

SYNCOPE CASE STUDIES

Reveal LINQ™
Insertable Cardiac Monitoring System



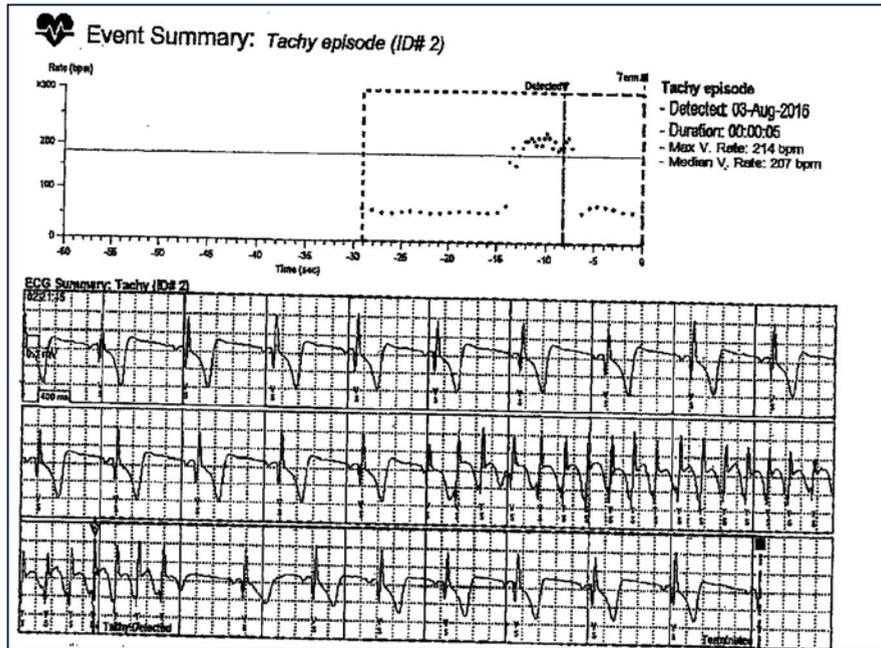
Medtronic
Further, Together

DISCLAIMER

This Syncope 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. 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.

SYNCOPE PATIENT CASE STUDY

SNAPSHOT: NS-SVT EVENT



BACKGROUND

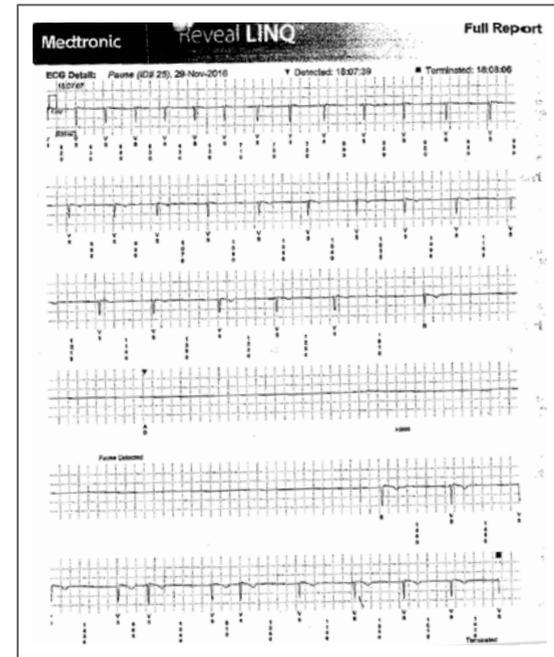
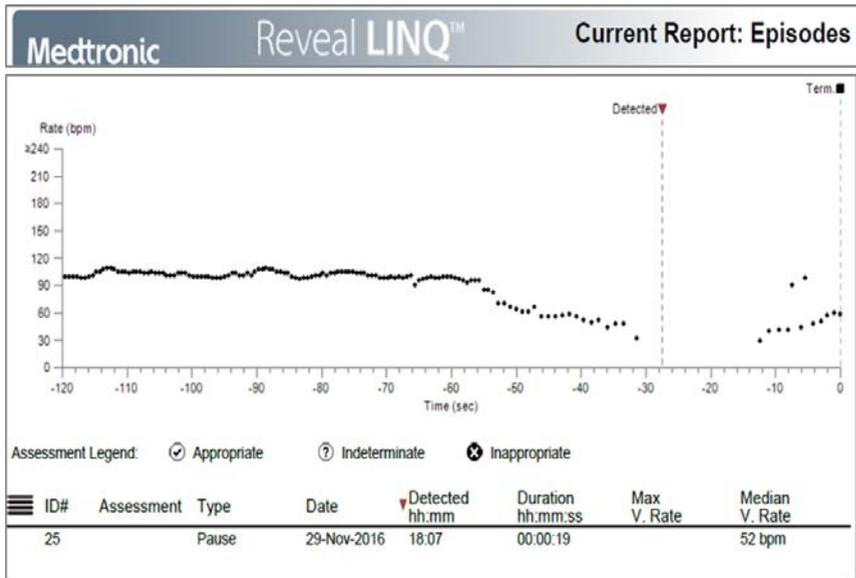
- A 53-year-old patient with dramatic syncopal event including facial trauma
- Full work up – negative
- EP recommended Reveal LINQ™ ICM
- Reveal LINQ ICM placed weeks later
- **Five months later**, nonsustained SVT event (240ms cycle length) detected while the patient slept
- EP study detected atrioventricular nodal reentrant tachycardia (AVNRT)
- Patient was treated with AVNRT ablation

