REVEAL AF IN YOUR CRYPTOGENIC STROKE PATIENTS

Are You Looking Long Enough?
One-third of ischemic strokes are cryptogenic (unexplained)\textsuperscript{1-6}

The number of stroke events in EU countries was 1.1 million in 2000 and is expected to increase to 1.5 million per year in 2025\textsuperscript{7}

Cryptogenic stroke accounts for approximately one-third of ischemic strokes in the majority of modern stroke registries and databases\textsuperscript{1-6}

AF detection and treatment matters

5-fold increase in ischemic stroke risk for AF patients.\textsuperscript{8}

2x more likely for AF-related ischemic stroke to be fatal as non-AF stroke.\textsuperscript{9}

67% decrease in AF patient stroke risk with oral anticoagulants.\textsuperscript{10}
AF detection and monitoring modality selection matters for cryptogenic stroke patients

- The ability to identify AF in patients with cryptogenic stroke has profound implications for long-term medical management\textsuperscript{12}
- Recurrence was more frequent and functional deficits were more likely to be severe among survivors of AF-related ischemic stroke\textsuperscript{9}
- Guidelines also recommend anticoagulant therapy for stroke prevention in most patients with AF\textsuperscript{13}

2016 ESC Guidelines for the management of atrial fibrillation\textsuperscript{11}

- Guidelines developed by the Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC)
- Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC
- Endorsed by the European Stroke Organisation (ESO)

Guidelines Recommendation

In stroke patients, additional ECG monitoring by long-term noninvasive ECG monitors or implanted loop recorders should be considered to document silent atrial fibrillation.

Class IIa

Level B
ARE YOU MONITORING CRYPTOGENIC STROKE PATIENTS LONG ENOUGH?

Short- and intermediate-term cardiac monitoring may miss many patients with paroxysmal AF.

**Key Findings from Crystal AF Study:**

84 DAYS is the median time to AF detection in cryptogenic stroke patients.

79% of first AF episodes were asymptomatic at 12 months.

88% of patients who had AF would have been missed if only monitored for 30 days.

*Based on Kaplan Meier estimates.*
INFORM YOUR CLINICAL DECISIONS WITH THE
REVEAL LINQ™ ICM SYSTEM

Up to 3 YEARS of continuous cardiac monitoring.

Simple, minimally invasive insertion procedure

- The Reveal LINQ™ ICM is placed just under the skin of the patient’s chest in a simple procedure
- The ultra-discreet heart monitor is not visible in most patients
- Patients prefer the Reveal LINQ™ ICM over external wearable monitors

Safe for use in MRI setting same day at 1.5 and 3.0 Tesla*

*Reveal LINQ™ ICM has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Please see the Reveal LINQ™ ICM clinician manual or MRI technical manual for more details.

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
As published in the *New England Journal of Medicine*¹⁴

**STUDY DESIGN**
- Randomized, controlled clinical trial with 441 patients
- Compared continuous, long-term monitoring with Reveal LINQ™ ICM vs. conventional follow-up
- Assessment at scheduled and unscheduled visits
- ECG monitoring performed at the discretion of the site investigator

**PATIENT INCLUSION CRITERIA**
- ≥ 40 years of age
- Cryptogenic stroke (or clinical TIA) with infarct seen on MRI or CT within the previous 90 days and no mechanism identified after:
  - 12-lead ECG
  - 24-hour ECG monitoring (e.g., Holter)
  - Transesophageal echocardiography (TEE)
  - CTA or MRA of head and neck to rule out arterial source
  - Screening for hypercoagulable states in patients < 55 years old

**END POINTS**
- **Primary**
  - Time to first detection of AF at 6 months of follow-up
- **Secondary**
  - Time to first detection of AF at 12 months of follow-up
  - Recurrent stroke or TIA
  - Actions taken after patient diagnosed with AF

The CRYSTAL-AF Study found that continuous monitoring with Reveal™ ICM is superior to standard medical care for the detection of AF in cryptogenic stroke patients.

Visit CRYSTAL-AF.com for complete study information.
Detection of Atrial Fibrillation by 36 months

Hazard ratio, 8.8 (95% CI, 3.5 - 22.2)
P < 0.001 by log-rank test

Clinical impact: more appropriate care

Short-term cardiac monitoring is NOT sufficient for AF detection in cryptogenic stroke

- Extensive external monitoring found few patients with AF:
  In the control group at 6 months, only 3 patients were found to have AF; yet there were 88 conventional ECGs, 20 24-hour Holters, and 1 event recorder used
- Reveal LINQ™ ICM detected over 7 times more patients with AF at the 12-month end point
REFERENCES

BRIEF STATEMENT
See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative or consult the Medtronic website at www.medtronic.com.

medtronic.com/manuals

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.