References


4. ACC/AHA Class I Indications for Ambulatory ECG.


Brief Statement

Indications Model 9526 Reveal® Plus Insertable Loop Recorder is an implantable patient- and automatically actioned monitoring system that records subcutaneous ECG and is indicated for: • Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias • Patients who experience transient symptoms that may suggest a cardiac arrhythmia The Model 6191 Activator is intended for use in conjunction with a Medtronic Model 9526 Reveal Plus Insertable Loop Recorder. Contraindications There are no known contraindications for the implantation of the Reveal Plus ILR. However, the patient’s particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated. Warnings/Precautions Model 9526 Reveal Plus ILR is a recorder. Patients with the Reveal Plus ILR should avoid sources of magnetic resonance imaging, defibrillation, high sources of radiation, electromechanical couplings, external defibrillation, electrosurgery, and radiofrequency ablation to prevent electrical reset of the device, and/or inappropriate sensing. Model 9526 Activator Activation of the Model 6191 Activator may cause arrhythmias or symptoms due to inappropriate sensing or electrical reset. Model 6191 Activator 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, body tissue rejection phenomena, including local tissue reaction, infection, device migration and erosion of the device through the skin. Programming is performed using the Medtronic/Vitatron CareLink Programmer. Programmer is comprised of prescription devices indicated for use in the interrogation and programming of implantable medical devices. Prior to use, refer to the Programmer Reference Guide as well as the appropriate programmer software and implantable device technical manuals for more information related to specific implantable device models. Programming should be attempted only by appropriately trained personnel after careful study of the technical manual for the implantable device and after careful determination of appropriate parameter values based on the patient’s condition and pacing system used. The Medtronic/Vitatron CareLink Programmer must be used only for programming implantable devices manufactured by Medtronic or Vitatron. For the device manual for detailed information regarding the implant programming, indications, contraindications, warnings, precautions, and potential complications/ adverse events, see the device manual for each individual device. For further information, please call Medtronic at 1-800-248-3782 (for customer service) or Medtronic at 1-800-328-2518 (for technical support). To learn more about syncope, visit www.fainting.com. Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Get Information, Get Answers, and Uncover the Symptom-Rhythm Correlation

Reveal® Plus is the only long-term monitoring tool available to assist you in the diagnosis of patients at increased risk of cardiac arrhythmias.

Reveal Plus
• Records subcutaneous ECG for up to 14 months
• Provides high diagnostic yield (43-88%)1-3
  – Twice the diagnostic yield of conventional testing in patients with unexplained syncope3
• May help rule in and rule out cardiac arrhythmias
• May uncover both symptomatic and asymptomatic episodes
• Is designed to improve patient acceptance and compliance

Who Benefits from this Monitoring System?
Patients with clinical syndromes or situations at increased risk for arrhythmias, including patients with
• Unexplained syncope
• Near syncope
• Episodic, recurrent palpitations
• Drug-refractory epilepsy, seizure-like events and convulsions

CASE STUDY
Patient History
• 44-year-old male, construction superintendent
• No structural heart disease
• 5 episodes of syncope/near syncope over 7 months, episodes of dizziness
• Hospitalized twice; 2 car accidents with loss of driving privileges and work restrictions

Diagnostic Testing
2 Holter Monitor Tests → Both negative
Carotid Sinus Massage → Negative
2 Tilt Table Tests → 1 normal, 1 abnormal
Echo → Normal
Electrophysiological Study (EPS) → Negative

• A Reveal Plus ILR was implanted
• One month post-implant, the ILR automatically captured asystole (> 10 seconds)
• A pacemaker was implanted and symptoms resolved – the patient regained his independence

Summary
Carotid sinus syndrome was ruled out. Tilt-table testing results were mixed. In the absence of structural heart disease, an EPS did not aid syncope diagnosis. The ILR proved to be a useful tool to diagnose unexplained symptoms and select appropriate therapy.
Simple Implant, Simple Follow-Up

- Leadless
- Subcutaneous placement
- Short, minimally invasive outpatient procedure
- Requires only local anesthesia
- In-office device programming and data retrieval using the Medtronic programmer

Automatic Detection Options

- Bradycardia
- Tachycardia
- Asystolic pauses

Reveal Plus Activator

(available with carrying case)
More Information, Accurate Diagnoses

- 42 minutes of stored data
- Patient-activated mode
  - Captures ECG during symptoms
  - Stores information before, during, and after activation
- Automatic detection mode
  - Uses programmable rate limits
  - May reveal asymptomatic episodes
  - Provides a second opportunity to capture events in patients who have difficulty using external devices

Compare Diagnostic Yields

Some testing options are limited in their ability to capture infrequent events. Due to the complex diagnosis of syncope, it’s important to use the monitoring option that can provide clear information.

Diagnostic Yield in Unexplained Syncope Patients

<table>
<thead>
<tr>
<th>TEST/PROCEDURE</th>
<th>YIELD*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG</td>
<td>2-11%</td>
</tr>
<tr>
<td>Holter Monitoring</td>
<td>2%</td>
</tr>
<tr>
<td>External Loop Recorder</td>
<td>20%</td>
</tr>
<tr>
<td>Reveal® Plus ILR</td>
<td>43-88%</td>
</tr>
<tr>
<td>Tilt Table Test**</td>
<td>11-87%</td>
</tr>
<tr>
<td>EP Study** without SHD***</td>
<td>11%</td>
</tr>
<tr>
<td>EP Study** with SHD***</td>
<td>49%</td>
</tr>
<tr>
<td>Neurological Testing (CT scan, carotid doppler)</td>
<td>0-4%</td>
</tr>
</tbody>
</table>

* Based on mean diagnosis time of 5.1 mos.7
** Provocative test
*** SHD structural or organic heart disease