



Medtronic

Reveal LINQ[®]

INSERTABLE CARDIAC MONITORING SYSTEM



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UNLOCK *the* ANSWER

Your heart and long-term monitoring



UNLOCK *the* ANSWER

Irregular heartbeats can be related to a variety of conditions, including unexplained fainting, heart palpitations, atrial fibrillation, and unexplained stroke. Fortunately, there are treatments available, but first the irregular heartbeats must be detected.

These irregular heartbeats may only occur every now and then, making the source of these conditions difficult to detect.

Long-term heart monitoring may help **unlock the answer** – providing your doctor with information to make a diagnosis and you with peace of mind.

The Importance of Long-Term Heart Monitoring

Unexplained Fainting

Fainting – also referred to as “passing out,” a “blackout” or “syncope” – is a sudden loss of consciousness that occurs when blood pressure drops and not enough oxygen reaches the brain. Most often, a fainting spell is brief and consciousness is regained in a few minutes, although there may be a period of confusion.

Some causes of unexplained fainting are harmless, but others may be serious. Abnormal heart rhythms are among the most serious causes of fainting and need to be detected.

*Unexplained fainting
and heart palpitations may
indicate a **more serious**
heart condition.*

Heart Palpitations

Heart palpitations are sensations that feel like your heart is pounding, racing, or fluttering. They may also feel like a skipped heartbeat or an extra heartbeat.

Heart palpitations usually are harmless. However, in some cases they may indicate a more serious heart condition, like an abnormal heart rhythm, that requires detection and treatment.

Atrial Fibrillation

Atrial fibrillation (AF or AFib) that occurs when the upper chambers of the heart beat very fast and unpredictably, producing an abnormal heartbeat. Because blood is not being pumped effectively to the rest of the body, it may pool and clot. If a clot dislodges, it can travel to the brain and cause a stroke.

*People with AF are
5 times more likely
to have a stroke.¹*

It is important to diagnose and treat AF because AF medications are highly effective in preventing another stroke.¹

Unexplained Stroke

In most cases, a stroke is caused by a blood clot or other debris that blocks the flow of blood and oxygen to the brain. A stroke of unknown cause is called a “cryptogenic” stroke.

AF is a major risk factor for stroke. Detecting AF after a stroke is critical because medications may help prevent another stroke.



Live More Confidently

The innovative Reveal LINQ®

Insertable Cardiac Monitoring System can help your doctor discover irregular heartbeats so you can get the treatment you need.



Actual size

Powerfully Small

SMALL

The Reveal LINQ Insertable Cardiac Monitor (ICM) is the smallest heart monitor on the market.

**3
YEAR**

It automatically detects and records abnormal heart rhythms for up to three years.²

MRI

It may be used in an MRI setting.[†]