TIMELINE



SYNCOPE PATIENT CASE STUDY

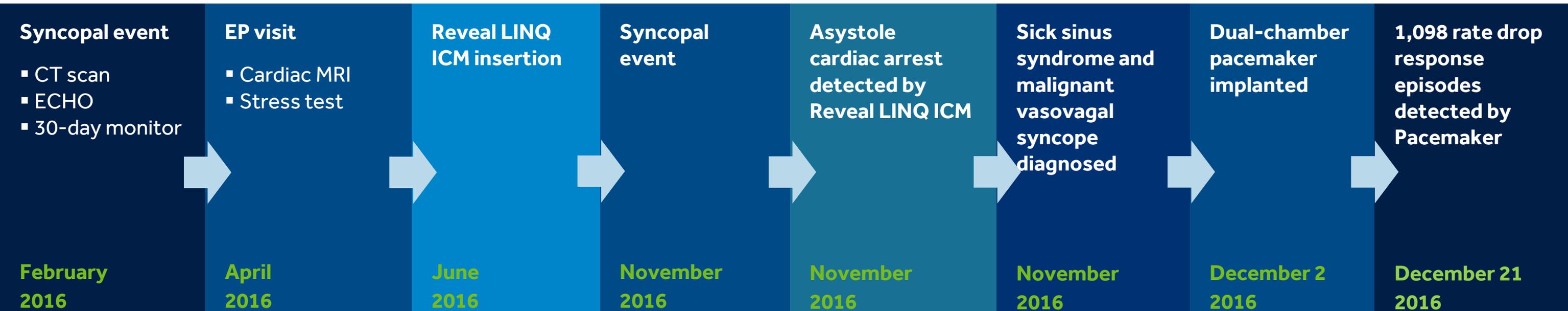
SNAPSHOT: SICK SINUS SYNDROME



BACKGROUND

- A 34-year-old female
- Full work up – negative
- EP recommended Reveal LINQ™ ICM
- **Five months later**, an asystole cardiac arrest with a 19-second sinus pause was detected.
- The patient's heart restarted without intervention.
- Patient was diagnosed with malignant vasovagal syncope.
- A Medtronic dual-chamber pacemaker was placed.
- 19 days later, the pacemaker interrogation revealed 1,098 rate drop response episodes.

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.

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Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Tel: (763) 514-4000
Fax: (763) 514-4879

medtronic.com

Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians
and medical professionals)

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