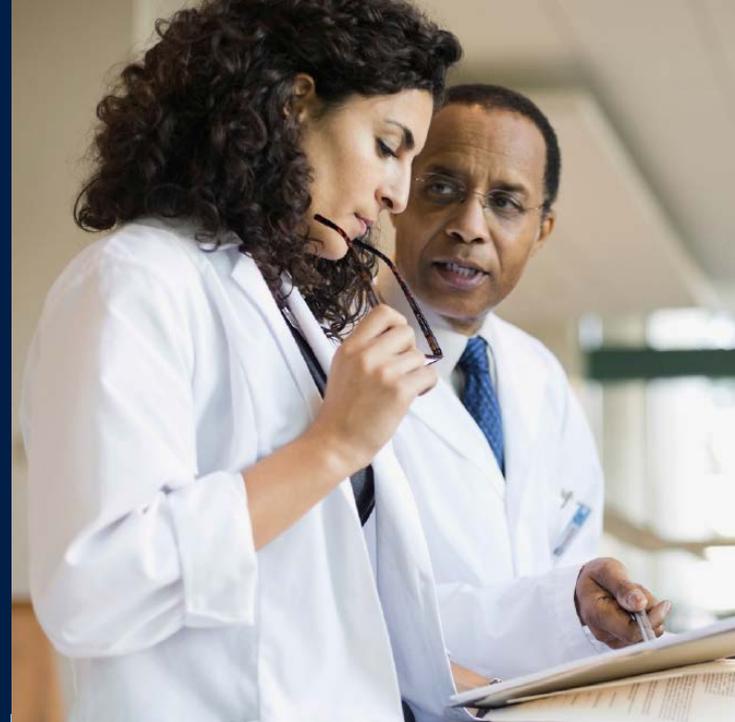# CRYPTOGENIC STROKE PATHWAY
DISCUSSION GUIDE

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Further, Together

POINTS TO CONSIDER WHEN DEVELOPING A PATHWAY
CRYPTOGENIC — NOW WHAT?

- How is cryptogenic stroke defined at your hospital?
  - Once a patient is deemed cryptogenic, what is the multi-disciplinary pathway, transition of care and follow-up plan in place for that patient?
  - You have a stroke protocol, but do you have a cryptogenic stroke pathway/protocol in place?

- Establish a plan for transition of care and long-term follow-up for these patients
  - Do you have the infrastructure/ staff to support?
  - What else needs to be developed to support your plan?
  - Metrics
    - Could this be a quality improvement project? A process improvement project?
    - What will you measure in your pathway?
    - What is your definition of success?

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EDUCATION NEEDS

- Neurologist needs to be able to explain Reveal LINQ™ ICM to a patient

  - Resource — Cryptogenic Stroke Patient Education Brochure and Reveal LINQ ICM demo

- Educate the entire stroke care team on why they should care about AF detection and long-term monitoring as standard of care for cryptogenic stroke patients

- Do you understand the patient impact when care is not coordinated at your hospital?

  - Have you done a patient audit of one of your cryptogenic stroke patients?

- How many of your cryptogenic stroke patients have recurrent stroke?

- How many cryptogenic stroke patients are found to have AF at:

  - 3 months

  - 6 months

  - 1 year

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DOES EVERYONE ON YOUR STROKE CARE TEAM KNOW THIS INFORMATION?

- 690,000 ischemic strokes every year in the US[1]

  - Leading cause of disability in the US and worldwide

- ~200,000 cryptogenic strokes yearly[1]

- Most cryptogenic stroke patients receive anti-platelet for secondary prevention[2]

- Long-term monitoring reveals AF in ~30% of cryptogenic stroke patients[3-9]