Simple and Discreet

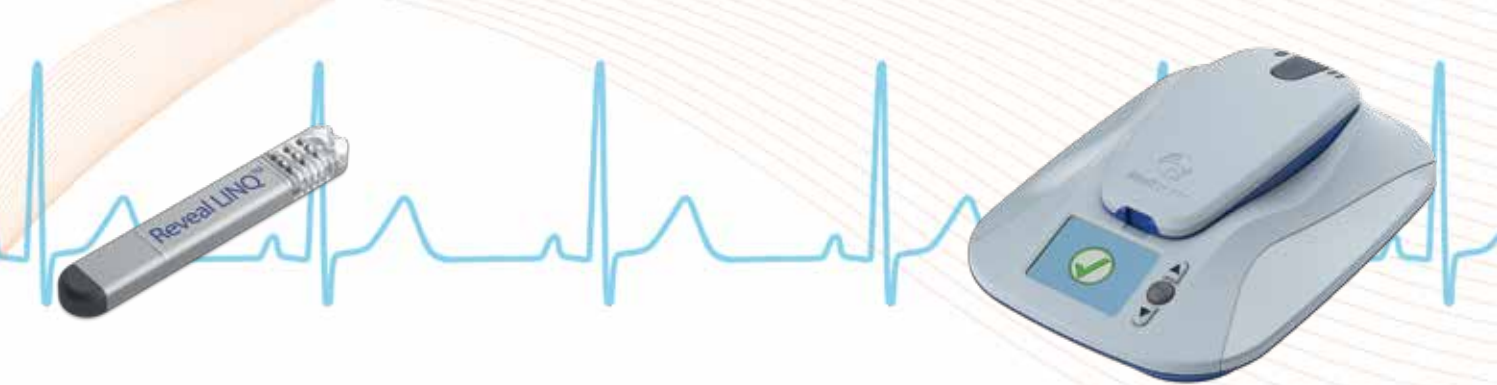
EASY

The Reveal LINQ ICM is placed just under the skin of your chest in a simple, minimally invasive procedure.



The ultra-discreet heart monitor is not visible in most patients.

[†] Reveal LINQ ICM has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Please see Reveal LINQ ICM clinician manual for more details.



Reveal LINQ ICM

Procedure Overview

Following is an overview of the minimally invasive Reveal LINQ ICM insertion procedure:

1. A small incision is made.
2. The Reveal LINQ ICM is inserted.
3. The incision is closed.

After a brief recovery period, most patients go home the same day.



MyCareLink® Patient Monitor

Remote Connectivity (optional)



The MyCareLink Patient Monitor keeps you connected to your doctor with wireless, remote monitoring.



Abnormal heart rhythm data is automatically sent to your doctor over a secure Internet server.

Reassuringly Easy



Uses a cellular signal and a power outlet. Setup is simple and easy.



The clear, understandable animated display will show you what to do.



Your MyCareLink Monitor can travel with you.*

* For correct operation your **monitor must always be plugged in** and in a location that receives adequate cellular signal. For automatic transmission, you must be within 6.5 ft (2 m) of your monitor.

Tracking Symptoms with the Patient Assistant



While the Reveal LINQ ICM will automatically record your heart rhythm data for your doctor, you can also mark symptoms when they occur using the Reveal® Patient Assistant.

The Reveal Patient Assistant is a small hand-held device. When placed over your Reveal LINQ ICM, it records your heart rhythms and marks the place on the heart record where symptoms occurred so your doctor can evaluate those heartbeats.

If you can't get to the Patient Assistant right away, simply write down the day and time of your symptoms to share with your doctor.



To use the Patient Assistant:

1. When you experience symptoms, press the heart-shaped button. 
2. Hold the Assistant over your Reveal LINQ ICM. When the response indicator lights up, you have made a successful recording. 
3. Call to schedule a follow-up appointment as directed by your doctor.

Answers to Your Questions

Reveal LINQ Insertable Cardiac Monitor

What are the benefits of a Reveal LINQ ICM? Because the Reveal LINQ ICM is designed for long-term monitoring, it increases the chance of capturing your abnormal heart rhythms or your heart symptoms, if they are unpredictable or occur infrequently.

What are the risks of an ICM? All surgical procedures carry some risk. Since the ICM is inserted just beneath the skin, there is a possible risk of infection, and/or sensitivity to the ICM material. Talk with your doctor about any risks particular to your situation.

What happens after the cardiac monitor stores an ECG? After you experience a symptom, whether you are able to tag the symptom with the Patient Assistant or not, you should make an appointment with your doctor to read the saved recordings.

If I get an ICM will I have to change my daily routine? In general, people who get a Reveal LINQ ICM can perform almost all their normal activities, however your doctor may ask you to limit some of your activities based on your heart symptoms.

How long will I have the ICM? Your doctor will determine how long the Reveal LINQ ICM is used to monitor your heart. The device can be used for up to three years.²

MyCareLink Patient Monitor

Can I travel with the MyCareLink Patient Monitor?

Yes. The MyCareLink Monitor is small, lightweight, and easy to pack. Its simple setup, operation, and global cellular access make it convenient to use almost wherever you go.* It should easily pass through airport security checkpoints. Make sure to bring your Device Identification Card with you in case you are questioned by airport security. If you would like to confirm availability of coverage in a specific country, please go to www.medtronicheart.com.

