Medtronic

Monitor longer. Fight secondary stroke.

Improve stroke patient outcomes with insertable cardiac monitoring[1,2]

LINQ™ family of ICMs

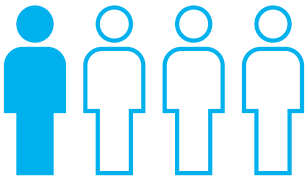
Reveal LINQ™ ICM and LINQ II™ ICM

Secondary stroke prevention is essential

Every year, more than

795,000

people in the United States have a stroke. Nearly 25% are in people who have had a previous stroke.[3]



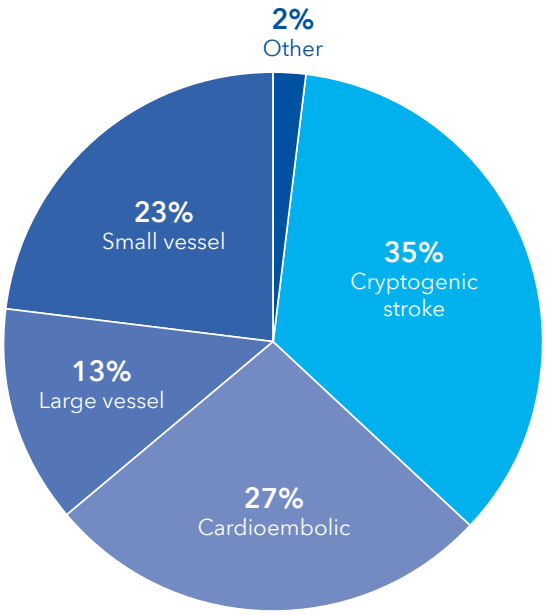
One in four stroke survivors will experience another stroke within five years.[4]

AF detection and treatment matter for improved patient outcomes.

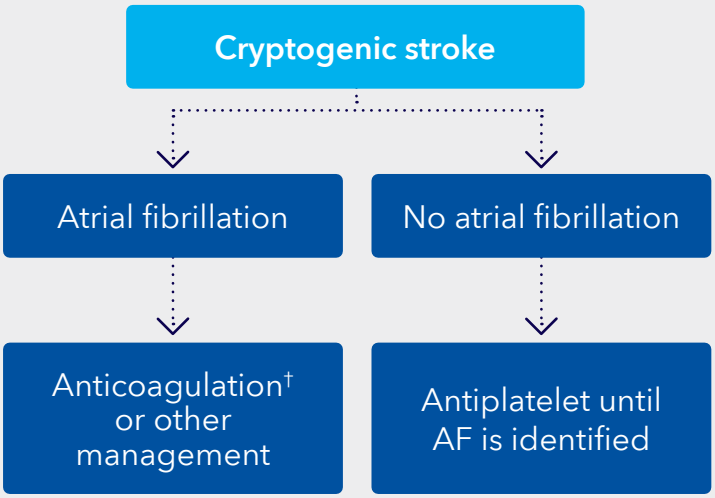
Cryptogenic stroke and atrial fibrillation

Despite a comprehensive workup, 35% of ischemic strokes are cryptogenic.[5]

Cryptogenic stroke patients are at high risk for atrial fibrillation (AF). Up to 30% of patients with cryptogenic stroke have previously undetected AF up to three years post-stroke.[6]



Detection of AF in cryptogenic stroke patients changes treatment[5]:



5x

AF is associated with a five-fold increase in the risk for ischemic stroke.[7]