  - These patients benefit from anticoagulant therapy

Ischemic Stroke

- Large Vessel
- Cryptogenic Stroke
- Small Vessel
- Cardioembolic
- Other

30%

15%

5%

30% Cryptogenic Stroke

20%
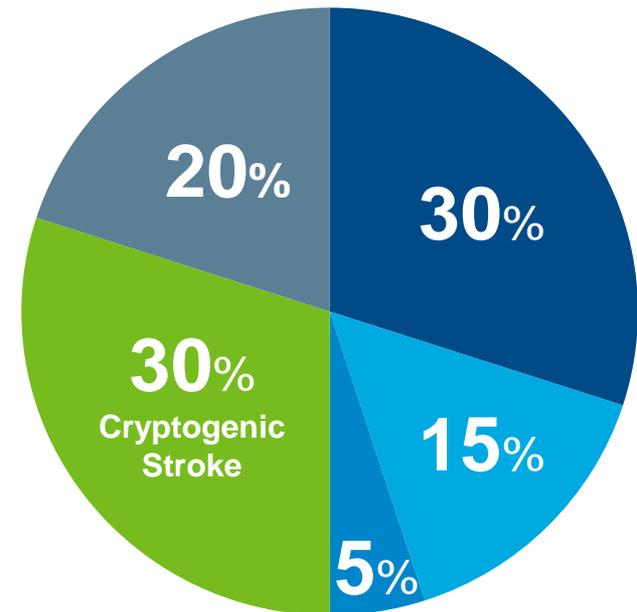
[1] Mozzafarian D, et al. *Circulation*. 2015;131:e29-e322.
[2] Kernan WN, et al. *Stroke*. 2014;45:2160-2236.
[3] Sacco RL, et al. *Ann Neurol*. 1989;25:382-390.
[4] Petty GW, et al. *Stroke*. 1999;30:2513-2516.
[5] Kolominsky-Rabas PL, et al. *Stroke*. 2001;32:2735-2740.
[6] Schulz UG, et al. *Stroke*. 2003;34:2050-2059.
[7] Schneider AT, et al. *Stroke*. 2004;35:1552-1556.
[8] Lee BI, et al. *Cerebrovasc Dis*. 2001;12:145-151.
[9] Sanna T, et al. *N Engl J Med*. 2014;370:2478-2486.

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DO THEY KNOW THE RISK FOR STROKE IN PATIENTS WITH AF?

