Each year, approximately 795,000 Americans experience a stroke—610,000 of which are new strokes and 185,000 of which are recurrent strokes.

Atrial fibrillation (also known as AF or “a-fib”) is a common cardiac condition defined by irregular or rapid heartbeats. Failure to recognize and treat AF can lead to strokes as patients with AF are five times more likely to have a stroke.

Undiagnosed AF is believed to be responsible for a significant portion of cryptogenic strokes. However, because AF often has no symptoms and may occur infrequently, it may not be detected by conventional monitoring techniques such as in-hospital monitoring, electrocardiography, or traditional ambulatory cardiac monitors (e.g., Holter).

Unlike conventional monitoring methods, continuous, long-term cardiac monitoring devices, such as the Reveal LINQ™ Insertable Cardiac Monitor (ICM), automatically and continuously detect and record abnormal heart rhythms for up to three years.

Detecting AF allows physicians to change a patient’s medical therapy (e.g., from anti-platelet to oral anticoagulation per guidelines) to potentially help reduce his/her risk of having a second stroke.
ABOUT THE MEDTRONIC REVEAL LINQ™ ICM SYSTEM

- Cleared by the U.S. Food & Drug Administration (FDA) in February 2014, the Reveal LINQ ICM is the newest generation Reveal ICM and the smallest cardiac monitor available (~1 cc, or one-third the size of a AAA battery).
- Common uses include monitoring syncope patients for potential episodes of bradycardia/asystole, monitoring cryptogenic stroke patients for possible episodes of AF, and monitoring patients suffering from intermittent chest palpitations for potential episodes of atrial or ventricular arrhythmias.
- The Reveal LINQ ICM is placed under the skin of the chest, and its battery allows for up to three years of monitoring.\(^{15}\)
- Additionally, the device communicates wirelessly with a patient bedside monitor that uploads device data to the Medtronic CareLink™ network.

SUPPORTING EVIDENCE

- The CRYSTAL AF (CRY ptogenic STroke And underLying Atrial Fibrillation) study, published in *The New England Journal of Medicine*, found that continuous cardiac monitoring with the Reveal™ ICM was superior to standard care (SoC) at detecting AF in patients who had a cryptogenic stroke, detecting AF at a rate seven times higher than SoC monitoring at 12 months.\(^{16}\)
- A study presented at the American Heart Association’s 2015 International Stroke Conference found that the Reveal LINQ ICM detected AF in everyday clinical practice at a much higher rate (37 percent relative increase) than was found in the CRYSTAL AF study, suggesting that AF may go undetected at an even greater rate than previously thought.\(^{17}\)
- A separate new analysis presented at the same meeting demonstrated that long-term cardiac monitoring is a cost-effective method of detecting AF in cryptogenic stroke patients to potentially prevent a recurrent stroke.\(^{18}\)
- Research presented at the 2016 American Academy of Neurology Annual Meeting showed that in a real-world population of cryptogenic stroke patients, 72 percent of AF patients would have gone undiagnosed if cardiac monitoring had been limited to 30 days.\(^{19}\)

CRYSTAL-AF study results

<table>
<thead>
<tr>
<th>Months since randomization</th>
<th>Atrial Fibrillation Detected (% of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1.4%</td>
</tr>
<tr>
<td>6</td>
<td>14%</td>
</tr>
<tr>
<td>12</td>
<td>12.4%</td>
</tr>
<tr>
<td>18</td>
<td>7.3X</td>
</tr>
<tr>
<td>24</td>
<td>6.4X</td>
</tr>
<tr>
<td>30</td>
<td>8.8X</td>
</tr>
<tr>
<td>36</td>
<td>10%</td>
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</tbody>
</table>

Hazard ratio, 8.8 (95% CI, 3.5 - 22.2)

P < 0.001 by log-rank test

<table>
<thead>
<tr>
<th># at risk</th>
<th>Control</th>
<th>ICM</th>
</tr>
</thead>
<tbody>
<tr>
<td>220</td>
<td>221</td>
<td>220</td>
</tr>
<tr>
<td>194</td>
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</tr>
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<td>36</td>
</tr>
<tr>
<td>7</td>
<td>8</td>
<td>7</td>
</tr>
</tbody>
</table>

The Reveal LINQ ICM continuously records heart rhythm data and sends them wirelessly to the MyCareLink™ Patient Monitor.

The MyCareLink Patient Monitor transmits data from the Reveal LINQ ICM to the clinic via a global cellular connection.

The clinic receives easy-to-use and clinically actionable Reveal LINQ reports via the CareLink™ Network.
1. Heart Disease and Stroke Statistics 2015 Update Circulation. 2015; 131; e29-e542. Published online before print December 17, 2014. doi: 10.1161/CIR.0000000000000152


13. Refer to the Reveal LINQ™ ICN Manual for use parameters.


Brief Statement

Indications

Reveal LINQ™ LNQ11 Insertable Cardiac Monitor and Patient Assistant

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

This device has not been specifically tested for pediatric use.

Patient Assistant

The 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 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.

Patient Assistant

Operation of the 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. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic’s website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.