How does the MyCareLink Patient Monitor work?

The monitor sends the information from your Reveal LINQ device to your doctor automatically over a secure Internet server. The patient manual provided with the monitor contains details on setup and usage.

Do I need wireless Internet access or a cellular data plan?

No, the Reveal LINQ ICM automatically transmits your heart rhythm data to the MyCareLink Monitor with built-in wireless technology. The MyCareLink Monitor connects to global satellite cellular signals to transmit the data to your doctor. There is no cost to you for data transmission.

Does the MyCareLink Patient Monitor automatically send information to my clinic every day?

Your clinic will typically schedule automatic daily transmissions while you sleep. Data is transmitted every day as long as your monitor is plugged in and you are within 6.5 ft (2 m) of the monitor when a transmission occurs.* Placing the monitor on a nightstand next to where you sleep is an easy way to help ensure successful transmissions.

How will I know if my transmissions are being sent?

This screen indicates the most recent date that the data from your cardiac monitor was successfully transmitted to your clinic.



What should I do if I see an orange alert screen?

When you see this alert screen, call the displayed phone number so that your healthcare provider can determine if you experienced a heart-related event. Your clinic will also be notified. Press the button next to the X to dismiss the alert.



When would I need to do a manual transmission?

If you mark symptoms with your Reveal Patient Assistant, your doctor may ask that you transmit data from your MyCareLink Patient Monitor before your next automatic transmission. The patient manual contains details on sending manual transmissions.

How do I know if my manual transmission went through?

A green check mark will appear on the display screen of the monitor when your device information has been successfully transmitted. If you miss the green check mark, a date will appear on the screen noting that the transmission was successful.



* The monitor must always be plugged in and in a location that receives adequate cellular signal.

Brief Statement

References

REVEAL LINQ® LNQ11 Insertable Cardiac Monitor and Patient Assistant 9538

Indications: REVEAL LINQ LNQ11 Insertable Cardiac Monitor

The Reveal LINQ Insertable Cardiac Monitor is an implantable patient-activated and automatically activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain, that may suggest a cardiac arrhythmia

9538 Reveal® Patient Assistant: The Reveal Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management feature in the Reveal Insertable Cardiac Monitor to initiate recording of cardiac event data in the implanted device memory.

Contraindications: There are no known contraindications for the implant of the Reveal LINQ Insertable Cardiac Monitor. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Warnings/Precautions: REVEAL LINQ LNQ11 Insertable Cardiac Monitor

Patients with the Reveal LINQ Insertable Cardiac Monitor should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the Medical procedure and EMI precautions manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal LINQ MRI Technical manual.

9538 Reveal Patient Assistant: Operation of the Model 9538 Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer monitors, etc., may adversely affect the performance of this device.

Potential Complications: Potential complications include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

Medtronic MyCareLink® Patient Monitor, Medtronic CareLink® Network and CareLink® Mobile Application

Intended Use: The Medtronic MyCareLink Patient Monitor and CareLink®

Network are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. The CareLink Mobile Application is intended to provide current CareLink Network customers access to CareLink Network data via a mobile device for their convenience. The CareLink Mobile Application is not replacing the full workstation, but can be used to review patient data when a physician does not have access to a workstation. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. CareLink Network availability and mobile device accessibility may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. Mobile device access to the Internet is required and subject to coverage availability. Standard text message rates apply.

Contraindications: There are no known contraindications.

Warnings and Precautions: The MyCareLink Patient Monitor must only be used for interrogating compatible Medtronic implantable devices.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events.

If you have any questions about the Medtronic Reveal LINQ or MyCareLink monitor please consult your physician

¹ Naccarelli GV, Varker H, Lin J, Schulman KL. Increasing prevalence of atrial fibrillation and flutter in the United States. Am J Cardiol. 2009;104:1534-1539

² Medtronic Reveal LINQ LNQ11 Clinician Manual