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%
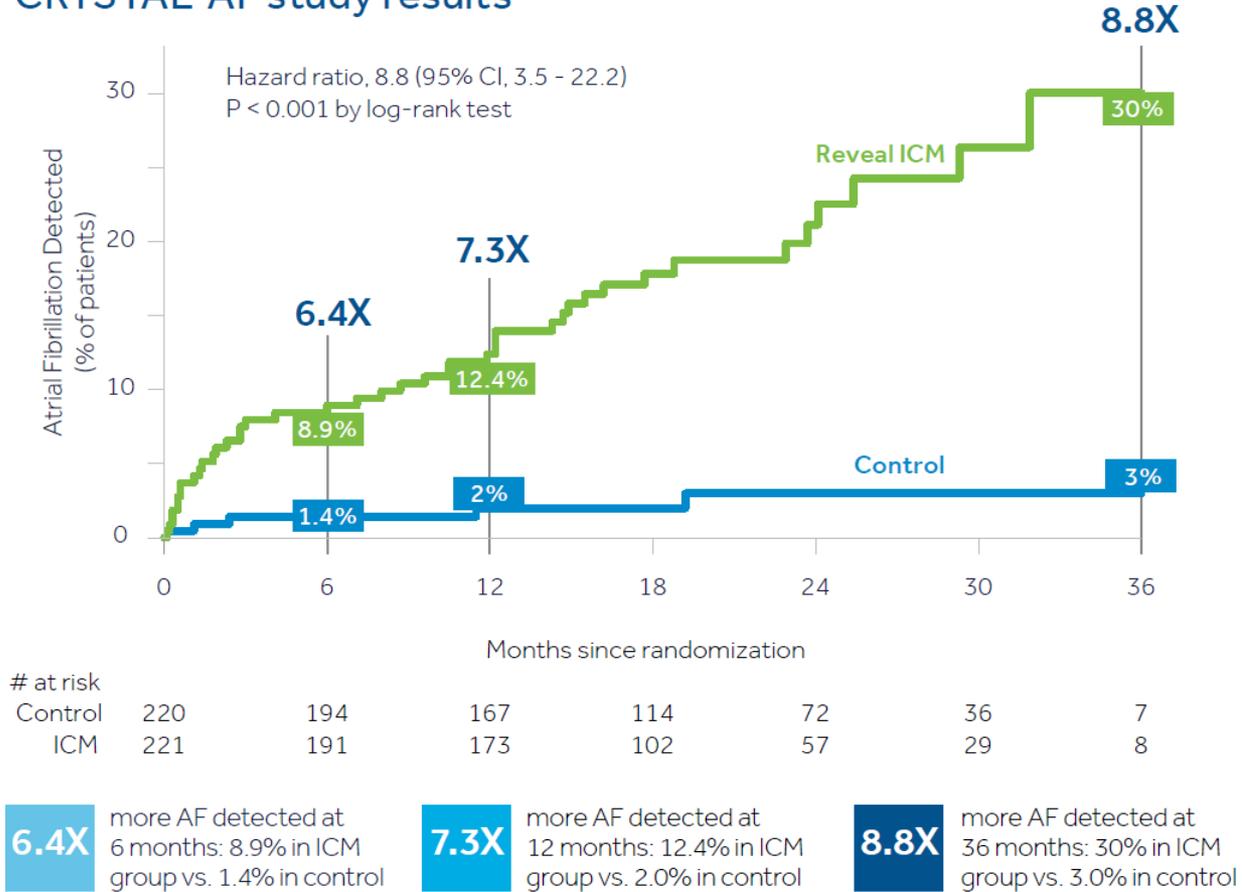decrease in AF patient stroke risk with oral anticoagulants.[3]

[1] Wolf PA, et al. *Arch Intern Med*. 1987;147:1561-1564.
[2] Lin HJ, et al. *Stroke*. 1996; 27:1760-1764.
[3] Stroke Prevention in Atrial Fibrillation Study. *Circulation*. 1991;84:527-539.

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CRYSTAL-AF STUDY: CONTINUOUS MONITORING WITH ICM IS SUPERIOR TO STANDARD MEDICAL CARE FOR THE DETECTION OF AF IN CRYPTOGENIC STROKE PATIENTS

CRYSTAL-AF study results

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

8.8X — 30%
7.3X — 12.4%
6.4X — 8.9%
Reveal ICM
Control — 3%
2%
1.4%

Atrial Fibrillation Detected (% of patients)

