St. Jude Medical, Sylmar, California, United States
60026829/J
20111061

RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	ST MONITORING TO DETECT ACS EVENTS IN ICD PATIENTS STUDY (Analyze ST)

This consent form contains important information to help you decide whether to participate in a research study.

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.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

Informed Consent for the Analyze ST Clinical IDE Study

TITLE:	ST MONITORING TO DETECT ACS EVENTS IN ICD PATIENTS STUDY (Analyze ST)
PROTOCOL NO.:	60026829/J WIRB® Protocol #20111061
SPONSOR:	St. Jude Medical Sylmar, California United States
INVESTIGATOR:	Name Address City, State Zip Country
SITE(S):	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name Telephone

Introduction

You are being asked to take part in this research study because your doctor has determined that you may qualify to take part in the Analyze ST IDE study. This consent form explains why this research is being done and what your role will be if you decide to participate. This form also talks about the possible risks that may happen if you take part in this study. This study is sponsored by St. Jude Medical.

Please read this form, and ask your study doctor any questions about the study so that you can have your questions answered before you decide if you want to take part in the study. Please take your time and talk about this information with your family, friends, or family doctor.

This consent form may contain some 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 understand.

If you agree to be in the study, you will need to sign this form. Taking part in this study is entirely voluntary.

What is the purpose of this study?

The purpose of this study is to test the accuracy of a feature in your **I**mplantable **C**ardioverter **D**efibrillator (ICD) that detects changes in your heartbeat. The name of the feature is the ST Monitoring Feature.

The ST Monitoring Feature is the only investigational part of the ICD and is only one feature in your ICD. All the other things that your ICD does to treat your heart problems are the same in this ICD as in other available market-released ICDs. Your participation in this study will not change the standard treatments your ICD will provide you. It is not known if the information provided to your study doctor by the ST Monitoring Feature will help or not. This study will be collecting information to determine if it will or not.

Fast heart beat is a heart rhythm problem and is called an arrhythmia, known as ventricular tachycardia (VT) or life threatening quivering (trembling) of the heart, known as ventricular fibrillation (VF). When the heart beats too fast, it is unable to pump enough oxygen-rich blood to the brain and the rest of the body. When this happens, you may lose consciousness (faint) and/or may die unless the heart begins to beat regularly again.

An ICD is an electronic, battery-powered medical device that is implanted in the chest area to continually monitor your heart and deliver appropriate therapy when an abnormal heart rhythm is detected. It is designed to help your heart beat regularly. If your heart is beating too fast, the ICD will deliver electrical pulses or shocks to the heart muscle to help your heart beat regularly again. Also, if your heart beats too slowly, electrical impulses will be delivered to the heart muscle to help your heart beat normally again.

By enrolling in this study, you will receive an ICD that has the capabilities described above but also has an experimental feature (ST Monitoring Feature) that has not been approved. This investigational feature being studied is designed to record your heart rhythm tracing when your heart is not getting enough oxygen due to a blockage in a heart blood vessel. In addition, it can alert your study doctor or you of these changes when they happen.

An external transmitter, called Merlin@home, is a monitor that will be used to talk with your ICD. You will be able to use this transmitter to send medical information to your study doctor from your home automatically every night while you are sleeping and at scheduled times between your study doctor visits. Your study doctor will be able to view your medical information on how your ICD has been functioning between visits through a computer system located at the study doctor's office. This computer system is called Merlin.net. This monitoring of your study device from home is already available in many ICDs and is available to you regardless of whether you decide to participate in the study.

The tracings recorded by the investigational feature in response to changes in your heart will be passed on to the study doctor. Your study doctor will assess if you should come in for a clinic visit based on this information from your study device, as well as your previous history and how you are feeling. If at any time you should have chest pain or chest pressure, you are advised to seek medical assistance immediately. These symptoms may indicate that your heart is not getting enough oxygen. This condition may lead to a heart attack. If you go to the study doctor for visits in-between your standard visits, or go to the hospital or emergency room, the records from your visit will be collected along with information from your study device.

What will happen if you take part in this research study?

If you decide to take part in this study, some tests will be done to help your study doctor determine if you qualify. You will have a physical examination. If you are a woman of child-bearing potential, you will be required to take a pregnancy test before you can participate in the study. Your study doctor will decide if she/he needs to perform further testing during your screening period. Once all of the tests have been completed, your study doctor will decide if you qualify to take part in the Analyze ST IDE study. If you do not qualify for the study, your participation will end.

There may be a representative of the sponsor at your study visits and the representative may assist with some of the study procedures. The study doctor may direct a representative from the sponsor to collect the signal information. At the study doctor's direction, the sponsor representative may also program your study device or run tests to see if your study device is working as expected. The sponsor's representative will work under the direction of your study doctor.

