SYNCOPE THERAPY AWARENESS PRESENTATION
## THE SYNCOPE CHALLENGE

<table>
<thead>
<tr>
<th>Magnitude</th>
<th>Syncope accounts for 740,000 ER visits per year, accounting for 237,000 hospitalizations*¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient Challenge</td>
<td>Approximately half of patients admitted to hospital leave without a diagnosis.²</td>
</tr>
<tr>
<td>Patient’s Frustration</td>
<td>In reaching a diagnosis patients see 3 different specialists, undergo 13 tests, and 1/3 have significant associated trauma.³</td>
</tr>
<tr>
<td>Cardiac Causes</td>
<td>Cardiac syncope is common, doubles the risk of death, and is associated with a 6-month mortality rate greater than 10%.⁴</td>
</tr>
</tbody>
</table>


*Data obtained from National Hospital Ambulatory Medical Care Survey between 1992 to 2000.*
UNEXPLAINED SYNCOPE + CARDIAC SYNCOPE
OVER 50% OF PATIENTS

Syncope remains unexplained in approximately 1/3 of cases

Neurally Mediated
vasovagal, carotid sinus, situational
24%

Cardiac
abnormal rhythms, structural damage
18%

Unknown
34%

Orthostatic/Drug-induced
ANS failure, medication
11%

Neurologic
Seizure, stroke, TIA etc
10%

Cardiac syncope:
- Carries a 6-month mortality rate of greater than 10%
- Doubles the risk of death

Overall Survival of Participants with Syncope According to Cause

EVIDENCE LEVEL DEFINITIONS – NEW DESCRIPTORS

CLASS (STRENGTH) OF RECOMMENDATION

CLASS I (STRONG)  
Benefit >> Risk

Suggested phrases for writing recommendations:
- Is recommended
- Is indicated/useful/effective/beneficial
- Should be performed/administered/other
- Comparative-Effectiveness Phrases‡:
  - Treatment/strategy A is recommended/indicated in preference to treatment B
  - Treatment A should be chosen over treatment B

CLASS IIa (MODERATE)  
Benefit >> Risk

Suggested phrases for writing recommendations:
- Is reasonable
- Can be useful/effective/beneficial
- Comparative-Effectiveness Phrases‡:
  - Treatment/strategy A is probably recommended/indicated in preference to treatment B
  - It is reasonable to choose treatment A over treatment B

CLASS IIb (WEAK)  
Benefit ≥ Risk

Suggested phrases for writing recommendations:
- May/might be reasonable
- May/might be considered
- Usefulness/effectiveness is unknown/unclear/uncertain or not well established

CLASS III: No Benefit (MODERATE)  
(Cautiously, USE A or B only)

Benefit = Risk

Suggested phrases for writing recommendations:
- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

CLASS III: Harm (STRONG)  
Risk > Benefit

Suggested phrases for writing recommendations:
- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

LEVEL (QUALITY) OF EVIDENCE‡

LEVEL A

- High-quality evidence‡ from more than 1 RCT
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

LEVEL B-R

- Moderate-quality evidence‡ from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

LEVEL B-NR

- Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

LEVEL C-LD

- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

LEVEL C-EO

Consensus of expert opinion based on clinical experience

Note: types of clinical data qualify level of evidence
- i.e. “randomized”/”non randomized”

**SYNCOPE INITIAL EVALUATION**

- **Transient loss of consciousness***
  - **Suspected syncope**
    - **NO**
      - **Evaluation as clinically indicated**
    - **YES**
      - **Initial evaluation: history, physical examination and ECG (Class I)**
        - **Cause of syncope certain**
          - **Treatment**
        - **Risk assessment**
        - **Cause of syncope uncertain**
          - **Further evaluation**

CHARACTERISTICS IDENTIFYING PATIENTS MOST LIKELY TO BE ASSOCIATED WITH A CARDIAC CAUSE

Older age (>60yr)
- Male Sex
- Presence of ischemic heart disease, structural heart disease, previous arrhythmias, or reduced ventricular function
- Brief (palpitations) or no symptoms prior to loss of consciousness
- Occurs with exertion
- Occurs in supine position
- Low number of events (1 or 2)
- Abnormal cardiac examination
- Family history of inheritable conditions or premature SCD (<50 yr of age)
- Presence of known congenital heart disease

Historical Characteristics Associated with Increased Probability of Cardiac Causes of Syncope

<table>
<thead>
<tr>
<th>Class</th>
<th>LOE</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>B-NR</td>
<td>Evaluation of the cause and assessment for the short- and long-term morbidity and mortality risk of Syncope are recommended</td>
</tr>
</tbody>
</table>