Months since randomization

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

6.4X more AF detected at 6 months: 8.9% in ICM group vs. 1.4% in control

7.3X more AF detected at 12 months: 12.4% in ICM group vs. 2.0% in control

8.8X more AF detected at 36 months: 30% in ICM group vs. 3.0% in control
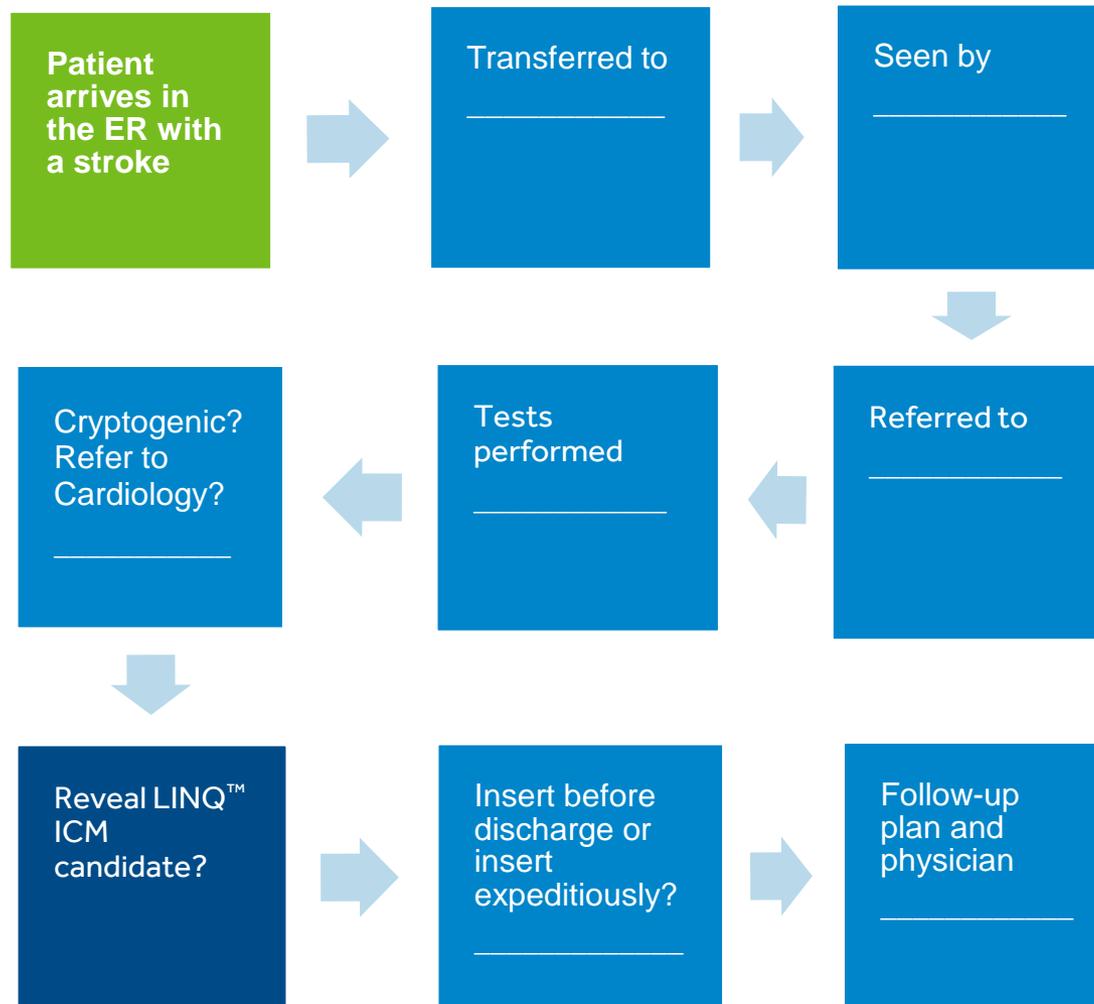
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CRYPTOGENIC STROKE PATHWAY
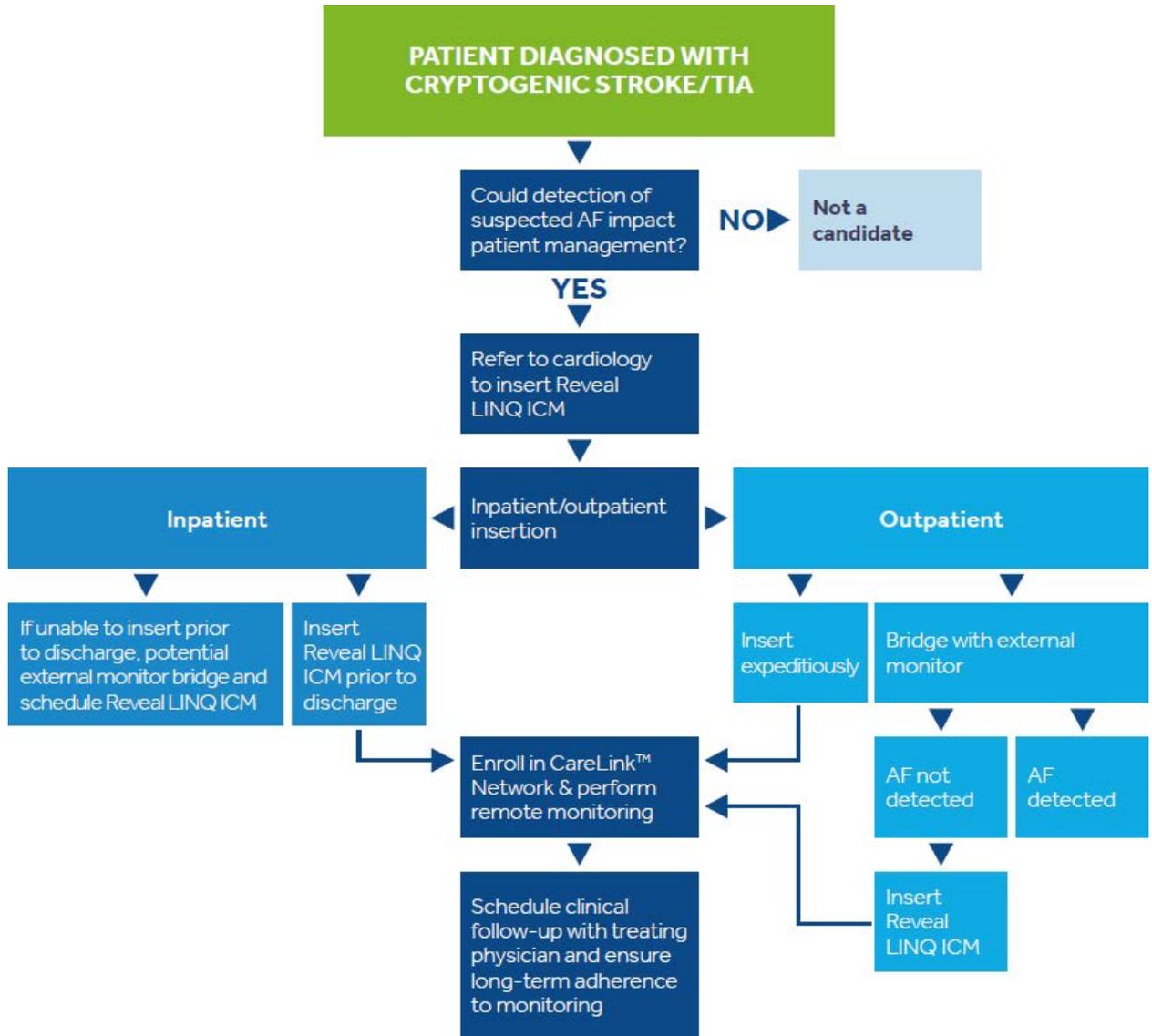## EP/CARDIOLOGY AND NEUROLOGY CONVERSATIONS