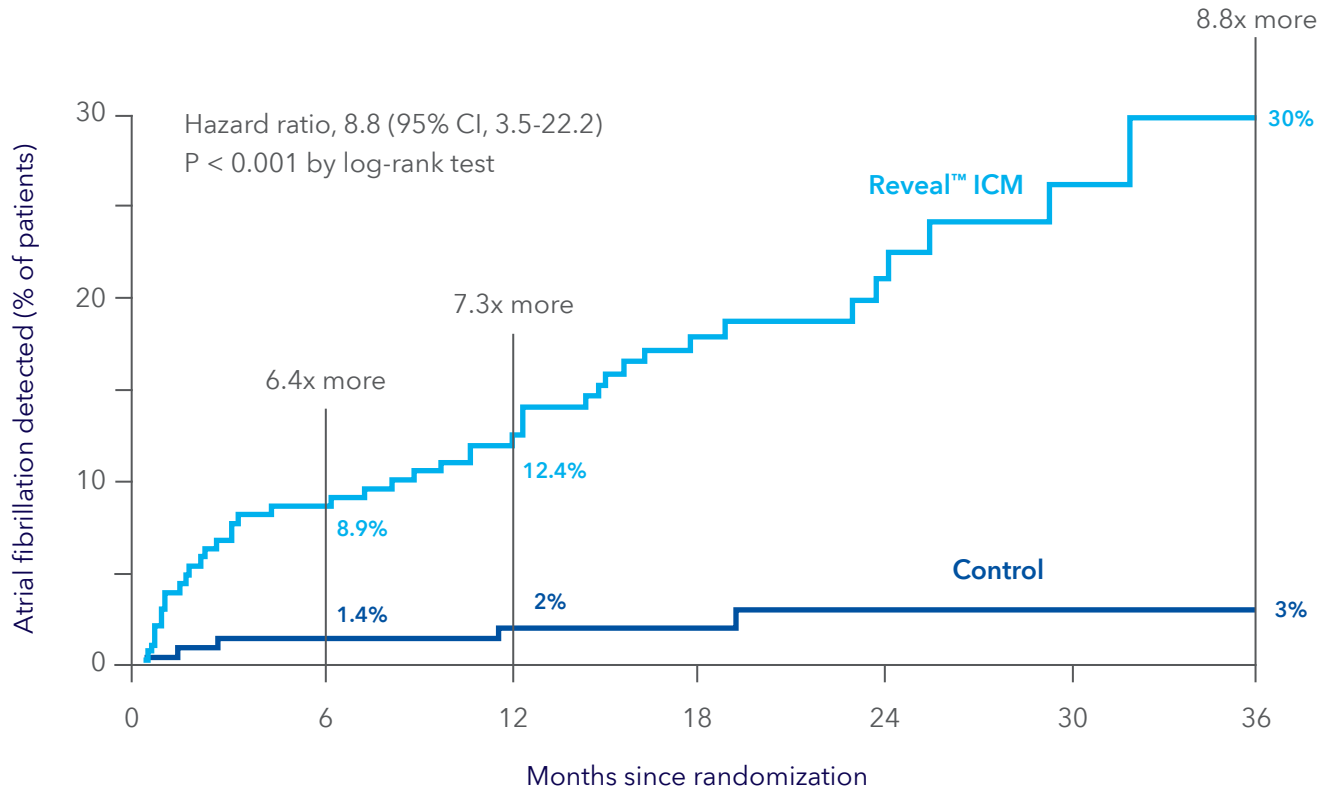
2x

more likely for AF-related ischemic stroke to be fatal than non-AF stroke.[8]

†If patient is appropriate candidate.

Monitor longer

CRYSTAL-AF study results as published in the *New England Journal of Medicine*[6]



# at risk							
Control	220	194	167	114	72	36	7
ICM	221	191	173	102	57	29	8

88%

of patients who had AF would have been missed if only monitored for 30 days[6]

Based on Kaplan-Meier estimates.

79%

of first AF episodes were asymptomatic at 12 months[6]

97%

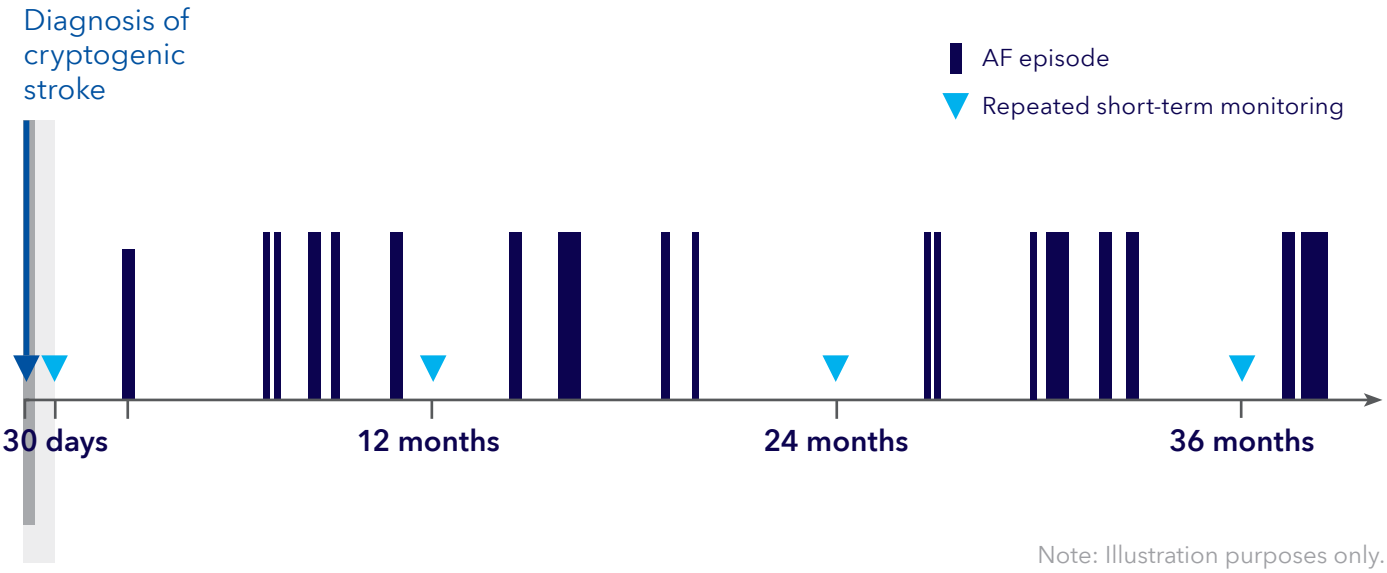
of patients with AF detected received oral anticoagulation[6]