## CHARACTERIZING RISK SCORE OF SYNCOPAL PATIENTS

<table>
<thead>
<tr>
<th>Class</th>
<th>LOE</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>B-NR</td>
<td>Evaluation of the cause and assessment for the short- and long-term morbidity and mortality risk of syncope are recommended</td>
</tr>
</tbody>
</table>

### Short-term (<30 d) risk factors

- Older age (>60yr)
- Male Sex
- Palpitations or no symptoms prior to loss of consciousness
- Occurs with exertion
- Structural heart disease
- Heart failure
- Cerebrovascular disease
- Family history of SCD
- Trauma
- Bleeding evidence
- Persistent abnormal vitals/ECG
- Positive troponin

### Long-term (>30d) risk factors

- Older age (>60yr)
- Male Sex
- Absence of nausea/vomiting before syncope
- Ventricular arrhythmias detected
- Cancer
- Structural heart disease
- Heart failure
- Cerebrovascular disease
- Diabetes mellitus
- High CHADS2 score
- Abnormal ECG
- Low GFR (kidney function)

| IIb   | B-NR | Use of risk stratification scores may be reasonable in the management of patients with syncope |

### High-risk patients should be considered for cardiac monitoring early in evaluation

After initial evaluation and if cardiac cause is suspected, cardiac monitoring should be performed – Class I Recommendation

- ICMs should be placed in all patients with infrequent symptoms.
### CARDIAC MONITORING RECOMMENDATIONS

<table>
<thead>
<tr>
<th>Class</th>
<th>LOE</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>C-EO</td>
<td>The choice of a specific cardiac monitor should be determined on the basis of the <strong>frequency</strong> and <strong>nature</strong> of syncope events.</td>
</tr>
<tr>
<td>IIa</td>
<td>B-R</td>
<td>To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an ICM can be useful</td>
</tr>
</tbody>
</table>
| IIa   | B-NR  | To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, the following external cardiac monitoring approaches can be useful:  
|       |       | 1. Holter monitor  
|       |       | 2. Transtelephonic monitor  
|       |       | 3. External loop recorder  
|       |       | 4. Patch recorder  
|       |       | 5. Mobile cardiac outpatient telemetry                                                  |

- Cardiac monitoring is necessary
- Patient selection is based on **frequency** of symptoms, **likelihood of arrhythmic cause** and **patient characteristics**
- Randomized clinical trials demonstrate the value of ICM monitoring in syncope patients

## MONITORING SELECTION CRITERIA
### THE RIGHT DEVICE FOR THE RIGHT PATIENT

<table>
<thead>
<tr>
<th>Duration</th>
<th>24 – 48 hrs</th>
<th>2-14 days</th>
<th>Up to 1 month</th>
<th>≤3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Selection</td>
<td>Daily symptoms</td>
<td>Weekly symptoms</td>
<td>Monthly symptoms (some up to 6 wks)</td>
<td>Monthly symptoms</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Holter Monitors</th>
<th>Extended Holters</th>
<th>External Loop Recorders</th>
<th>Mobile Cardiac Telemetry</th>
<th>Insertable Cardiac Monitors</th>
</tr>
</thead>
</table>

Diagnostic choice should be based on frequency of symptoms and nature of syncope events.

Class I ICM Guidelines

- Indicated in early phase of evaluation in patients with recurrent syncope of uncertain origin, absence of high risk criteria, and a high likelihood of recurrence within battery longevity of the device.

- Indicated in high risk individuals in whom comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment.

### Frequency of Syncope

<table>
<thead>
<tr>
<th>Frequency of Syncope</th>
<th>Suggested ECG Monitoring Technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Several times a week</td>
<td>24-48h Holter monitoring</td>
</tr>
<tr>
<td>Every 1-2 weeks</td>
<td>External loop recorder</td>
</tr>
<tr>
<td>Less than once per month</td>
<td>Implantable loop recorder</td>
</tr>
</tbody>
</table>

SYNCOPE GUIDELINES: ARE THEY FOLLOWED?
SIGNIFICANT PROPORTION OF HCPs STATE THEY WOULD USE MONITORING INCONSISTENT WITH GUIDELINES

Type of monitor recommended based on the frequency of syncope episodes

Based on syncope guidelines, more ICMs should be used for the infrequent episodes

ICMs are underutilized

ICMs are recommended by clinical guidelines\(^1,2\) — yet significantly underutilized

Up to 3 in 4 Patients who met appropriate criteria for ICM implantation did not receive one\(^3\)

Patients endure ongoing diagnostic testing and still come away with no answers.