- Stroke neurologist and implanting cardiologist/EP should meet
- Objectives of meeting:
  - Agree on the ideal candidate for Reveal LINQ™ ICM
  - Develop a streamlined plan for referral
    - Note infrastructure and personnel needed to execute the referral
  - Clarify patient care responsibilities
    - Who "owns" the patient?
      - If patient is found to have AF – what actions will be taken?
      - Who owns the patient follow-up and subsequent medical management change? (i.e., who will prescribe a needed OAC?)
      - How much AF is enough to start OAC?
        - Make sure EP and neurology agree on the time threshold for AF
      - If the EP owns the patient once AF is detected, what is the feedback mechanism to neurology? To the patient?
  - Complete the "Cryptogenic Stroke Patient Follow-up Guide"

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PATIENT EXPERIENCE
WHAT DOES IT LOOK LIKE? WHO IS RESPONSIBLE?

Patient arrives in the ER with a stroke → Transferred to _____ → Seen by _____

↓

Cryptogenic? Refer to Cardiology? _____ ← Tests performed _____ ← Referred to _____

↓

Reveal LINQ™ ICM candidate? → Insert before discharge or insert expeditiously? _____ → Follow-up plan and physician _____

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.

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PATIENT DIAGNOSED WITH A CRYPTOGENIC STROKE/TIA

<u>Points to Consider:</u>

- How is cryptogenic stroke defined at your hospital?

  - Does everyone agree on this definition?

  - Does everyone have knowledge of this definition?

- What diagnostic tests need to be performed before you deem someone cryptogenic?

  - TEE +/-

  - Why or why not?

  - How do you define a TIA?

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PATIENT DIAGNOSED WITH A CRYPTOGENIC STROKE/TIA

Best practices:

- Make sure everyone agrees on the diagnostic work-up and your hospital's definition of cryptogenic stroke

- TIA is an image-confirmed, neurology-confirmed event before patients are put into the pool of consideration for cardiac monitoring

COULD DETERMINATION OF AF IMPACT PATIENT MANAGEMENT?

Points to Consider:

- Would medical management change if you detected AF?
  - If not — the patient doesn't need to be considered for monitoring
  - OAC is no longer the only option for these patients
    - If a patient is contraindicated for NOAC, would LAA be an option if AF was found?

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COULD DETERMINATION OF AF IMPACT PATIENT MANAGEMENT?

Best practices:

- When in doubt, look for AF
  - The longer you look, the more you find
  - Finding AF and treating it in cryptogenic stroke patients may reduce their risk for a second stroke
    - OAC can reduce the risk of stroke by 67%[1]

67%

decrease in AF patient stroke risk with oral anticoagulants.[1]

[1] Stroke Prevention in Atrial Fibrillation Study. *Circulation.* 1991;84:527-539

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REFER TO CARDIOLOGY FOR REVEAL LINQ™ ICM INSERTION

Points to Consider:

- Do you refer to cardiology/EP or do you order a consult?

- Do you need a consult if the patient has already been determined to be a candidate for monitoring?

- Is there any other reason that the patient would not be a candidate for an ICM?

- Do you need a 30-day monitor?

  - Could you insert during the initial stroke admission?

    - If not, how soon could you bring them back for insertion?

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REFER TO CARDIOLOGY FOR REVEAL LINQ™ ICM INSERTION

Best practices:

- Refer to cardiology for a Reveal LINQ ICM

  - No consult needed if you have already determined and agreed upon the patient selection for Reveal LINQ ICM

  - Cardiology should not repeat the work-up

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INPATIENT/OUTPATIENT INSERTION
INPATIENT

Points to Consider:

- How do you ensure Reveal LINQ™ ICM is scheduled/inserted prior to discharge?

- How do you ensure it is not increasing the length of stay?

- Will the implanting physician follow the device?
  - Which device clinic is following the cryptogenic stroke patients?
  - How is neurology updated about their stroke patients?
  - Reasons to consider inpatient insertion:
    - High-risk patient — clinical considerations
    - No insurance
    - High-risk patient — practical considerations
      - Patient lives a long distance from hospital
      - High risk of losing patient to follow-up

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INPATIENT/OUTPATIENT INSERTION
INPATIENT

<u>Best practices:</u>

- Insert Reveal LINQ™ ICM during the initial stroke admission

  - Easier to educate patient and obtain consent

  - Ensures compliance and that the stroke patient is not lost to follow-up

- Educate patient with family member/caregiver present to ensure they understand how the system works

- Advise patient about what to expect for the copays and ongoing monitoring with Reveal LINQ ICM

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INPATIENT/OUTPATIENT INSERTION
OUTPATIENT

Points to Consider:

- Is there a plan to get the patient a Reveal LINQ™ ICM?

  - How do you ensure that Reveal LINQ ICM is scheduled prior to initial stroke discharge?

  - What is the plan for the transition of care?

  - Has the patient been educated about Reveal LINQ ICM and the cardiac monitoring plan by the neurologist?

