CLINIC CASE STUDY

Doylestown Cardiology Associates
Doylestown, PA

The Paceart Optima™ System:
Exceptional Follow-Up Productivity
from a Solo Clinic

Medtronic

OVERVIEW

Diane Czaplicki (at right) has been a Clinical Coordinator with Doylestown Cardiology Associates since November 2003. At that time, pacemaker and defibrillator follow-up was manually maintained, with patient records created and stored as physical paper and charts. Any search and documentation of information required frequent trips to a set of filing cabinets.

Today, Czaplicki's device follow-up clinic is a model of efficiency, and Czaplicki credits the Paceart Optima™ System and its integration with device follow-up systems across manufacturers and connectivity to the clinic's electronic health record system (EHR). She can be mobile throughout the office, checking devices in any office exam room because of the wireless network that enables the transfer of data into the Paceart Optima System with SessionSync™ Data Transfer. She also has access to patient data from the exam room computers and can receive data from the satellite clinic setting. She can schedule patient follow-ups from the Paceart Optima System, from the remote follow-up network for each device manufacturer, or the EHR. Appointments sync to all systems thanks to an HL7® interface between the Paceart Optima System and the EHR. The ability to capture and review electronic device data and maintain a seamless workflow is an enormous benefit for Czaplicki, who manages about 1,500 patients.

Remarkable Efficiencies over Time

During Czaplicki's 11+ years at Doylestown Cardiology, the device clinic has grown from following just a few hundred implanted patients to more than 1,500 patients—without increasing nursing staff. Czaplicki has help from a nurse practitioner who handles a small number of device patients, as well as a pacemaker technician who completes transtelephonic monitoring and enters data into the Paceart Optima System.

How does Czaplicki account for years of productivity gains? She credits the Paceart Optima System for enormous strides in efficiency. Her journey with the system began when she started at the follow-up clinic.

"I would never be where I am today, managing this many patients with quality care without the organization that Paceart Optima provides for device data. This allows me to focus on the patients I see each day—and get everything done. Our clinic has grown, but the growth has been manageable because the Paceart Optima System provides the right tools to keep us organized," says Czaplicki.

CLINIC HIGHLIGHTS

Practice Staff	▪ Nine cardiologists (2 of which are EPs) ▪ One allied health professional (RN) ▪ One pacemaker technician: performs TTM, demographic analysis and scheduling
Patients Currently Monitored	1,500 patients annually resulting in about 4,400 visits per year (clinic, remote, and satellite), from a combination of Medtronic, St. Jude Medical, Boston Scientific, Biotronik and other manufacturers
Other Locations	▪ Connectivity with all hospital units that have CareLink Express™ Service for Medtronic devices ▪ One satellite location
Use of Remote Monitoring	Roughly 50% of patients are followed remotely
Resources	▪ One dedicated device clinic room ▪ 14 standard exam rooms with mobile access for device check-ups ▪ Satellite office three miles away
Type of Devices Followed	ICDs, pacemakers, insertable cardiac monitors and implantable loop recorders

WORKFLOW EFFICIENCIES STEM FROM SIMPLIFIED CONNECTIVITY

Czaplicki says system integration is a critical element for efficiency. She has worked closely with the clinic information technology personnel and vendor technical services to take advantage of multiple levels of connectivity.

- The Paceart Optima System enables Doylestown Cardiology Associates to centrally manage device data for patients who have implanted cardiac devices from various manufacturers—Medtronic, St. Jude Medical, Boston Scientific and Biotronik

  Data from remote Medtronic device interrogations are auto-exported from the CareLink™ Network with an attached PDF report for each encounter. This includes CareLink Express interrogations performed at the satellite location, hospital floors and the emergency room. Data can also be easily exported from other device manufacturers either with a similar automated process or a one-button export feature. For in-office interrogations, non-Medtronic vendor interrogations can be saved on a thumb drive, which is then uploaded into the Paceart Optima System—making the discrete data import much easier. An uploaded pdf report can be imported as well. "If I had to manually enter data, I would never be able to handle this volume," says Czaplicki.

- SessionSync Data Transfer enables diagnostic data to move directly from the Medtronic CareLink™ 2090 Programmer into the patient's Paceart Optima System record. Czaplicki's clinic has a wireless network enabled for the SessionSync feature, allowing her mobility through the office with the CareLink Programmer.

