this study. You may or may not receive the cryoanalgesia. If you receive the cryoanalgesia, the potential benefits outweigh the risks of participation in this study.

The benefits may include but are not limited to, the following:

- Improved post-operative pain control
- Less post-operative pulmonary (breathing) complications
- Improved blood pressure and heart rate
- Less changes to mental status

- Advancing the medical and scientific knowledge that may benefit future patients with similar conditions may be gained through this clinical study.
- There may also be other benefits that are unforeseen at this time.

9.0 ALTERNATIVE PROCEDURES/TREATMENTS

Pain control is very important when recovering from this type of surgical procedure. Your pain will be managed whether you received cryoanalgesia or not. Although there are a number of ways to manage post-operative pain, IV medications containing opiates are most commonly used. All opiates have side effects that include changes in mental status and respiratory depression. Other options include:

- Epidural analgesia
- Intercostal nerve blocks

10.0 VOLUNTARY PARTICIPATION

Your participation in this study is completely voluntary. You may refuse to participate or withdraw from the study at any time for any reason. Your decision does not affect the care you receive.

11.0 WITHDRAWAL FROM THE CLINICAL INVESTIGATION

You may withdraw your consent to participate in the study and you may withdraw permission to use your health data at any time.

You can withdraw from study participation

If you decide to stop your participation in this study, let your study coordinator or doctor know.

You can withdraw permission to use your health information

Information that has already been collected or sent to the study sponsor or their representatives cannot be withdrawn.

If you should decide to withdraw your permission to use your health information, we request you to do so in writing by contacting Dr. [redacted]

You may be withdrawn from participation in the study

The study doctor and/or sponsor may withdraw you from the study at any time without your permission. This may happen because:

- your doctor feels it is to your benefit
- you have not followed the instructions given to you
- the sponsor has stopped the study
- or for any other reason

His/her mailing address is: [redacted]

12.0 PRIVACY

The information obtained about you will be stored and evaluated only for the purposes of carrying out this clinical research study. Your identity will be protected to the greatest possible extent. You will be assigned a study ID that does not include your name.

Study records that identify you will be kept confidential as required by law. Except as required by law you will not be recorded by name or under your address, telephone number, or other direct personal identification. Your study documentation may be disclosed; however, you will be identified only by your study ID. The information associated with this ID will be stored in a safe place and is accessible only to study personnel.

According to legal provisions, this study-related information may be transmitted, stored, or used without identifying you by name to:

1. The sponsor of the study, or their associated study representatives, and IRB/EC for scientific evaluation;
2. Your records may be reviewed in order to meet federal or state regulations.

The study results will be retained in your research record for at least two years or until after the study is over, whichever is longer. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from the study.

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. You can search this Web site at any time.

13.0 CONTACT

If you have any questions or concerns regarding this clinical research study, or if any problems arise, you may call your [redacted]

14.0 SIGNIFICANT NEW INFORMATION

Any significant new information that is learned during the course of this clinical study and that may relate to your willingness to continue participation will be provided to you.

15.0 QUESTIONS ABOUT YOUR RIGHTS

If you are injured or have a medical problem as a result of this clinical study or have any questions about your rights as a participant in a clinical study, you may [redacted] information concerning the rights of subjects participating in clinical investigation studies.

CONSENT

I have received written information concerning the: The *cryo*ICE™ CryoAnalgesia study **F**or pain management in post tho**R**acic procedures via interc**OST**al cryoanalgesia (FROST)

In addition, Dr [redacted] has also provided me with comprehensive oral explanations about the nature, importance, and scope of the *cryo*ICE™ in particular concerning the purpose, procedures, benefits, and risks as well as obligations. All my questions have been answered in a manner understandable to me. I have no further questions at present. I know that I may ask questions at any time, including after the surgical procedure.

I hereby give my voluntary consent to participation in the study. I am aware of the fact that I may withdraw my consent at any time and that this will not result in any disadvantages to me.

I agree to transfer of my health information in some anonymous form for data processing and scientific evaluation to authorized professionals and to the transfer of such data to the regulatory authorities for review.

Finally, I also give my consent to scientific publication of the research results subject to the provisions of the privacy laws. If the study is performed in several countries, I also agree to access by the competent foreign supervisory agencies to my personal study data.

I was handed a copy of the Patient Informed Consent Form by the Investigator/study staff.

_____ _____

Printed Name/ Légal Représentative Name Date

_____ _____

Patient Signature/ Légal Représentative Name Date

In my judgment, the patient is voluntarily and knowingly giving informed consent and possesses the legal capacity to give the informed consent to participate in this study.

_____ _____

Printed Name of Person Conducting Informed Consent Date

_____ _____

Signature of Person Conducting Informed Consent Date