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INPATIENT/OUTPATIENT INSERTION
OUTPATIENT

Best practices:

- Establish a plan for transition of care and long-term follow-up for these patients
  - Do you have the infrastructure/staff to support?
  - What else needs to be developed to support your plan?
    - If you use a 30-day monitor first, what system checks do you have in place to ensure that if the 30-day is negative the patient receives a Reveal LINQ™ ICM?
    - If more than 30 days of monitoring is the original plan, the neurologist should educate the patient about Reveal LINQ ICM as the next step if the 30-day monitor is negative
    - Provide stroke neurologists with Reveal LINQ ICM demos and education brochures to show patients
  - At insertion— Advise patient about what to expect for the copays and ongoing monitoring with Reveal LINQ ICM

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PATIENT EDUCATION BEST PRACTICES

- Educate patients/caregivers about Reveal LINQ™ ICM

- Make sure the patient/caregiver understands the full plan for cardiac monitoring after a cryptogenic stroke

- Explain why it is important to find AF after a cryptogenic stroke and to have a risk reduction strategy to help prevent another stroke

- Reference the "Reveal LINQ Patient Education Guide for Clinicians"

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PATIENT EDUCATION BEST PRACTICES

PRE-INSERTION
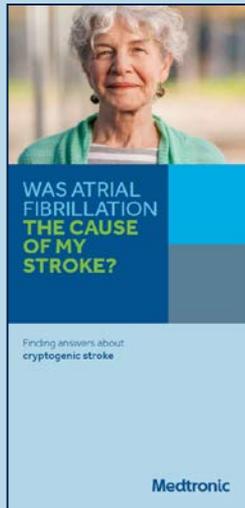
Cryptogenic Stroke Education

Reveal LINQ System Intro Brochure

Reveal LINQ System Introduction Video

POST-INSERTION

Reveal LINQ System Patient Information Kit

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PATIENT EDUCATION BEST PRACTICES

MonitorYourHeart.com/LINQ

Designed to be an ongoing resource for your patients providing additional guidance on:

- Information about Cryptogenic Stroke and long-term monitoring

- Setup and ongoing use of the Reveal LINQ™ ICM System

- Answers to frequently asked questions

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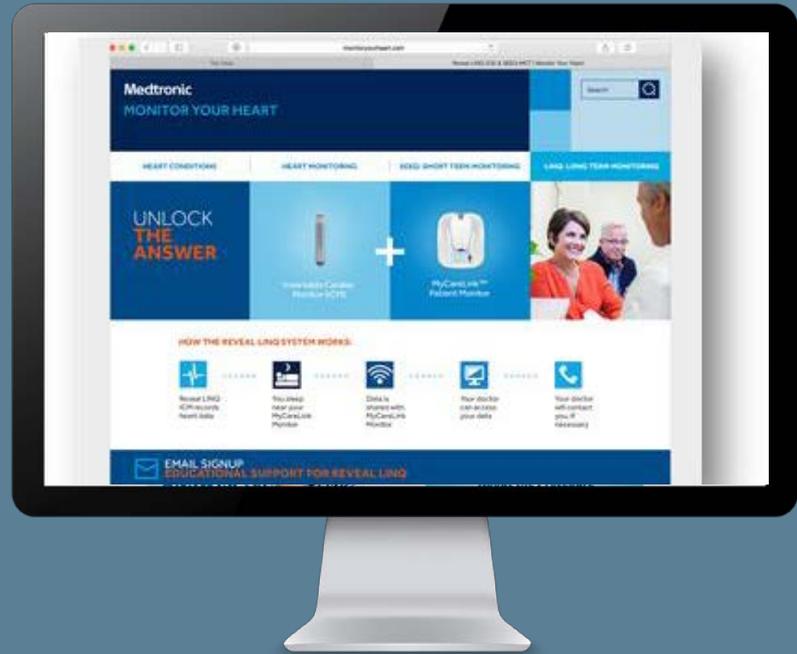
ENROLL IN CARELINK™ NETWORK AND PERFORM REMOTE MONITORING

Points to Consider:

- It is the EP and device clinic responsibility to enroll and perform remote monitoring
- What does your specific cardiac monitoring protocol look like for cryptogenic stroke patients?
  - How do you want your alerts set?
  - How many minutes of AF do you want to be notified about?
  - What does the communication look like between the device nurse and the stroke coordinator?

