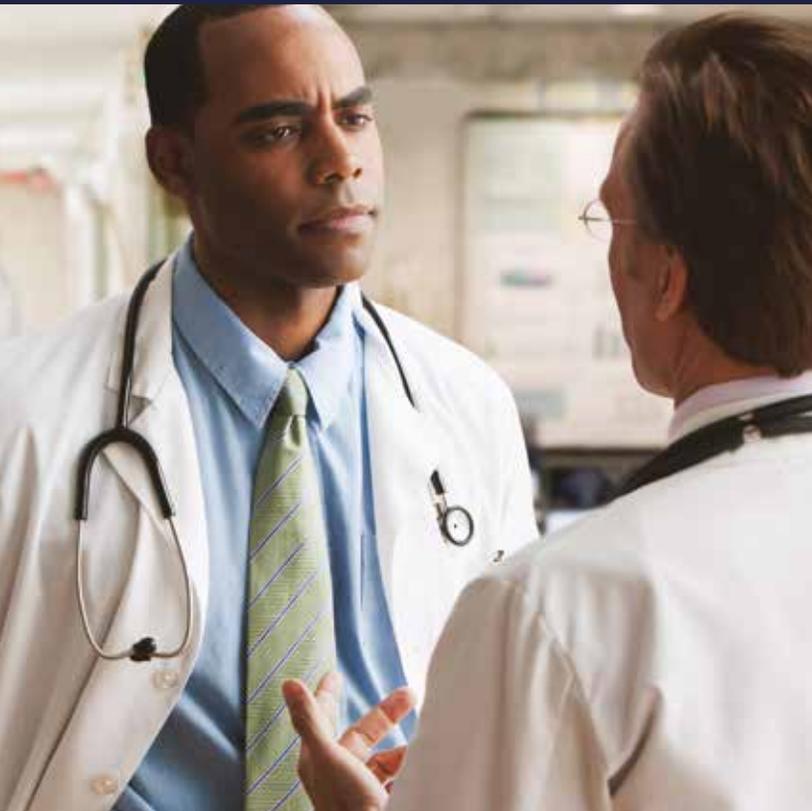


CRYPTOGENIC STROKE PATHWAY: PLANNING AND IMPLEMENTATION GUIDE



Together, let's
improve stroke care

Medtronic

WHAT IS A CRYPTOGENIC STROKE PATHWAY?

A Cryptogenic Stroke Pathway is a consistent approach to a follow-up plan and transition of care for patients with a stroke of unknown source.

This implementation guide is intended to extend your acute stroke protocol to include a monitoring plan for cryptogenic stroke patients. It includes monitoring for AF with the best monitoring mechanisms available to optimize outcomes.

WHY ESTABLISH A CRYPTOGENIC STROKE PATHWAY?

After initial stroke discharge, many patients are not receiving any additional cardiac monitoring. Establishing a monitoring pathway to detect and treat AF can **significantly reduce a patient's risk for another stroke**. The ability to identify AF in patients with cryptogenic stroke has profound implications for long-term medical management.

5-FOLD

increase in ischemic stroke risk for AF patients.¹



2X

more likely for AF-related ischemic stroke to be fatal as non-AF stroke.²

67%

decrease in AF patient stroke risk with oral anticoagulants.³



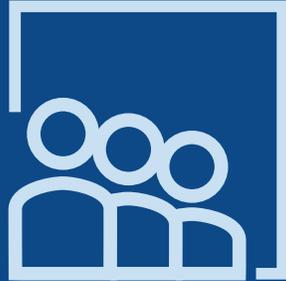
Many cryptogenic stroke patients are lost to follow-up. Pathways for transition of care and follow-up help to ensure these patients receive better care.

