Brief Statement

9526 Reveal® Plus Insertable Loop Recorder

The Reveal Plus ILR is an implantable patient- and automatically activated monitoring system that records subcutaneous ECG and is indicated for:

- patients who experience transient symptoms that may suggest a cardiac arrhythmia.
- patients with clinical syndromes or situations that put them at increased risk of cardiac arrhythmias.

Possible risks associated with the implant of a Reveal Plus Insertable Loop Recorder include, but are not limited to, infection at the surgical site, device migration, erosion of the device through the skin and/or sensitivity to the device material.

Treatment with a Reveal Plus Insertable Loop Recorder is prescribed by your physician. Please talk to your doctor to see if it is right for you. Although many patients benefit from the use of these products, results may vary. Not everyone responds to the treatment in the same way.
Just ask Lauren Niemi and her mom.

When Lauren Niemi was seven years old, she fainted on the monkey bars at school. After asking Lauren many questions, Theresa, Lauren’s mom, thought the fainting episode was an isolated event. When Lauren continued to faint, Theresa knew she needed to search for answers.

Theresa called Lauren’s doctor to discuss Lauren’s fainting spells. She was told that it’s normal for some kids to experience fainting. “How can this be normal?” asked Lauren’s mom.

Lauren’s doctor had her undergo many tests, which provided no answers.

Theresa was scared and frustrated because there was something wrong with her daughter and no one could tell her what it was.

Because other tests didn’t provide enough information to make a diagnosis, Lauren’s doctor decided to give Lauren a Medtronic Reveal® Insertable Loop Recorder (ILR). This implanted monitor allowed Lauren’s doctor to continuously record the heart’s rate and rhythm which provides Lauren’s doctor a view of what happens when Lauren faints.

On Lauren’s ninth birthday, she fainted while climbing a cargo net at a pizza parlor. Lauren was hanging upside down from her ankle and her dad quickly climbed up to get her down.

During this episode, the heart monitor captured information on Lauren’s heart. Upon reviewing the information from the heart monitor, Lauren’s doctor learned that Lauren’s heart was beating too fast, causing her to faint.

The next day Lauren received a Medtronic defibrillator to safeguard her heart.

Now 13, Lauren is on the “A” Honor Roll and her favorite activity is dance. Since the defibrillator was implanted, medication has prevented Lauren from fainting. “The defibrillator is there as a backup,” says Lauren’s mom. She added that it’s nice security that she and Lauren’s dad appreciate very much.

If Fainting Has a Cardiac Cause...

such as an abnormal heart rhythm, treatment options can include a lifestyle change, medication, a pacemaker or implantable cardioverter defibrillator (ICD), or a catheter ablation procedure. Your doctor will decide on the treatment based upon your condition.
What Happens When I Faint?

Fainting, also called syncope, is a sudden loss of consciousness, which occurs when the blood pressure drops and not enough oxygen reaches the brain. If you do faint or “pass out,” the episode can last for a brief amount of time – usually a few seconds. There are times when fainting may look like a seizure. People faint for many reasons, including:

• Standing too fast
• Exhaustion
• Emotional upset and/or stress
• Overheating
• Abnormal heart rhythms
• Illness or some medications

Some causes of fainting are not easy to explain. Some can be life threatening.

Consider This

Whether you faint once or if you repeatedly faint without any explanation, you should seek the help of a physician. If you experience dizziness, heart palpitations, or seizure-like episodes, these are also good reasons to see a physician.

Gathering the Facts About Fainting

A correct diagnosis of infrequent but recurring fainting starts with gathering the facts about your own fainting episodes. Your physician or team of physicians will want to hear the details. At the end of this booklet is a set of questions to help you gather information about your fainting episodes. Fill in the questionnaire to share with your physician.

When to Seek a Physician’s Advice on Your Fainting:

• If you faint once or several times without explanation
• If you faint during exercise
• If you have heart palpitations or other heart irregularities before or after fainting
• If your family history includes undiagnosed fainting or sudden cardiac death

Ask your doctor for an answer about the cause of infrequent but multiple fainting spells.
Be prepared to discuss the specifics of your fainting episodes with your physician. Some questions you could ask include:

1. Could fainting be related to my heart?
2. What tests are needed to find out why I faint? What will the tests show?
3. Should I see a heart specialist doctor to help determine the cause of fainting?