Continuous monitoring with an insertable cardiac monitor (ICM) is superior to standard medical care for the detection of AF after cryptogenic stroke.[6]

External cardiac monitoring is not enough

Short-term monitoring could lead to undiagnosed patients[6]

Long-term, continuous monitoring (up to three years)



Note: Illustration purposes only.

Short-term monitoring **(up to one week)**

Intermediate-term monitoring **(up to 30 days)**

Medtronic ICM is superior to 30-day external loop recorder for AF detection[9]

15.3% AF detected in ICM arm ···· versus ···· **4.7%** in 30-day external loop recorder arm

Reveal LINQ ICM finds **3x** more AF over **12 months.**

Prevent secondary stroke

Cryptogenic stroke and TIA patients who underwent prolonged cardiac monitoring (PCM) compared to conventional cardiac monitoring show[1]:

Find AF.

2.5x

Increased incidence of AF detection.

Treat AF.

2.1x

Increased incidence of anticoagulant initiation.

Reduce stroke.

55%

Decreased risk of recurrent stroke.

Improve patient outcomes

Based on real-world claims data analysis[2,10]

Faster time to AF diagnosis

Hazard ratio (95% CI) = 1.50 (1.40–1.60)

Faster time to OAC initiation

HR = 1.57 (1.42–1.73)

Reduced readmissions

21% decrease in annual readmissions
for ICM vs. ECM (p = 0.0006)

Reduced rate of mortality

HR = 0.70 (0.55–0.89)

Neurology and cardiology guidelines recommend ICM for cryptogenic stroke patients

2022

2022 ESO guideline for AF screening in adult patients with cryptogenic stroke and TIA[11]

To maximize AF detection, clinicians should monitor cryptogenic stroke/TIA patients with implantable cardiac monitors, starting as soon as possible.

2021

2021 AHA/ASA guideline for the prevention of stroke in patients with stroke and TIA[5]

– Class 2a LOE B-R

In patients with cryptogenic stroke who do not have a contraindication to anticoagulation, long-term rhythm monitoring with mobile cardiac outpatient telemetry, implantable loop recorder, or other approach is reasonable to detect intermittent AF.

2020

2020 ESC guidelines for management of atrial fibrillation[12]

– Class 2a LOE B

In selected stroke patients without previously known AF, additional ECG monitoring using long-term, non-invasive ECG monitors or insertable cardiac monitors should be considered to detect AF.

2019

2019 AHA/ACC/HRS guideline for management of patients with AF[13]

– Class 2a LOE B-R

In patients with cryptogenic stroke (i.e., stroke of unknown cause) in whom external ambulatory monitoring is inconclusive, implantation of a cardiac monitor (loop recorder) is reasonable to optimize detection of silent AF.

Inform your clinical decisions with the LINQ family of ICMs

Reveal LINQ™ ICM and LINQ II™ ICM

Accuracy matters.

When you need answers, trust the most accurate insertable cardiac monitor (ICM) on the market.[14-26] Our proven ICMs deliver the data you need to make the right diagnosis for your patients, with continuous monitoring for up to 4.5 years.†

LINQ II ICM:
The world's most accurate ICM.[14-26]

Reveal LINQ ICM:
The world's smallest ICM, powered by TruRhythm™ detection.[27]

Industry-leading detection algorithms

The LINQ family of ICMs features the lowest published rate of AF false positives, and for greater confidence, the atrial fibrillation (AF) and Pause AccuRhythm™ AI algorithms further enhance the accuracy of the LINQ II ICM data. [14-15, 28-30]

See what artificial intelligence can do.