A **Cryptogenic Stroke Pathway** allows all healthcare professionals involved in the continuum to ensure a standard of care. Through this pathway, hospitals can:

- Provide underserved patient population a better risk reduction strategy to prevent a secondary stroke
- Establish cross-functional healthcare professional relationships to ensure integrated care delivery
- Ensure multidisciplinary stroke care involving both neurological and cardiovascular care
- Enhance hospital reputation in providing exemplary stroke care

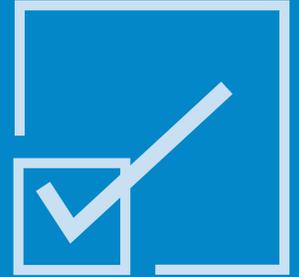
1

Identify champions and align the multidisciplinary team



2

Agree on the pathway and education plan



PLANNING THE CRYPTOGENIC STROKE PATHWAY

3

Communicate and educate about new pathway to a prioritized list of healthcare providers in the hospital



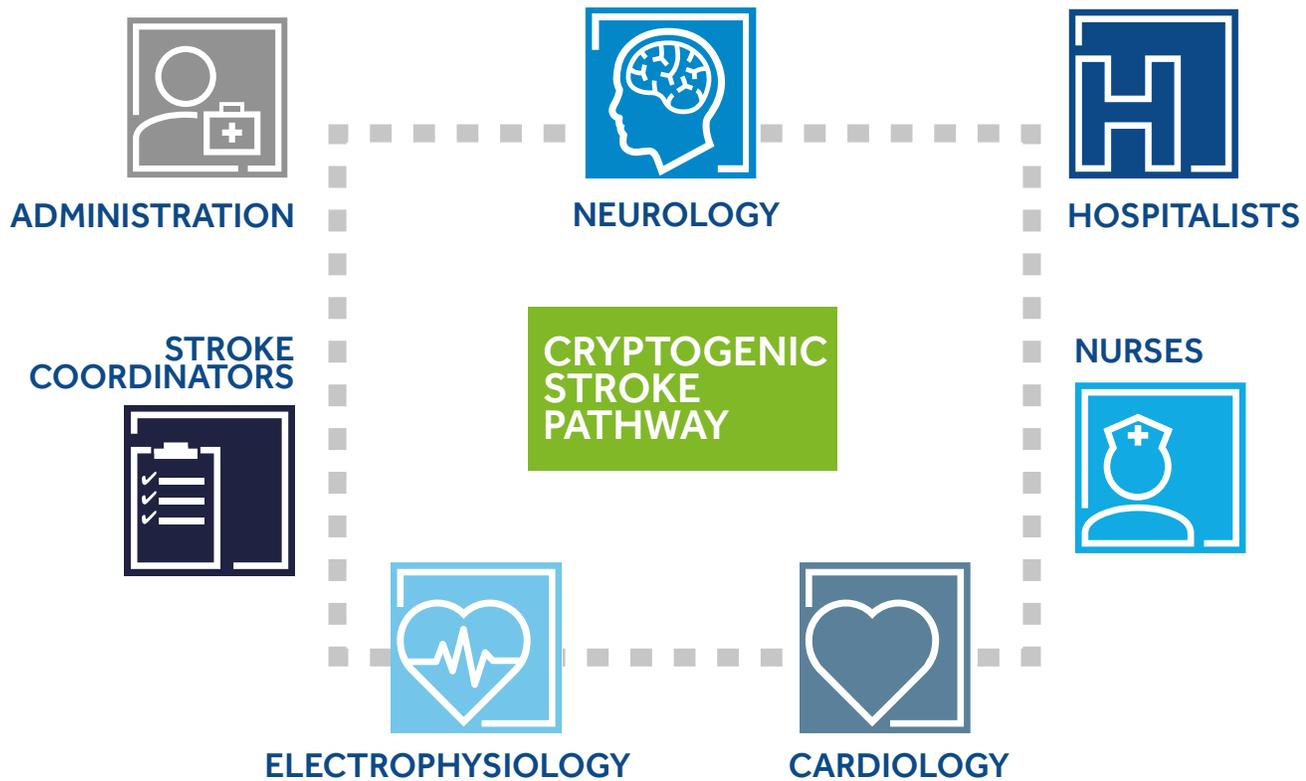
4

Meet with cryptogenic stroke care team on a regular basis to assess implementation



THINGS TO CONSIDER

When developing the Cryptogenic Stroke Pathway, it is important to involve all stakeholders involved in the care of the patient.



Foundational Considerations

- Who will champion this effort?
- How is cryptogenic stroke defined at your hospital?
- You have an acute stroke protocol, but do you have a cryptogenic stroke pathway in place?
- Once a patient is deemed cryptogenic, what is the multidisciplinary pathway, transition of care, and follow-up plan in place for that patient?

Execution of Cryptogenic Stroke Pathway

- Do you have the infrastructure and staff in place to support the implementation?
- What else needs to be developed to support your plan?

