

CRYPTOGENIC STROKE CASE STUDIES

Reveal LINQ™

Insertable Cardiac Monitoring System



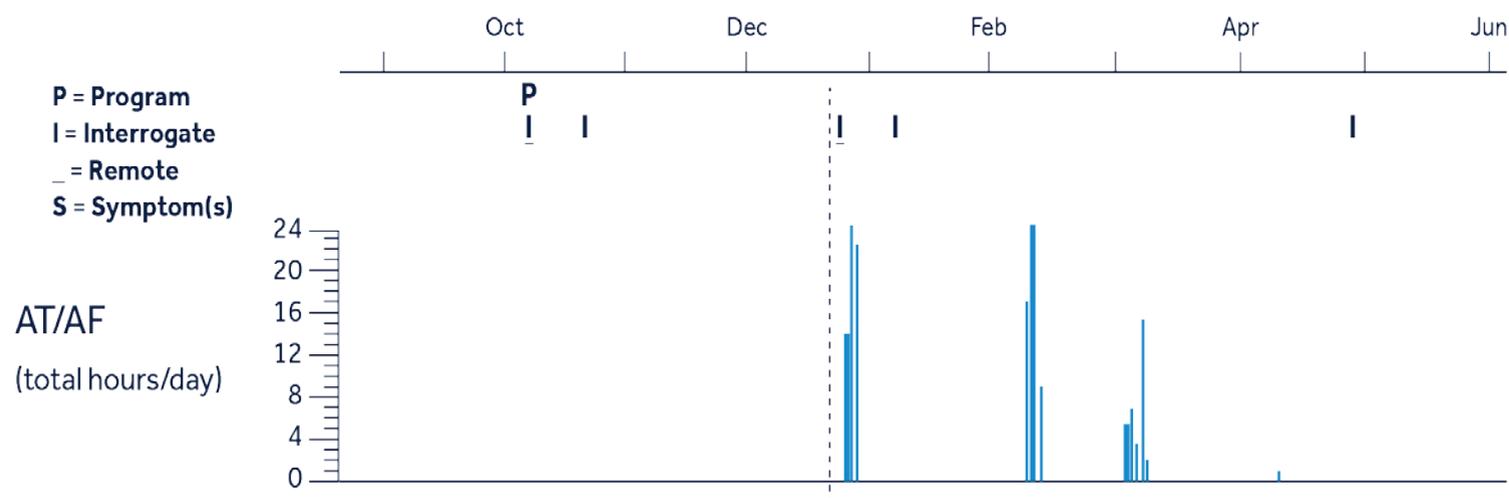
Medtronic
Further, Together

DISCLAIMER

This Cryptogenic Stroke Case Studies document is provided for general educational purposes only and should not be considered the exclusive source for this type of information. Patient information (names, serial numbers, date, etc.) has been changed or removed to protect the privacy of the patients used in this Cryptogenic Stroke Case Studies document . At all times, it is the professional responsibility of the practitioner to exercise independent clinical judgment in a particular situation. Changes in a patient's disease and/or medications may alter the efficacy of a device's programmed parameters or related features.