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ENROLL IN CARELINK™ NETWORK AND PERFORM REMOTE MONITORING

Best practices:

- Proper device clinic staffing and a specific remote monitoring protocol for Reveal LINQ™ ICM cryptogenic stroke patients are essential to success

- Establish a feedback loop
  - Neurology wants to know if AF is detected
  - They also need to have confidence and know that their patients are being monitored
    - Could set up a satellite cryptogenic stroke clinic with viewing privileges
    - Or notify neurologist and stroke coordinator when:
      - AF is detected
      - A summary report is received
        - No news of AF detection is still news

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SCHEDULE CLINICAL FOLLOW-UP WITH TREATING PHYSICIAN AND ENSURE ADHERENCE TO MONITORING

Points to Consider:

- Who is the treating physician?

- Is the patient/caregiver clear on which physician is doing what in their care?

- Reveal LINQ™ ICM Patient Management

  - Do you have a strategy for checking for disconnected monitors?

  - Do you have your CareAlert™ notifications set to your clinical preference for information?

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SCHEDULE CLINICAL FOLLOW-UP WITH TREATING PHYSICIAN AND ENSURE ADHERENCE TO MONITORING

<u>Best Practices:</u>

- Fill out a "Cryptogenic Stroke Patient Follow-up Guide"

- Refer to "Best Practices for Reveal LINQ Patient Management" for tips and tricks on the best way to remotely manage your Reveal LINQ ICM patients

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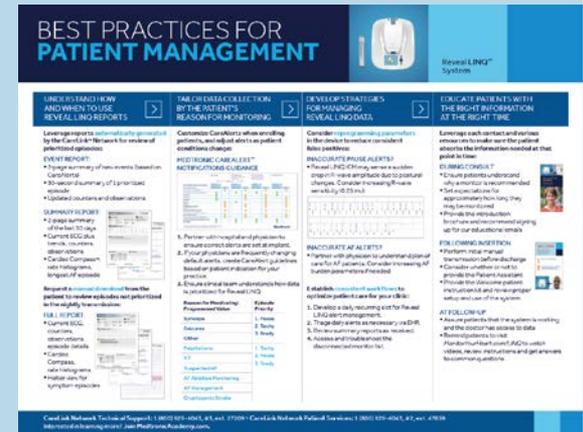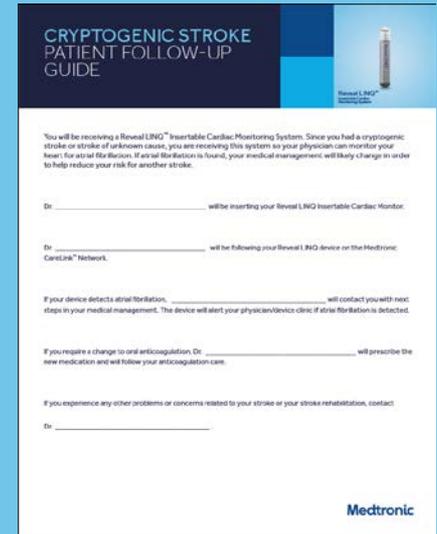
BRIEF STATEMENT

Reveal LINQ™ LNQ11 Insertable Cardiac Monitor and Patient Assistant

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.
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 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 this device to sale by or on the order of a physician.

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BRIEF STATEMENT (CONTINUED)

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

The Medtronic MyCareLink Patient Monitor and the Medtronic CareLink Network are indicated for use in the transfer of patient data from Medtronic implantable cardiac devices. These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability and alert notifications are subject to Internet connectivity and access, and service availability. The MyCareLink Patient Monitor must be on and in range of the device. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

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.

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