3 specialists visited on average

13 Inconclusive tests

1 in 4 Undergo more than 20 tests

PATIENT EXPERIENCE

- 70% of patients had been hospitalized at least once for syncope.
- 36% of patients had experienced significant trauma in association with a syncopal episode.
- Overall, patients had seen an average of 3 different specialists for their syncope.

The median number of tests performed per patient was 13 (inter-quartile range 9 - 20)

<table>
<thead>
<tr>
<th>Test</th>
<th>Total Recruitment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard ECG</td>
<td>556 (98%)</td>
</tr>
<tr>
<td>Echocardiography</td>
<td>490 (86%)</td>
</tr>
<tr>
<td>Basic laboratory tests</td>
<td>488 (86%)</td>
</tr>
<tr>
<td>Ambulatory ECG monitoring</td>
<td>382 (67%)</td>
</tr>
<tr>
<td>In-hospital ECG monitoring</td>
<td>311 (55%)</td>
</tr>
<tr>
<td>Exercise testing</td>
<td>297 (52%)</td>
</tr>
<tr>
<td>Orthostatic blood pressure measurements</td>
<td>275 (48%)</td>
</tr>
<tr>
<td>MRI/CT scan</td>
<td>267 (47%)</td>
</tr>
<tr>
<td>Neurological or psychiatric evaluation</td>
<td>270 (47%)</td>
</tr>
<tr>
<td>EEG</td>
<td>222 (39%)</td>
</tr>
<tr>
<td>Carotid sinus massage</td>
<td>205 (36%)</td>
</tr>
<tr>
<td>Tilt test</td>
<td>201 (35%)</td>
</tr>
<tr>
<td>Electrophysiology testing</td>
<td>144 (25%)</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>133 (23%)</td>
</tr>
<tr>
<td>External loop recording</td>
<td>67 (12%)</td>
</tr>
<tr>
<td>ATP test</td>
<td>15 (3%)</td>
</tr>
<tr>
<td>Other Tests</td>
<td>52 (9%)</td>
</tr>
<tr>
<td>No tests performed</td>
<td>1 (0%)</td>
</tr>
</tbody>
</table>

## SYNCOPE DIAGNOSIS
### TESTING OPTIONS & YIELD

<table>
<thead>
<tr>
<th>Test / Procedure</th>
<th>Yield*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG</td>
<td>2-11%¹</td>
</tr>
<tr>
<td>Holter Monitoring</td>
<td>2%²</td>
</tr>
<tr>
<td>External Loop Recorder</td>
<td>20%³</td>
</tr>
<tr>
<td>Tilt Table</td>
<td>11%+⁴,⁵</td>
</tr>
<tr>
<td>EP Study without structural heart disease</td>
<td>11%⁶</td>
</tr>
<tr>
<td>Neurological (CT scan, carotid doppler)</td>
<td>0-4%⁵</td>
</tr>
<tr>
<td>Reveal ICM</td>
<td>78%⁷</td>
</tr>
</tbody>
</table>

*Based on mean diagnosis time of 5.1 mos.²

ICM SUCCESS IN DIAGNOSING PATIENTS WITH SYNCOPE

PICTURE STUDY
570 Patients

Study Design
- Investigated the effectiveness of Reveal™ ICM in the diagnosis of unexplained recurrent syncope in everyday clinical practice
- Helped inform current guidelines

Conclusion
A Reveal ICM should be implanted rather than later in the evaluation of unexplained syncope

Flowchart adapted from:

ICMs ARE A COST-EFFECTIVE DIAGNOSTIC TOOL
REDUCE COST WITH EARLIER UTILIZATION

Multiple studies show ICM monitoring resulted in cost savings in syncope patients compared to conventional testing through fewer tests and hospital admissions.¹⁻⁴

88%

of patients who are guideline eligible for an ICM/ILR are over-tested with other modalities before being offered an ICM/ILR.⁵

↑$

Over-testing increases cost with no improvement to diagnostic yield.⁵

OPPORTUNITIES TO REDUCE COSTS WITHOUT COMPROMISING DIAGNOSTIC YIELD⁶:

- Appropriate use of guideline-recommended tests in the initial evaluation of syncope
- Decreased repetition of inconclusive test
- Avoidance of early use of specialized tests usually performed only on specific suspicions about the underlying mechanism (e.g., MRI/CT and EEG)
- Utilize ICM earlier in the care pathway

ECONOMIC VALUE
REVEAL LINQ ICM AND THE CARE CONTINUUM

Long-term benefits of Reveal LINQ™ ICM
Accurate diagnosis and defined care continuum