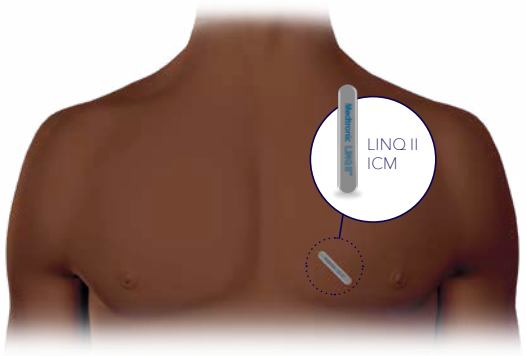
The AccuRhythm™ AI platform is an artificial intelligence system that applies deep learning algorithms to LINQ II ICM data flowing into the CareLink™ network. The algorithms address the two most common sources of ICM false alerts – AF and pause.[28-30]

† Nominal settings

High patient satisfaction

More than twice as many patients reported being very satisfied with Reveal LINQ ICM versus the 30-day external loop recorder (43%, n = 54 in ICM arm, versus 20%, n = 26 in external loop recorder arm)[9]

- Medtronic ICMs are inserted just under the skin of the patient's chest in a short and simple procedure.
- The heart monitor is one-third the size of a AAA battery (1.2 cc) and is not visible in most patients.
- Use of Medtronic ICMs doesn't require a change in daily activities.



"It has put my mind, my heart, my body at rest knowing that I have the Medtronic LINQ."

- Pam
Reveal LINQ ICM patient

Scan QR code to watch Pam's story

Not every person will receive the same results.

Benefits of an ICM-first monitoring strategy are significant

- Greater AF detection yield with ICM[6,9]
- Higher patient satisfaction with ICM[9]
- Patient compliance with short-term monitors is sub-optimal[31]
- Patients are lost to follow-up with short-term monitors[2,32]
- Short-to-long monitoring causes delays in AF detection[2]
- ICM is cost-effective vs. SOC[33]
- ICM is cost-saving vs. external monitors first[33]

Less than 5% of ischemic stroke patients who initially receive a short-term monitor go on to receive an ICM.[†2,32]

[†]Of patients with a clinical interaction with an electrophysiologist (EP) at any point in their care pathway.

Planning the cryptogenic stroke pathway

LINQ™ family of ICMs

View hospital pathway examples

Pathway based on the consensus of the Cryptogenic Stroke Pathway steering committee. February 2016.

Medtronic Disclosure Statement: This pathway is provided for educational purposes and should not be considered the exclusive source for this type of information. It is the responsibility of the practitioner to exercise independent clinical judgment.

Refer to the brief statement for indications, warnings/precautions, and complications for Medtronic ICMs.

†If bridging with an external monitor before ICM, review short-term monitor results prior to ICM insertion. If AF is not detected, insert ICM.

Why do you need a cryptogenic stroke pathway?

Top reasons to pursue better multidisciplinary stroke care‡

For your patients

- Better risk reduction strategy to prevent a secondary stroke
- Ensures quality post-stroke care
- Care focused on patient needs
- Can help provide reassurance and peace of mind

For your hospital

- Better risk reduction strategy to prevent a secondary stroke
- Coordinated and integrated care
- Consistent and reproducible approach
- Enhanced hospital reputation for providing exemplary care
- Stand out when pursuing Comprehensive Stroke Certification

‡Feedback based on the consensus of the Cryptogenic Stroke Pathway steering committee. February 2016.

ICM for large and small vessel stroke patients

STROKE AF study: AF in non-cardioembolic stroke of presumed known origin.[34]

Study design summary:

- Prospective, multisite, randomized clinical trial enrolling 496 patients at 33 centers in the United States
- Randomization 1:1 to continuous monitoring arm with Reveal LINQ ICM or control arm following site-specific standard of care (SOC) for detection of cardiac arrhythmias
- Follow-up: minimum 12 months, with maximum duration of 36 months