CRYPTOGENIC STROKE PATIENT CASE STUDY

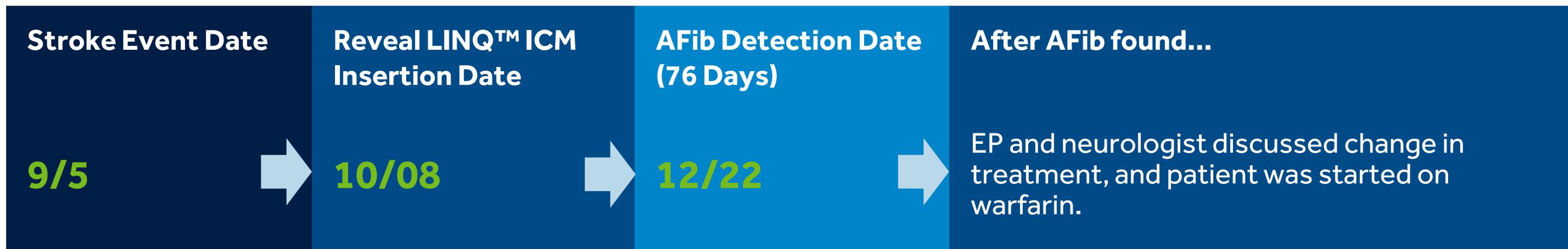
SNAPSHOT: AFIB BURDEN



BACKGROUND

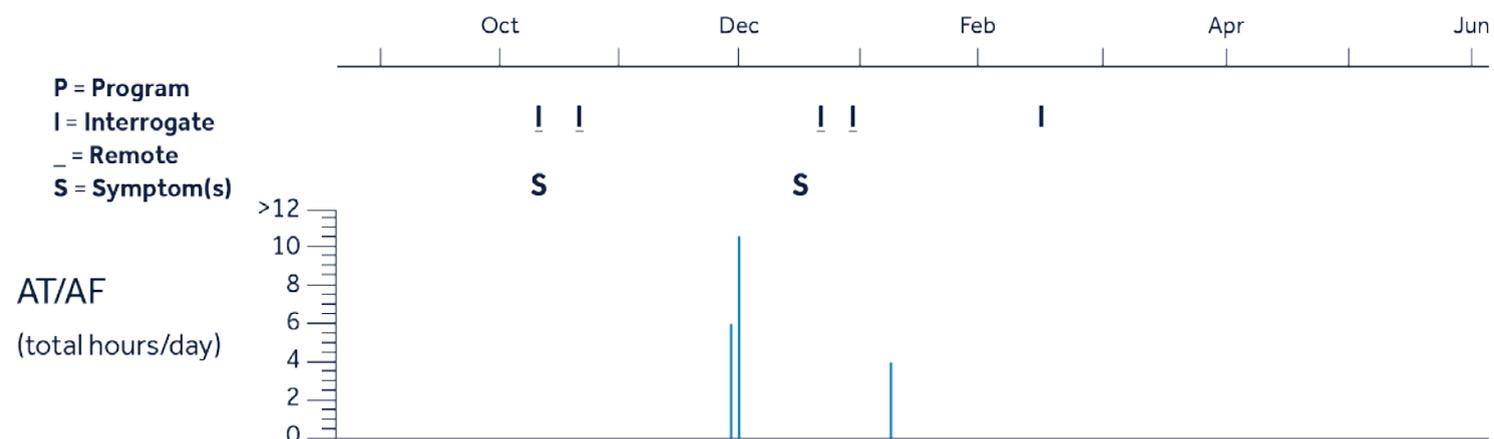
- A 64-year-old patient with first stroke
- Full work up (including TEE) – negative
- Neurologists deemed Cryptogenic
- 30-day monitor/aspirin prescribed
 - No AFib detected
- EP recommended Reveal LINQ™ ICM
- Reveal LINQ™ ICM placed 30 days later
- **76 days later**, AFib detected and patient's treatment changed from aspirin to warfarin.