- The clinic's EHR, NextGen, has an HL7 interface with the Paceart Optima System so that a patient's comprehensive health information is able to move back and forth between the EHR and the Paceart Optima System, making information seamless and available in one location

Czaplicki credits system integration for enabling her to manage patient follow-up from diverse locations. She can access patient device data from the main office, the clinic's satellite at the Health and Wellness Center, or from hospital rooms that have computer access. Despite not checking the patient herself, she has a log of the pertinent information in the Paceart Optima System. "Without connectivity, I would be paralyzed," says Czaplicki.

Czaplicki's efficiencies do not go unnoticed by office staff. They are aware of the volume of follow-ups moving through the clinic, yet they know they can depend on Czaplicki to have the "whole story" when it comes to patient data, which ultimately leads to better patient care, she says.

LESS MANUAL ENTRY, MORE QUERY

Czaplicki remembers the days of handling handwritten and typed reports. Along with manual reporting came the tasks required for processing physical paper: sorting and gathering typed letters, filing paperwork and searching for records. Responding to a device advisory meant manually looking through every patient chart and collecting needed information by hand. The process of identifying missed appointments and patients lost to follow-up involved a manual chart check for every patient. With the Paceart Optima System, these tasks are handled by simply running a report from the electronic system.

A decade ago, Czaplicki also manually typed information into the Paceart™ System data fields that today are filled automatically. She says less typing means less opportunity for data entry error.

Today's Paceart Optima System automatically pulls in discrete data such as program settings, testing, percentage pacing, and detection intervals. Data collection is both efficient and accurate.

Generating the patient report has also become more efficient. Czaplicki creates the report narrative mostly from saved F9 comments, which are quick keys for commonly used words and phrases.

In addition to automated data entry, the Paceart Optima System creates efficiency through easily queried data, which helps clinic personnel answer questions and run quarterly reports. Electronic signatures also play a vital role in speeding the transfer of patient reports, tasks, and even verbal summaries in the EHR.

SIMPLIFIED SCHEDULING

Using the Paceart Optima System as the single data management system for tracking devices has greatly simplified scheduling, another important element in clinic workflow.

Czaplicki can also run a report to identify missed appointments and provide the information to the front desk so the staff can call patients to reschedule. Once an encounter is started for a particular visit, she has immediate access under the scheduling tab to check for future appointment dates and can update the appointments more timely and quickly, she says.

Integrated scheduling through an HL7 interface provides the ability to schedule Medtronic patients from the NexGen EHR, with data moving seamlessly into

"I remember the big push to accurately input data so it could be managed over time. Initially, the database was populated manually, which was difficult because we had to inventory every patient to enter their data into the Paceart System—all while maintaining high standards for accuracy. But the push to incorporate highly accurate data paid off in a system that produced dependable reports," says Czaplicki.

"This allows me to pull in sentences or paragraphs of data —descriptions that I have pre-saved in the Paceart Optima System for the way that I explain certain visit types. I'm able to pull over F9 comments to create the narrative with minimal retyping, which also decreases erroneous entries and inconsistent language."

the Paceart Optima System and to the CareLink Network. For non-Medtronic devices, remote follow-up appointments flow from the remote network to the EHR and then to the Paceart Optima System. According to Czaplicki, this flow of data greatly eases the scheduling process, saves time, and reduces potential error. In addition, remote follow-up appointments for patients on the CareLink Network are electronically communicated to the patient's home monitor for automatic transmissions.

COST EFFICIENCIES

The efficiency gains at Doylestown Cardiology Associates include cost efficiencies, primarily due to the ability to hold FTEs steady for patient follow-up since creation of the device clinic. Additional cost efficiencies are attributed to reduced paper and ink, reduced square footage needed for filing cabinets, and the avoided cost of purchasing the filing cabinets themselves.

But the value of cost savings pales compared to the effect on patient care.

"The underlying premise of why we have Paceart Optima is not just so I can be more efficient," says Czaplicki. "Patient care is improved because our data is better organized and easily accessible, and we're not overwhelmed with data that we can't manage."

Diane Czaplicki is a paid consultant of Medtronic, Inc. This case study is the opinion of one clinician. Results may vary.

Data presented in this case study were prepared by Doylestown Cardiology Associates without involvement of Medtronic.