Study Device and Lead Implant Procedure:

If this is your first time having an ICD and wires (leads) placed within your body, the next three sentences will apply. During your surgery, your study doctor will insert the wire into the vein, and gently guide the wire through the vein into your heart. Once the wire is in your

heart, your study doctor will test it to see if it is in a good place. Your study doctor will connect the wire into the ICD, and place the ICD into a small pocket made just beneath the skin on your upper chest before closing the pocket with stitches. If you are having an ICD replacement, the replacement procedure will be shorter because you already have the wires in place.

This placement of the new ICD or replacement of the ICD is the same as the procedure or replacement for any market-released ICD system (ICD and wires).

Investigational device follow up:
As part of the study you will be required to return for follow-up study visits. Some of these visits may be done using the telephone and the Merlin@home box that will be given to you to take home. How many visits can be done using the telephone and how many you will need to do at the study doctor's office will be up to your study doctor. These visits are very important and will be done at the following times:

- Programming visit (about 1 month after your implant)
- Baseline visit (about 4 months after your implant)
- 6-month visit (about 6 months after your Baseline visit)
- Every 6 months until study completion
- Additional in-clinic visits as requested by your doctor

The following tests will be done at the follow-up study visits:

- Study personnel will check to make sure the new feature is turned ON and functioning properly
- Study personnel may reprogram or adjust your ICD settings to make sure your ICD is functioning optimally
- Study personnel will ask you about any symptoms you may have had since your last visit and what medications you are taking and whether there have been any changes to the medications you take.

A sponsor representative may also program your study device or collect information from your study device under the study doctor's supervision.

At your Baseline visit, you will have an electrocardiogram (ECG), which follows the tracings of your heart. During the ECG, your study doctor or study nurse will attach leads with gel to your chest to measure your heart's tracing or heart rhythm. Your study doctor will also check your ICD study device and determine if the investigational feature is working correctly. If he determines that it is not, the investigational feature will be turned off. You will still be asked to return for study visits or perform them over the phone to collect information on your study device. If your study doctor decides that the investigational feature is working correctly, a patient notifier will be programmed on.

The patient notifier is a vibrating buzzer inside the study device that will vibrate if changes to your heart rhythm are seen. You will be instructed by your study doctor what to do when you feel this vibration.

If you decide to take part in this study, you will need to carry an identification card that states you have a St. Jude Medical Investigational Device and are taking part in a research study. This card will help any doctor or nurse know that your study device settings should not be changed without talking with your study doctor.

During the course of the study, new software for your implanted device may become available. When new software becomes available for the study, you may be asked to come in to see your doctor before your next scheduled visit or the change may be made whenever your next visit occurs. Your doctor will use the programmer (computer that talks to your device) to update the software in your device. The upgrade will be done at your doctor's office and will take approximately 3 to 5 minutes. You will not feel anything when this is done. During the update, your device will have limited functionality. Once the software upgrade is completed, your device will be working normally.

If you are hospitalized during this study, please inform the treating doctor that you are taking part in this research study and show him/her your identification card. If you have any changes in your address or telephone number over the length of this study, please report those changes to your study doctor and to St. Jude Medical at 800-423-5611 ext. 5802, or ask for Device Tracking.

How long will the study last?

A total of 5,228 subjects will be enrolled in the Analyze ST IDE study and up to 200 US investigational sites will conduct the study.

The study is expected to take about 48 months depending on how fast subjects are signed up to participate. Your participation in the study will be at least 12 months and may be up to 6 years depending on when you are enrolled in the study.

What are the possible discomforts and risks?

Your study doctor will review the risks related to a standard ICD surgery. The risks related to the use of the Investigational Device are expected to be similar to those related to any market-released ICD. Risks associated with receiving the investigational ICD are that you may be asked to have some additional testing (such as one or more ECGs, blood tests, stress testing, CT scan, MRI scan, echocardiogram, or a cardiac catheterization) done on your heart based on information from the new feature if your physician feels it is indicated for your care.

Risks associated with testing that may be done if your study doctor suspects that you are having a heart attack or blockages in your heart include, but are not limited to:

- Allergic reaction to materials used during the test
- Arrhythmias
- Bleeding
- Blood filling the sac around your heart
- Bruising
- Changes in blood pressure and/or heart rate
- Chest pain
- Infection
- Puncturing the heart or lungs during the test
- Nausea
- Shortness of breath
- Stroke
- Death

There may also be discomfort associated with receiving a "false alarm" from your study device and seeking medical attention as a result. This could include a lengthy wait at an emergency room or overnight stay in a hospital for observation.

There is also the possibility that the ST Monitoring Feature may not generate an alert when your heart is not getting enough oxygen. If at any time you should have chest pain, chest pressure, sweating, arm pain, difficulty breathing or any other concerning symptoms, you are advised to seek medical attention immediately even if you do not receive an alert from your study device.

There may be other risks to you that are not known at this time.

Risks for Women of Childbearing Age

You should discuss your participation with your study doctor if you become pregnant while taking part in the study.

What are the possible benefits to you or to others?

If you decide to take part in this study, you may or may not personally benefit by participating in this study. You may benefit from having additional contact and diagnostic tests with your study doctor. The information gathered in this study may add to the understanding of treatment options for other ICD patients and may improve the identification and treatment of heart problems through the design of new products and therapies.