TIMELINE



CRYPTOGENIC STROKE PATIENT CASE STUDY

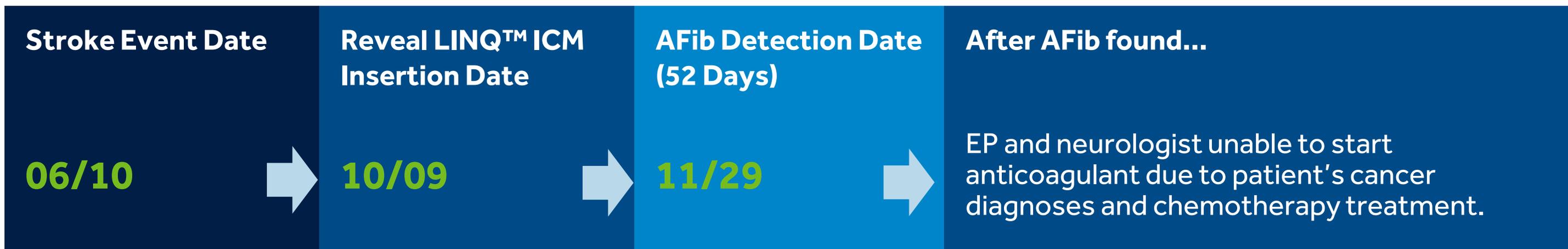
SNAPSHOT: AFIB BURDEN



BACKGROUND

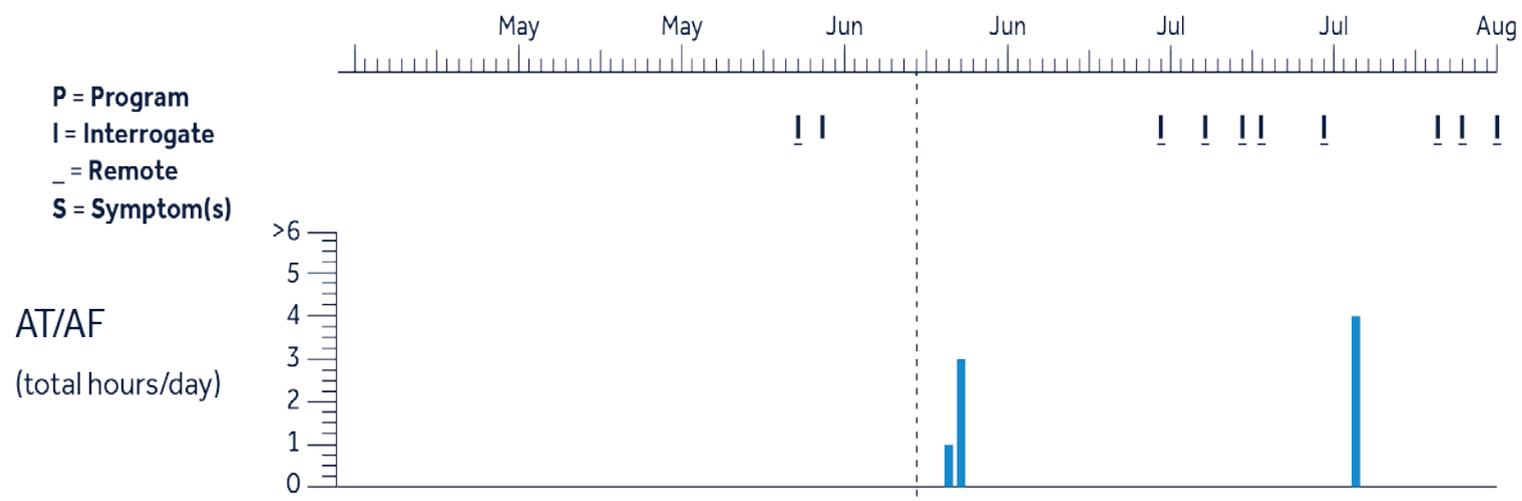
- A 58-year-old patient with stroke
- Full work up – negative
- Neurologists deemed Cryptogenic
- 30- day monitor/antiplatelet prescribed
 - No AFib detected, no further tests
- Two months later, Neurologist referred to EP for Reveal LINQ™ ICM
- Reveal LINQ™ ICM placed by EP
- **52 days later** – AFib detected
 - Patient diagnosed with cancer and needed chemotherapy; anticoagulant not recommended