Metrics

- Could this be a quality or process improvement project for your hospital?
- What will you measure in your pathway?
- What is your definition of success?

CHECKLIST FOR SUCCESS



Identify Physician Champion and Ensure Multidisciplinary Buy-In

- Ideal to have both neurology and cardiology champions
- Ongoing communication among all specialties involved in the stroke care of the patient.
 - It is essential to establish patient ownership, coordination of care, and a transition of care plan
- The cardiac monitoring plan must be very clear at the onset and consistent throughout the continuum
 - Ensures patients are not lost to follow-up and all parties are aware of where the patient is within the continuum



Ongoing Education of all Stakeholders

Patient/Caregivers

- Tell the patient/caregivers about the cardiac monitoring plan and why it is important to look for AF after a cryptogenic stroke
- Designate nurse responsible for patient education throughout the care continuum (bedside nurse, nurse educator, nurse navigator, etc.)

Healthcare Professional Team

- Identify and educate whole care team on Cryptogenic Stroke Pathway (including hospitalists, nurses, fellows, PCPs, etc.)
- Use in-services and existing educational vehicles at hospital for continued education



Develop Stroke Care Team Communication Plan

- Communication is important prior to insertion, after insertion, when AF doesn't/does occur, and prior to OAC initiation (if deemed necessary)
- Consider EMR notification
- Develop feedback loop
- Hold monthly interdisciplinary "Workflow" assessment meetings involving inpatient and outpatient care to ensure standardization of the process

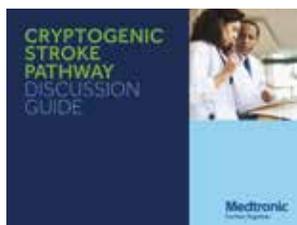


Partner with Medtronic

- Understand available resources to assist your team in planning and implementation
- Learn best practices for utilizing Reveal LINQ™ ICM for cryptogenic stroke

READY TO IMPLEMENT?

Planning and Implementation Tools



Pathway Planning Materials

Includes multidisciplinary team discussion guide (PPT) to help foster clarity around pathway development.



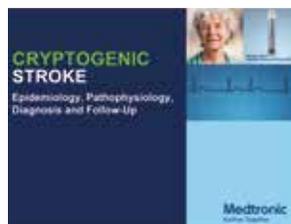
Patient Education

Disease state and device educational materials, including a procedural video and patient responsibility sheet.



Patient Management Resources

Materials including information about best practices for Reveal LINQ patient management.



Healthcare Professional Education

Includes slide decks for use with colleagues during educational programs, and overview documents pertaining to data on cryptogenic stroke.