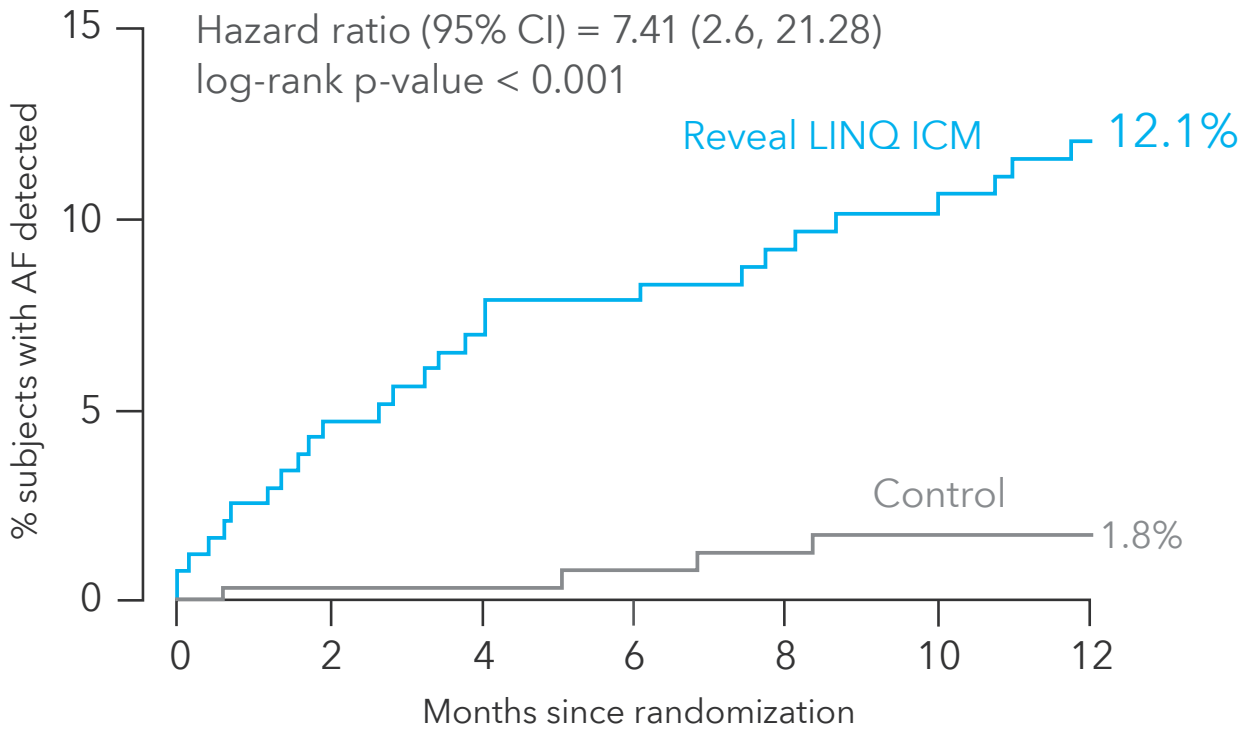
Primary objective

To determine whether long-term cardiac monitoring is superior to SOC for AF detection in patients with stroke attributed to large- or small- vessel disease through 12 months of follow-up.

45.5%

of first recurrent strokes are of a different etiology than the index stroke.[35]

Detection of AF at 12 months



Results:

- Reveal LINQ ICM is superior to usual care for AF detection in large- and small-vessel stroke patients.
- 96.3% of first AF episodes were asymptomatic
- 55.5% of patients with AF detected with an ICM had an episode lasting greater than one hour.
- Median time to detection of AF was 99 days in the ICM arm.

Even the most aggressive intermittent monitoring strategy would have missed 78% of patients who had ≥ two minutes of AF detected.

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AccuRhythm AI ECG Classification System Brief Statement

Intended Use
The intended use of the system is to reduce false positive cardiac arrhythmia episodes.

Contraindications
There are no known contraindications for AccuRhythm AI Models ZA400, ZA410, or ZA420.

Precaution
The AccuRhythm AI algorithms ECG classification system may incorrectly adjudicate a true positive episode as an AI false episode, causing that episode to be suppressed in the remote monitoring system.

See the device manual for detailed information regarding the intended use, contraindications, warnings, precautions, and potential complications / adverse events. For further information, call Medtronic Technical Services at (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.

Brief Statement for Medtronic LINQ Family Insertable Cardiac Monitor (ICM) System and Remote Monitoring

Indications
The Reveal LINQ ICM is an insertable automatically-activated and patient-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 tested specifically for pediatric use.

The LINQ II ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in adult patients, and in pediatric patients who are at least 2 years old, 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

Contraindications
There are no known contraindications for the insertion of the LINQ Family ICMs or their accessories. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

Warnings and Precautions
Patients with a LINQ Family ICM 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 Warnings, Precautions and Guidance Manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the LINQ II or Reveal LINQ ICM MRI Technical Manual.

Wireless accessories available for use with a LINQ Family ICM may experience connectivity or performance issues. See product manuals for details and troubleshooting instructions.

Potential Adverse Events
Potential adverse events from the LINQ Family ICM include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

There are no known adverse events associated with the use of any LINQ Family ICM wireless accessories.

See the device manuals for detailed information regarding the implant procedure, indications / intended use, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at (800) 328-2518 (Technical Services), (800) 551-5544 (Patient Services), and/or consult Medtronic's website at www.medtronic.com.

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

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