TIMELINE



CRYPTOGENIC STROKE PATIENT CASE STUDY

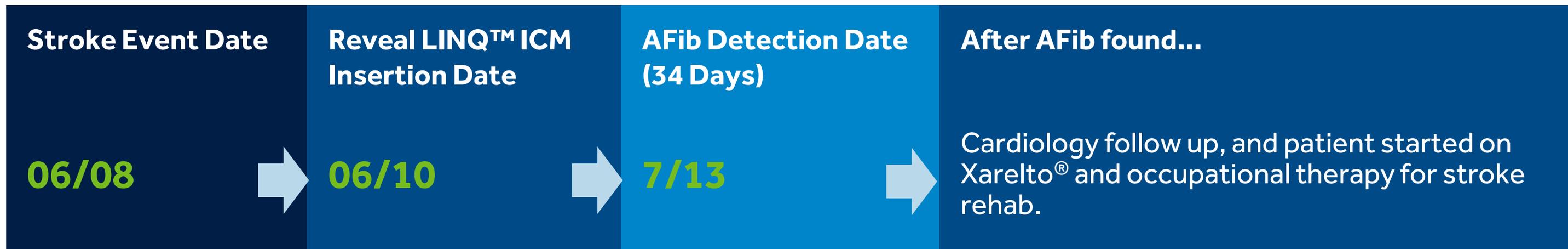
SNAPSHOT: AFIB BURDEN



BACKGROUND

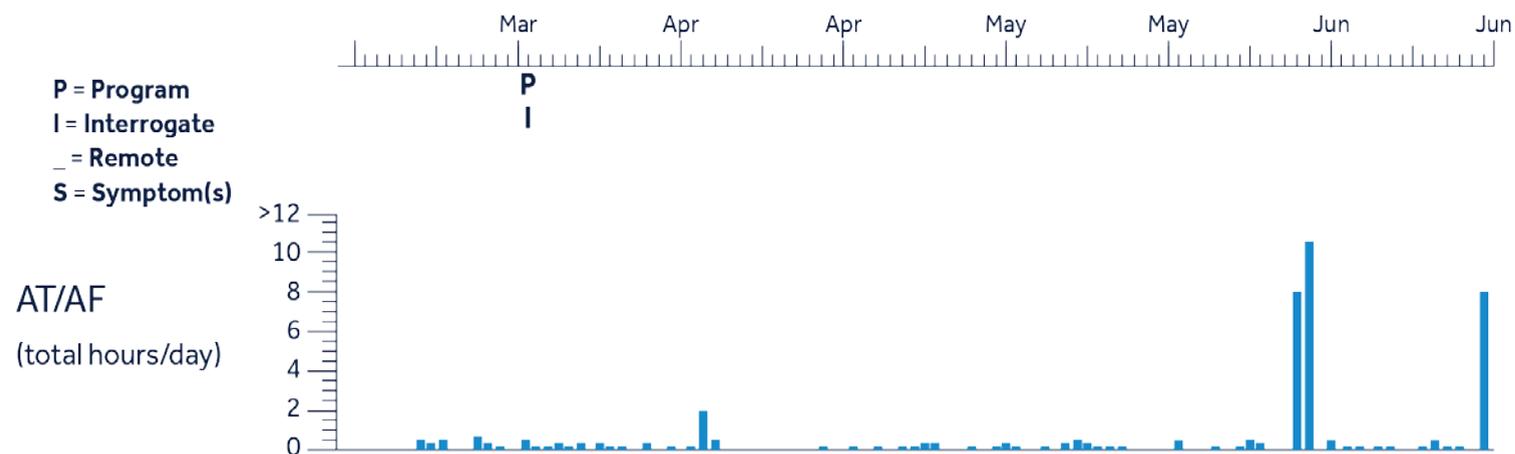
- A 58-year-old male presented with code stroke outside window for tPA (Alteplase)
- Admitted 6/8 with Cryptogenic Stroke/RM2 branch occlusion
- Reveal LINQ™ ICM placed 6/10
- Readmitted 6/12 with stroke extension
 - ICM interrogation w/o arrhythmia
- **34 days later** – AFib detected via remote transmission
- Cardiology follow up
 - Ventricular rates elevated but relatively controlled
 - CHADS₂ VASC 3+
 - Discontinued Plavix® and aspirin
 - Started Xarelto® 20 mg