PATIENT CARE CONTINUUM

NO ICM IMPLANTED
× Care continuum is variable or unknown
× Further diagnostic testing, with mixed results
× Increased costs and inefficient use of resources
× Potential loss of patient to follow-up
× A “revolving door” experience for patients

ICM IMPLANTED
✓ Accurate diagnosis of cardiac arrhythmia
✓ Timely and informed treatment decisions
✓ Long-term patient care
✓ Broad benefits from remote monitoring with MyCareLink™ Patient Monitor
✓ Identify indicated patients with treatment needs

VS.
EXPERIENCE THE REVEAL LINQ™ ADVANTAGE

REVEAL LINQ™ INSERTABLE CARDIAC MONITOR AN OVERVIEW
Indications for use

The Reveal LINQ™ insertable cardiac monitor (ICM) 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

The device has not been tested specifically for pediatric use.
REVEAL LINQ™ SYSTEM ADVANTAGES
AN ADVANCED MONITORING SOLUTION

Solution Enablers

Insertion Tools
Patient Assistant
NEW App-based Reveal LINQ Mobile Manager
NEW Monitoring Service Solutions

Reveal LINQ ICM
Wireless
MyCareLink™ Patient Monitor
Cellular
CareLink™ Network & Reports
The smallest, most powerful insertable cardiac monitor

One-third the size of a AAA battery (1.2 cc)

Up to a 3-year longevity for long-term monitoring\(^1\)

MR Conditional at 1.5 and 3.0 Tesla

Minimally invasive, simplified insertion procedure\(^2\)

96.7% of patients very satisfied or satisfied with Reveal LINQ ICM after insertion\(^3\)

---

\(^1\) Reference the Reveal LINQ ICM Clinician Manual for usage parameters.
REVEAL LINQ™ SYSTEM ADVANTAGES
SIMPLE INSERTION PROCEDURE

Best location:
45 degrees to sternum over 4th intercostal space, 2 cm from left edge of sternum

97%
Of physicians found the insertion tool simple and intuitive.¹

Requires minimal procedure time and clinical resources

REVEAL LINQ™ SYSTEM ADVANTAGES
TRANSFORMING CARDIAC MONITORING

Transforming your ability to diagnose and treat even the most difficult-to-detect arrhythmias

Evidence superiority.\(^1\)\(^-\)\(^5\)
Real-world impact.\(^1\),\(^6\),\(^7\)

Proven arrhythmia detection.\(^1\),\(^8\),\(^9\)
Informed clinical decisions.

Innovative solutions.
Simplified experience.

---

**CLINICAL RIGOR**
**EVIDENCE SUPERIORITY.**
**REAL-WORLD IMPACT.**

<table>
<thead>
<tr>
<th>Most Studied ICM</th>
<th>With an evidence portfolio of 500+ published clinical articles and abstracts¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most Clinically Validated ICM</td>
<td>Across Cryptogenic Stroke, Syncope, and Atrial Fibrillation patient populations²-⁴</td>
</tr>
<tr>
<td>Only ICM with Premier Clinical Evidence</td>
<td>Published in multiple premier journals, including <em>Heart Rhythm</em>, <em>The New England Journal of Medicine</em>, and <em>JACC⁵</em></td>
</tr>
</tbody>
</table>

TRURHYTHM™ DETECTION INSIDE ACCURACY EVOLUTION

Reveal™ XT
With FullView™ Software

AF Industry’s first AF detection algorithm

NEW Pause algorithm with diminishing R-wave analysis

NEW AF algorithm and improved noise discrimination

AF NEW AF algorithm with increased accuracy

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SMART FILTERING

**NEW** second sensing filter analyzes rhythms for possible undersensing in Brady and Pause

SELF-LEARNING

Exclusive fifth-generation atrial fibrillation algorithm learns and adapts to patient’s rhythm over time
**ADVANCED MONITORING**

**INNOVATIVE SOLUTIONS. SIMPLIFIED EXPERIENCE.**

**STREAMLINED INSERTION WORK FLOW**

Simple, minimally invasive outpatient insertion procedure

New app-based device management with the Reveal LINQ™ Mobile Manager

**ACTIONABLE REPORTS**

- Supported by an enhanced Medtronic CareLink™ network
- Industry’s highest diagnostic yields, with actionable reports\(^1\)\(^-\)\(^4\)

**SIMPLIFIED PATIENT MANAGEMENT**

Resources to support clinic efficiency and data review

- **New Medtronic Academy Learning Plan**
- **New Patient Education Resources**
- **New Reveal LINQ\(^\text{SM}\) Monitoring Service**

---

Clinical impact of Reveal™ ICM in syncope patients

Accurately Diagnose

13
Median number of inconclusive tests before ICM was implanted¹

78%
Patients that receive a diagnosis following a syncopal event with Reveal™ ICM¹

75% of Reveal-guided diagnoses were found to be cardiac related¹

Effectively Treat

25% Reveal ICM patients that receive device therapy within 36 months²

William’s story
Reveal LINQ™ ICM used to discover non-sustained SVT event

William remembered his fainting spells seemed to come out of nowhere. The first time it happened was just after he stood up to get a second cup of coffee. He was unconscious for 30 seconds while his parents and wife feared he was dead. Another time, he was having dinner while on a cruise ship when, without warning, his head fell forward and he lost consciousness.

