Inside of Folder

Why has my doctor given me this booklet?

Your doctor feels that you may be an appropriate candidate for a new medical study.

St. Jude Medical is a company that designs and manufactures medical devices used in the treatment of people with heart conditions. St. Jude Medical is currently sponsoring a clinical study called the Analyze ST clinical study, which is designed to test the safety and effectiveness of an investigational feature in an implantable cardioverter defibrillator (ICD) that detects changes in the heart's rhythm.

Your doctor has given you this booklet to provide you with a general idea of what would be involved in participating as a patient in this study. Once you have read the questions and answers here, if you are interested in learning more about being a participant in the Analyze ST clinical study, you should talk about the study at greater length with your doctor or the research nurse to make sure you understand everything that is involved. You may also want to discuss it with family members or close friends, and this booklet may help address some of the questions or concerns they may have. Before participation, you will be asked to read and sign a more detailed consent form.

What is the purpose of the study?

The Analyze ST clinical study is intended to test the safety and effectiveness of an investigational feature for ICDs called the ST Monitoring Feature.

Sometimes, blockages can form in blood vessels that reduce the amount of oxygen getting to the heart. If the heart is not getting enough oxygen, you may be at risk for a heart attack.

The ST Monitoring Feature is designed to detect and record changes in the heart's rhythm that occur when the heart is not getting enough oxygen and to alert the patient or doctor that it has detected the change. The hope is that ST Monitoring will provide an early warning, leading to intervention before the condition becomes more serious. Before we can know how accurate the ST Monitoring Feature is, we need to conduct an extensive clinical study of patients implanted with a device that includes this feature.

What will I have to do if I participate in the study?

If you meet the criteria necessary to take part in the study and choose to participate, you will be implanted with an ICD that includes the ST Monitoring Feature.

You may have heard of medical devices commonly called "pacemakers." ICDs are implanted in much the same way as pacemakers: they are placed under the skin in the chest and special, insulated wires called "leads" are connected to the heart through a vein and then attached to the device.

If you already have an ICD that needs to be changed, your existing device will be replaced by a new one, but you will keep the leads that were implanted with your old ICD.

The placement or replacement of the ICD will follow exactly the same procedure for any ICD system being implanted today.

Once you are implanted with the ICD, you will need to carry an identification card with you that states you are taking part in the study and asks any other doctors or nurses who might examine you to talk to your study doctor before changing any setting on your device.

What happens after I receive the study device?

As part of the study, you will be required to return for regular scheduled follow-up visits so that we can check your health and the device, and monitor how the ST Monitoring Feature is performing. The first follow-up will take place about a month after the implant, the second about three months after the implant and, after that, you will need to attend a follow-up every 6 months until the end of the study.

To make follow-ups more convenient, you will be given a transmitter regularly provided to patients with St. Jude Medical devices, called the Merlin@home® transmitter. The transmitter connects to your home telephone line and sends information from your device to your study doctor's office. This will allow you to conduct some follow-ups from your own home after your 12-month in-clinic visit, without having to go to your study doctor's office.

How does the Merlin@home® transmitter work?

The Merlin@home transmitter is set up in your bedroom, next to your bed, and connected to your home telephone line. It monitors your device each night while you sleep and transmits the data to your doctor's office.

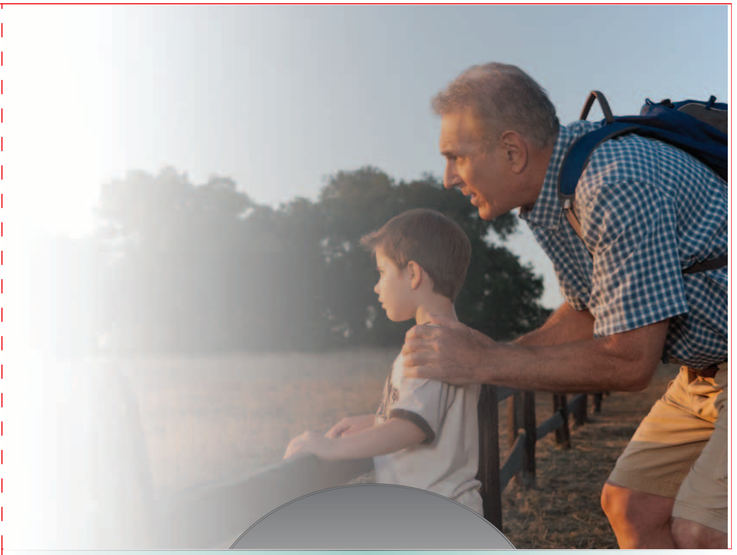
If the device detects changes in your heart rhythm, it will transmit that information to your study doctor via the Merlin@home transmitter.

How does the device notify me if it detects a change in my heart rhythm?

Your ICD will include a "patient notifier," a vibrating buzzer inside the device that notifies you if the ICD detects changes to your heart rhythm. Your study doctor will tell you what to do if you feel the vibration.

How long will the study last?

The study will enroll a total of 5,228 patients and is expected to last up to 48 months – or 4 years. Your participation will last at least 12 months and may be up to 48 months depending on when you are enrolled in the study.



ANALYZE ST

ST Monitoring To Detect
ACS Events in ICD Patients Study

Outside of Folder

Will taking part in the study help me feel better?

There is no guarantee that you will benefit from taking part in this study. You may benefit from having additional contact and diagnostic tests with your study doctor, but the purpose of the study is to test a feature for the first time, so we cannot yet say whether or not it will be beneficial. However, you will be given “gold standard” medical attention and your participation will help us to learn things about treatment options for patients that could benefit others in the future.

What if I am not interested in taking part in the study? Will that affect my relationship with my doctor?

Taking part in this – or any clinical trial – is entirely voluntary. You should not feel any pressure to participate if you are not certain that you wish to do so. If you decide not to take part, you will not suffer any penalty or lose any benefits to which you are otherwise entitled.

What if I agree to take part, but then change my mind? Can I withdraw my consent?

Yes. You may withdraw from the study at any time without any penalty or loss of benefits to which you are otherwise entitled. If you choose to withdraw after having agreed to participate, you should discuss your device follow-up needs with your doctor to make sure you continue to receive the care you need.

If I am interested, what should I do next?

Contact your doctor to let him or her know that you would like to learn more about the St. Jude Medical Analyze ST IDE clinical study. Make time to talk to them in detail about what is involved in the study and to find out whether you qualify to participate.

The Analyze ST Clinical Study Experience at a Glance

- Discuss the details of the trial with your physician, family members and friends
- If you decide to enroll in the trial, you will be implanted with an ICD with an investigational feature that detects changes in the heart’s rhythm that may indicate a blockage in blood vessels is restricting the flow of oxygen to the heart
- You will be required to attend scheduled follow-ups with your study doctor for the duration of the study
- You will be provided with a Merlin@home® transmitter so that some follow-ups can be conducted from home
- You will be instructed what to do in the event your device notifies you it has detected a change in your heart rhythm

St. Jude Medical is focused on reducing risk by continuously finding ways to put more control into the hands of those who save and enhance lives.

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A Patient’s Guide to Frequently Asked Questions About the Analyze ST Clinical Study

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