TIMELINE



CRYPTOGENIC STROKE PATIENT CASE STUDY

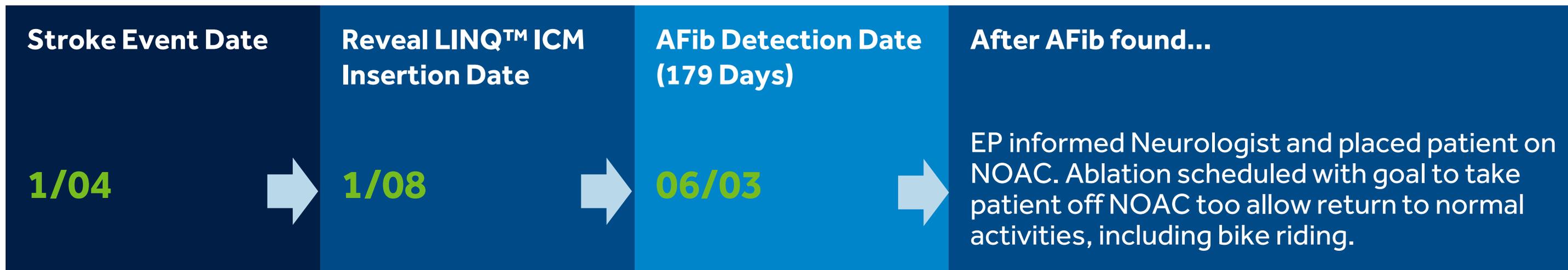
SNAPSHOT: AFIB BURDEN



BACKGROUND

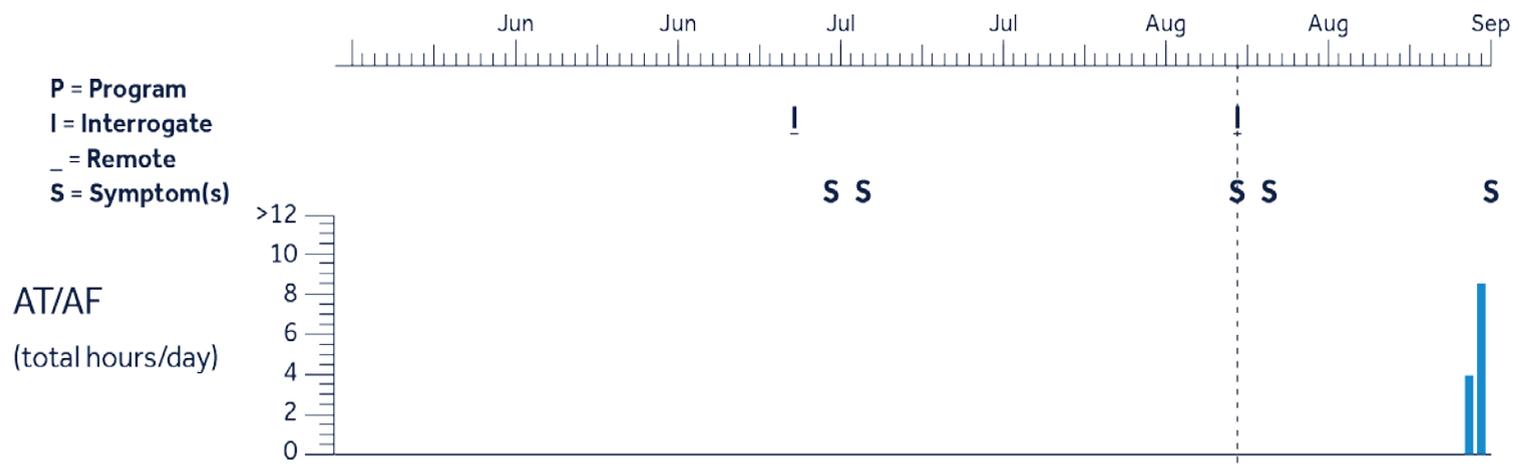
- A 63-year-old patient with CHADs 0 had a stroke
- Full work up (including CT w/o contrast, MRI, MRA & carotid duplex scan) – negative
- Neurologists deemed Cryptogenic
- Neurologist consulted Cardiology for TEE
 - TEE – negative
- Reveal LINQ™ ICM placed by EP
- **179 days later** – AFib detected
- Ablation scheduled with goal to take patient off NOAC to allow return to active life
- Note: Patient has baseline ECG with frequent PACs (PACs triggered AFib episode 4 months post-stroke)