Healthcare Professional Educational Programs

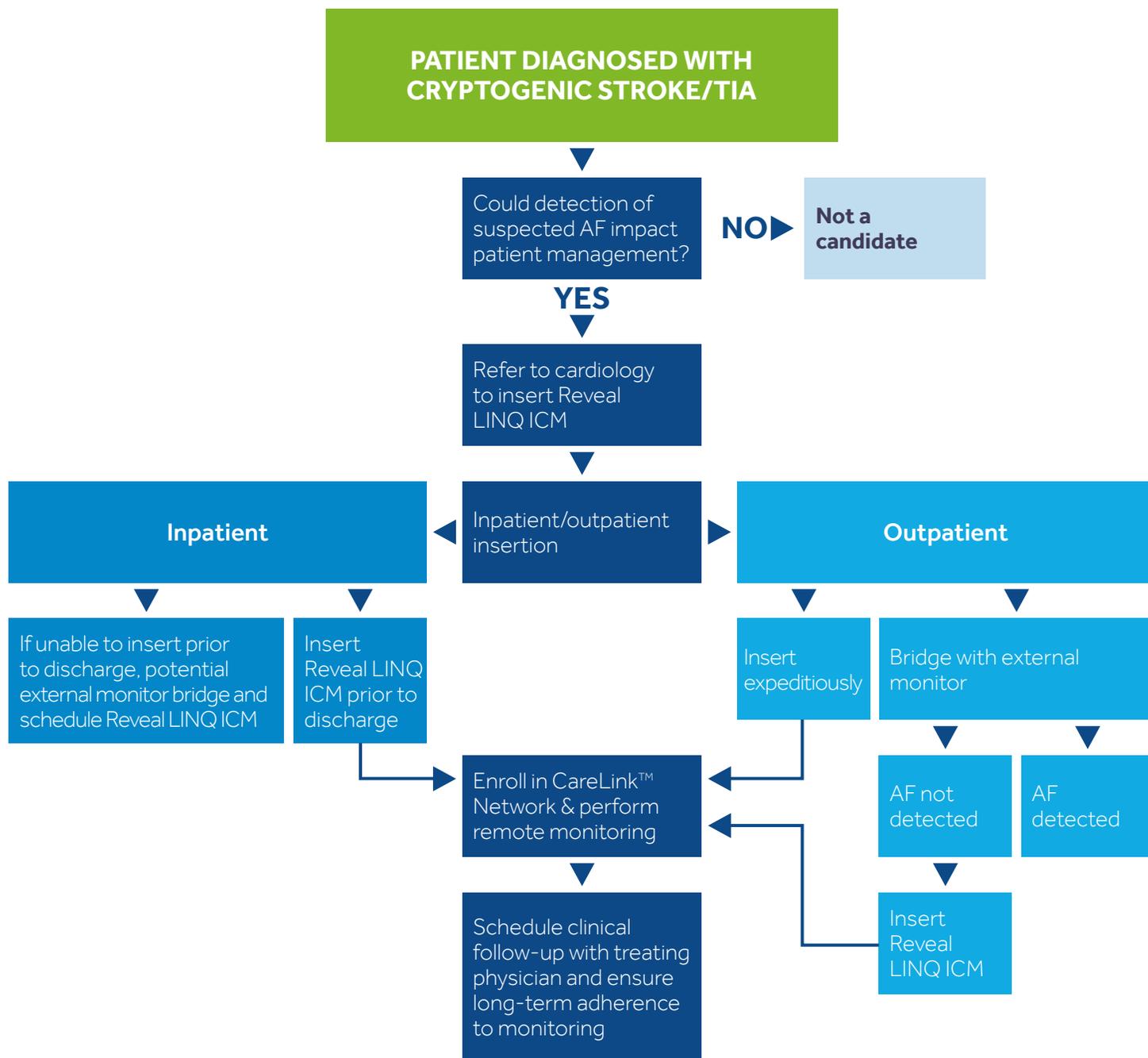
Online and live educational programs available to multidisciplinary stroke care teams to help educate on the disease and Reveal LINQ ICM as a therapy option.



Public Relations Media Kit

Includes media materials and sample press releases.

CRYPTOGENIC STROKE PATHWAY



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 the Reveal LINQ ICM.

WHEN TO CONSIDER LOOKING FOR AF IN CRYPTOGENIC STROKE PATIENTS

Appropriate

- Stroke detected by CT or MRI that is not lacunar⁴
- Absence of extracranial or intracranial atherosclerosis causing $\geq 50\%$ luminal stenosis in arteries supplying the area of ischaemia⁴
- No major-risk cardioembolic source of embolism⁴
- No other specific cause of stroke identified (e.g., arteritis, dissection, migraine/vasospasm, drug misuse)⁴
- First event — Stroke or High-Risk TIA*
- CHADS₂ score ≥ 2 (Minimal risk factors)

Not Appropriate

- Indication for chronic anticoagulation or already on anticoagulation
- Patients with a relative contraindication for long-term anticoagulation and not appropriate for LAA closure device

* ABCD2 Score >5

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



Reveal LINQ™
Insertable Cardiac Monitoring System

Reveal LINQ ICM Indications*

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias

*See full brief statement for complete indications for use.

References

¹ Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation: a major contributor to stroke in the elderly. The Framingham Study. *Arch Intern Med.* September 1987;147(9):1561-1564.

² Lin HJ, Wolf PA, Kelly-Hayes M, et al. Stroke severity in atrial fibrillation. The Framingham Study. *Stroke.* October 1996;27(10):1760-1764.

³ Stroke Prevention in Atrial Fibrillation Study. Final results. *Circulation.* August 1991;84(2):527-539.

⁴ Hart RG, Diener HC, Coutts SB, et al. Embolic strokes of undetermined source: the case for a new clinical construct. *Lancet Neurol.* April 2014;13(4):429-438.

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 specifically been 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 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.

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.

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.

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