Finding a Specialist for Fainting

The causes of fainting are varied. So too are the medical specialists who might need to diagnose your fainting episodes. Your doctor may refer you to one of these specialists for more evaluation:

**Cardiologist** — A doctor who specializes in the diagnosis, treatment, and prevention of diseases in the heart and blood vessels.

**Electrophysiologist** — A cardiologist who specializes in the diagnosis and treatment of abnormal heartbeats, including when the heart beats too fast, too slow, or in a way that pumps blood inefficiently.

**Neurologist** — A doctor who specializes in the diagnosis, treatment, and management of disorders of the brain and nervous system.

**Epileptologist** — A neurologist who specializes in the diagnosis and treatment of epilepsy.
Tests used to determine the cause of fainting may be different for each person. If your doctor suspects a heart condition is causing your fainting, one or all of these diagnostic options may be used to gather information about your heart. By looking at your heart rhythms before or after a fainting spell or conditions similar to fainting, your doctor can clearly identify whether or not your fainting is related to a cardiac cause.

- **Echocardiogram** — A device called a transducer is placed on the chest and sound waves are bounced off the heart. This provides a "moving" picture of the heart and the heart valves as well as information about how the heart is pumping.

- **Electrocardiogram (ECG)** — A test that records the electrical activity of the heart using electrode patches with wires attached to them that are placed on a person's chest, arms, and legs. The wires are connected to a monitor, which captures the ECG. The test takes a few minutes.

- **Electroencephalogram (EEG)** — A test that records brain wave activity to help determine if and/or where seizures may occur.

- **Electrophysiology (EP) study** — A procedure that reproduces abnormal heart rhythms and extra heartbeats to interpret the heart's electrical impulses and responses to the heartbeats. To get a reading, catheters are threaded into the heart. The procedure lasts about two hours.

- **External loop** — A test that uses a recorder to read the heart’s electrical activity after fainting. After the fainting episode occurs, the individual presses a button on the recorder to evaluate the heart’s activity. The recorder is continuously worn on the wrist or around the waist from several days up to one month.

- **Holter monitor** — A test that measures and records the heart’s electrical activity using electrode patches placed on a person's chest. To capture the heart’s activity, the patches have wires attached to them that are connected to a portable monitor about the size of a small tape recorder. The Holter monitor is worn continuously for one to two days.

- **Medtronic Reveal® Plus insertable loop recorder** — An implantable device that continuously monitors heart rhythms automatically or by using a patient activator. The device is implanted in a very simple outpatient procedure, and can remain inserted just beneath the skin in the upper chest area for up to 14 months.

- **Physical exam and medical history** — A medical professional will complete a thorough physical examination and ask detailed questions about an individual's symptoms and condition.

- **Stress test** — A test taken while a person exercises to measure how the heart functions when there is an increase in the body's demand for oxygen.

- **Tilt table** — A procedure that recreates the conditions that may cause fainting. An individual lies on a table that tilts by varying angles. While on the table the person is connected to a machine, which allows the doctor to measure how blood pressure, heart rate, and heart rhythm respond to changes in body position. The procedure takes about two hours.
Where Can I Get More Information About Fainting?

For more information about fainting or to read more stories of people who have fainted, visit www.fainting.com. If you have questions about your fainting episodes, talk with your doctor.

For more about Medtronic, visit: www.medtronic.com.

Call the toll-free Medtronic patient information phone line: 1-800-551-5544.

*Every 7 seconds, another life is improved by a Medtronic product or therapy. Medtronic provides lifelong solutions for people with chronic disease.*

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**My History of Fainting**

(Fill out and bring to your doctor visit.)

1. Have you had an unexplained fainting spell?
   - Yes_____  No_____  
   When did your fainting spells begin?__________________________

   How many fainting spells occurred over the last two years?__________________________
   What is the estimated amount of time between fainting spells?__________________________

2. What were you doing before you fainted?
   ____________________________
   ____________________________

3. Do you drive?
   - Yes_____  No_____  

4. Does your job put you at risk for fainting?
   - Yes_____  No_____  
   What do you do?__________________________
   ____________________________
   ____________________________

5. Have you been monitored or tested to find the cause of your fainting?
   - Yes_____  No_____  
   List tests__________________________
   ____________________________
   ____________________________

6. Are you receiving treatment for fainting spells (medications, lifestyle modifications, etc.) but the treatment is not helping?
   - Yes_____  No_____  
   List treatment__________________________
   ____________________________
   ____________________________

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