If you do not want to take part in this study, what other options are available to you?

You do not have to participate in this research study to receive treatment for your condition. You may receive a standard defibrillator (ICD) for your condition without participating in this study. Your study doctor can discuss other options available to you.

How will your privacy and the confidentiality of your research records be protected?

If you decide to take part in this study, your medical records and personal information will be kept private to the extent allowed by federal, state, and local law. No personal information about you, your illness, or your treatment will be made public.

Information (data) collected from the study will be sent to St. Jude Medical. This includes data that may be collected during your clinic visits or data that are collected using the Merlin@home transmitter. A special code (letter and number combination) will be used to identify your personal information.

The data may be given to governmental agencies, for example: the U. S. Food and Drug Administration (FDA) or similar government agencies in other countries. Only information about your medical condition as it relates to the Analyze ST IDE study will be provided to St. Jude Medical. In order to verify study data, monitors from governmental agencies (for example: FDA), St. Jude Medical (SJM), and the Western Institutional Review Board (WIRB) will also have the right to review your medical records as they relate to this study. In addition, publications using data collected during the study will not include your name or any information that can identify you.

A description of this study 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.

St. Jude Medical may export data to countries where different data protection laws apply.

If you receive medical care from a doctor other than your study doctor while taking part in this study, you must agree that your medical records will be made available for the collection of data related to this study.

If you choose to take part in this study, will it cost you anything?

You and your insurance company are responsible for the costs of all tests, procedures, and devices. There is no guarantee that your insurance company will cover 100% of these costs. You should check with your insurance company to verify coverage or payments of these procedures.

What if the study device needs to be removed?

In the event your Investigational Device or any part has to be removed, it will be returned to St. Jude Medical for analysis. Should you withdraw from this study and choose to have your Investigational Device or any part of it removed, the cost will be your responsibility.

In the event of your death, your implanted Investigational Device may be removed and returned to St. Jude Medical for analysis. The study doctor will get your family's approval before removing the device.

What if you are injured because of the study?

If the Study device is defective or malfunctions, the Sponsor will provide a replacement device and reimbursement for expenses according to the manufacturer's warranty.

The Sponsor also agrees to pay for the reasonable and necessary, and otherwise uncovered, treatment of injuries, undesirable side effects or adverse reactions that are caused by Study procedures which are not standard of care for you. The Sponsor is not responsible for medical risks or conditions that you would face if you were not in the Study. The Sponsor's payment does not limit or waive any rights that you may have against the Sponsor.

The Sponsor's payment will be based on the contract rates paid by Medicare. The Sponsor is not responsible for the negligence or actions of anyone other than the Sponsor, or for events that the Sponsor does not control. The Sponsor is not responsible for problems caused by your failure to follow study instructions, including attending all follow-up visits.

During the study, if you experience any medical problems or illnesses from taking part in this study, please contact [Dr. _____ at ___-___-_____].

What are your rights if you decide to take part in this study?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. If you wish to stop taking part in this research study for any reason, you should contact [Dr. _____ at ___-___-_____]. A decision to withdraw or to not take part in the study will not affect the quality of medical care that you receive.

Your study doctor or the sponsor, St Jude Medical, may decide to withdraw you from the study at any time without your consent. If it is felt to be in your best interest, or if the study is stopped, your study doctor may withdraw you from this research. If you have a problem as described in the risks section, or if you become ill during the research, you may have to stop participating in the study, even if you would like to continue. Your study doctor will make this decision. Your study doctor or study staff will discuss with you what follow-up is required if you are withdrawn from the study before the study is finished.

Reasons for having you stop participating in the study at any time without your consent may include the following:

- Your condition worsens
- Risks outweigh the benefits
- Study sponsor stops the study
- It is in your best interest
- You do not follow the procedures requested by your study doctor
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- Or for any other reason.

New Information

If important information is learned during the course of this study, your study doctor will be notified by St. Jude Medical. You will be told of any important new information that is learned during the course of this research study that may affect your condition or your willingness to continue to take part in this study.

Who can you contact for study information?

If you have any questions about the study or taking part in this study, or if at any time you feel you have had a research-related injury or a reaction to the study drug, please contact [Dr. _____ at ___-___-_____].

In addition, if you have questions about your rights as a research subject, or if you have complaints, concerns, or questions about the research, please contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of 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.

You are making a decision on whether or not to take part in the study. Your signature indicates that you have read the information in this form and have decided to take part in the study.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

You will be given a signed and dated copy of this form to keep.

Consent

By signing this consent form, I have not given up any of my legal rights.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form for the Analyze ST IDE study, you do not give up any of your legal rights. This document is not intended to limit study doctors from providing medical care to you as required under applicable Federal, State and local law.

I have read the information in this consent form. All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

Printed Name of Person Conducting the Informed Consent Discussion	Position
Signature of Person Conducting the Informed Consent Discussion	Date