William experienced an ambulance trip, multiple visits to the hospital and appointments with various physician specialties. Multiple tests showed nothing.

Years went by without incident until he was on another family vacation—this time to Paris. As he walked along a cobblestone street with his family, William collapsed.

“My face slammed into a cobblestone curb and knocked out my four front teeth. I had a cut under my chin, my mouth was gushing blood, I had a gash over my right eye, and I’d fractured my upper mandible on the left- side of my jaw. I also had hairline fractures of the orbital bones under my eyes.”

William returned to the U.S. for reparative surgery, and to meet with an Electrophysiologist who recommended the Reveal LINQ™ ICM. The device was inserted in February, 2016 and the following August, Dr. Sanchez called William to tell him that an episode was detected. The data showed that, while William slept, he experienced a non-sustained SVT event: 20 heartbeats in a 5-seconds span.

Today, following a successful ablation procedure, William is back to enjoying life. He works out multiple times a week and enjoys traveling with his family, playing basketball, tennis and golf.
**ADVANCED MONITORING**

**SYNCOPE PATIENT IMPACT**

**Kymberli’s story**

**Reveal LINQ™ ICM used to discover malignant vasovagal syncope**

On a February morning in 2015, Kymberli, the busy mother of four young children prepared for her triplets’ first birthday party. Suddenly, she felt queasy, confused and clammy. She passed out before she could say anything.

Kymberli was taken by ambulance to the emergency room. After a CT scan and a 2D echo, she was discharged and sent to a cardiologist. She was given a 30-day event monitor that showed nothing of concern related to her heart. The doctors thought it was possible that stress, dehydration or lack of sleep had triggered the event.

Kymberli wasn’t convinced. She made an appointment with an electrophysiologist specializing in the diagnosis and treatment of abnormal heart rhythms. He ordered a cardiac MRI and a stress test, both of which came back normal. Aside from a low heart rate and hypotension she’d had her entire life, Kymberli appeared healthy.

Her doctor recommended Reveal LINQ™ ICM. The device was inserted in June, 2015 and the following November Kymberli blacked out while home alone with the children. The data from Kymberli’s device was transmitted to her doctor’s office. Just minutes after receiving it, they contacted Kymberli and told her to call 911. The data showed Kymberli’s heart had stopped for 19 seconds.

Kymberli was diagnosed with malignant vasovagal syncope and sick sinus syndrome. A pacemaker was implanted to regulate Kymberli’s heart.

“The Reveal LINQ is the reason I’m here today,” says Kymberli. “Without it, my doctor wouldn’t have detected my heart’s 19 second pause. With that information, he could diagnose the malignant form of vasovagal syncope and prevent syncope with a pacemaker. Now I have comfort in knowing I’m OK and that my heart will keep beating.”

This story reflects one person’s experience. Not every person will receive the same results.
Debbie’s story
Reveal™ ICM used to discover a rare form of AT

After Debbie fainted the first time, she didn't think much about it. As a cardiac nurse, she knew there were many reasons people faint. But the fainting continued, and within a couple of months she was passing out three times a day. Her cardiologist decided to give Debbie a Medtronic Reveal insertable cardiac monitor (ICM).

Based on the information from the Reveal ICM, her doctors determined Debbie had a rare, aggressive form of atrial tachycardia (AT) that was very resistant to treatment. She tried new medications. Debbie’s doctors also relied on the Reveal ICM to monitor how her heart responds to the therapy.

With her fainting under better control, Debbie got back to practicing ballet.

She encourages people who experience fainting episodes to make a doctor appointment right away.

Photo shown is not actual patient. This story reflects one person’s experience. Not every person will receive the same results.
INDICATIONS, SAFETY, AND WARNINGS

If you are located in the United States, please refer to the brief statement below 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 763-514-4000 and/or consult the Medtronic website at 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 medtronic.com.

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.

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.

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.
INDICATIONS, SAFETY, AND WARNINGS

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.

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

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

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 implications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

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