TIMELINE



CRYPTOGENIC STROKE PATIENT CASE STUDY

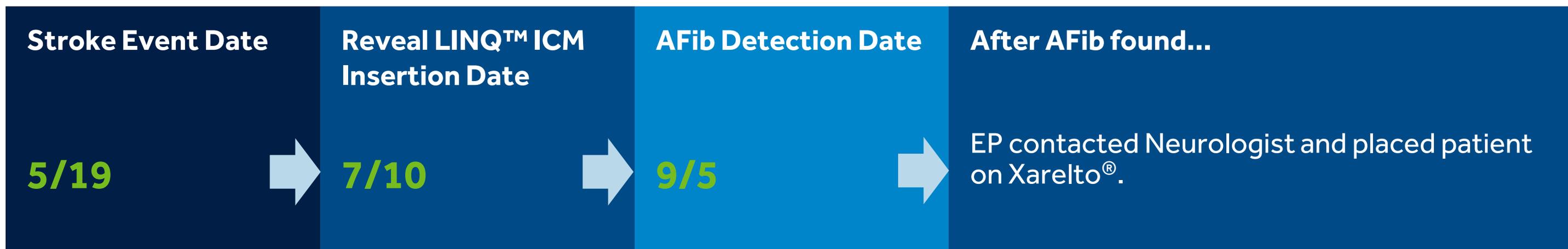
SNAPSHOT: AFIB BURDEN



BACKGROUND

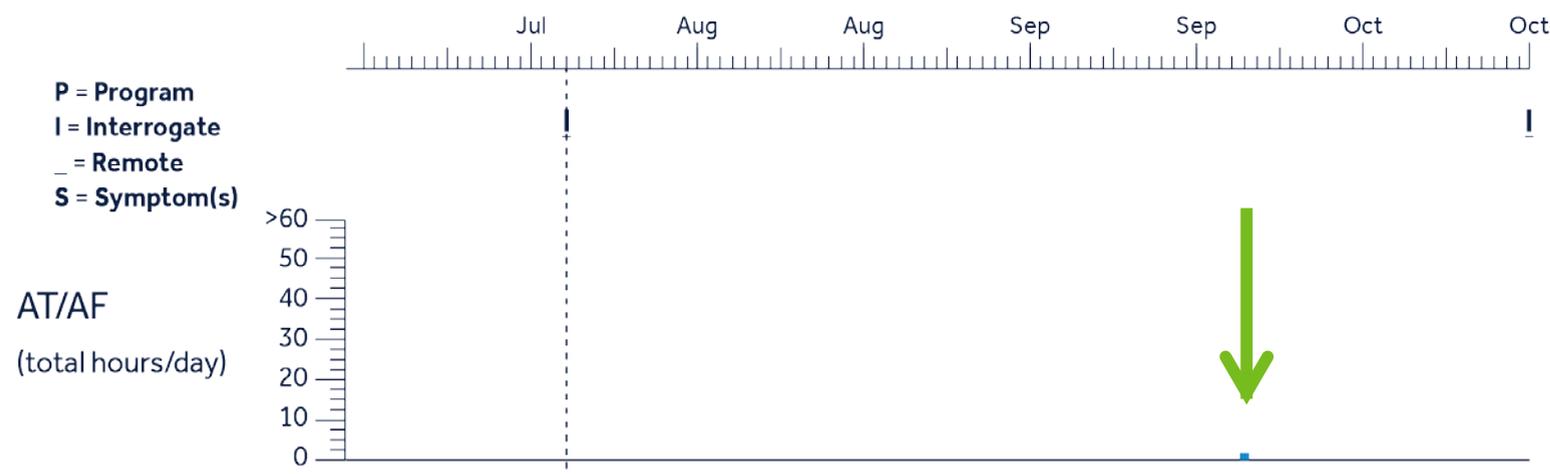
- A 74-year-old female with stroke 5/19
- Full work up (including echocardiogram and carotid doppler) – negative
- Neurologists deemed Cryptogenic
- Patient followed up with Neurologist 6/25
- Neurologist referred to EP for Reveal LINQ™ ICM
- Patient seen by EP 6/29
- Reveal LINQ™ ICM placed by EP 7/10
- **58 days later** – AFib detected
- Patient placed on Xarelto®

TIMELINE



CRYPTOGENIC STROKE PATIENT CASE STUDY

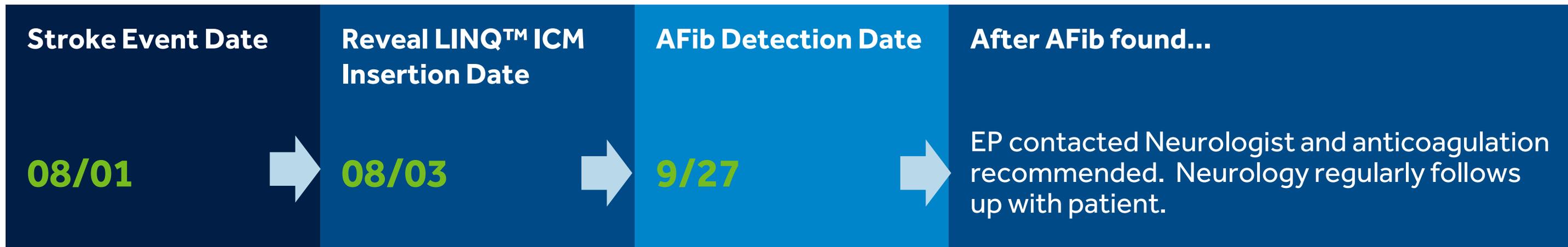
SNAPSHOT: AFIB BURDEN



BACKGROUND

- A 57-year-old patient with multiple chronic and acute strokes (confirmed by MRI)
- Full work up (including TEE) – negative
- Neurologist consulted Cardiology for TEE
 - TEE – negative
- Neurologists deemed Cryptogenic
- Reveal LINQ™ ICM placed by EP
- **56 days later** – AFib detected
- Anticoagulation recommended

TIMELINE



INDICATIONS, SAFETY, AND WARNINGS

If you are located in the United States, please refer to the brief statement(s) on the following pages to review applicable indications, safety and warning information. 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 1.763.514.4000 and/or consult the Medtronic website at www.medtronic.com.

If you are located outside the United States, see the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com.

Important Reminder: This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.



www.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.

INDICATIONS, SAFETY, AND WARNINGS (CONT.)

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.

INDICATIONS, SAFETY, AND WARNINGS (CONT.)

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.

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

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and medical professionals)

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