These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability, alert notifications, and patient messages are subject to Internet connectivity and access, and service availability. The CareLink and MyCareLink Patient Monitors, and the CareLink Express Monitors must be on and in range of the device. Physician alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

Brief Statement
Medtronic MyCareLink™ Patient and CareLink™ Monitors, Medtronic CareLink Express™ Monitor, Medtronic CareLink™ Network, Medtronic CareLink™ Mobile Application
Intended Use
The MyCareLink Patient Monitor, CareLink Monitor, CareLink Express 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 Express Monitor is for use in a clinical setting with Medtronic implantable cardiac devices. 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.

Contraindications
There are no known contraindications.

Warnings and Precautions
The MyCareLink Patient Monitor, CareLink Monitor and CareLink Express Monitors and Reader must only be used for interrogating compatible Medtronic implantable devices. Do not use a cellular phone while the antenna is positioned over the implanted device. The CareLink Monitor and CareLink Express Monitor are intended for use within the prescribing country.

The Medtronic CareLink programmer system 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 CareLink programmer must be used only for programming implantable devices manufactured by Medtronic or Vitatron.

Medtronic Paceart™

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information regarding Paceart, please call Medtronic at 1 (800) 722-3278 and /or consult Medtronic's website at www.paceart.com.

IPGs, CRT IPGs, ICDs, and CRT ICDs

Indications

Implantable Pulse Generators (IPGs) are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include various degrees of AV block to maintain the atrial contribution to cardiac output and VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm. See device manuals for the accepted patient conditions warranting chronic cardiac pacing. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications. For the MR-Conditional IPG, a complete SureScan™ pacing system consisting of a SureScan IPG and two SureScan leads is required for use in the MR environment.

Cardiac Resynchronization Therapy (CRT) IPGs are indicated for NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have an LVEF ≤ 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have an LVEF ≤ 50%, are on stable, optimal heart failure medical therapy if indicated and have atrioventricular block (AV block) that is expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant. Rate adaptive pacing is provided for those patients developing a bradycardia indication who might benefit from increased pacing rates concurrent with increases in activity. Dual chamber and atrial tracking modes are indicated for patients who may benefit from maintenance of AV synchrony. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications.

Implantable cardioverter defibrillators (ICDs) are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Notes for ICDs: The ICD features of the device functions the same as other approved Medtronic market-released ICDs. Due to the addition of the OptiVol™ diagnostic feature, the device indications are limited to the NYHA Functional Class II/III heart failure patients who are indicated for an ICD. The clinical value of the OptiVol fluid monitoring diagnostic feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure. **Additional notes for DR ICDs:** The use of the device has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias. The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 17%, and in terminating device classified atrial fibrillation (AF) was found to be 16.8%, in the VT/AT patient population studied. The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 11.7%, and in terminating device classified atrial fibrillation (AF) was found to be 18.2% in the AF-only patient population studied.

CRT ICDs are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications: New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction ≤ 30%, and NYHA Functional Class II. NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤ 50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant.

Some ICDs and CRT ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias. The RV Lead Integrity Alert (LIA) feature is intended primarily for patients who have a Medtronic ICD or CRT-D device and a Sprint Fidelis lead (Models 6949, 6948, 6931, and 6930) based on performance data. The RV LIA feature may not perform as well with a St. Jude Medical Riata™/Durata® lead or a Boston Scientific Endotak lead as it does when used with a Medtronic Sprint Fidelis lead. This is because different lead designs may have different failure signatures and conditions that may or may not be detected early by the RV LIA feature.

Contraindications

IPGs and CRT IPGs are contraindicated for concomitant implant with another bradycardia device and concomitant implant with an implantable cardioverter defibrillator. There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician. Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate. Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance. Antitachycardia pacing (ATP) therapy is contraindicated in patients with an accessory antegrade pathway.

ICDs and CRT ICDs are contraindicated in patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis; patients who have a unipolar pacemaker implanted, patients with incessant ventricular tachycardia (VT) or ventricular fibrillation (VF), and patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

Warnings/Precautions

Changes in a patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device.

Additionally, for CRT ICDs and CRT IPGs, certain programming and device operations may not provide cardiac resynchronization. Also for CRT IPGs, Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and/or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set. Use of the device should not change the application of established anticoagulation protocols.

For MR-Conditional IPG Systems, before performing an MRI scan, refer to the SureScan pacing system technical manual for additional information, patients and their implanted systems must be screened to meet the MRI Conditions of Use. Do not scan patients who do not have a complete SureScan pacing system consisting of a SureScan IPG and two SureScan leads; patients who have broken, abandoned or intermittent leads; or patients who have a lead impedance value of < 200 Ω or > 1,500 Ω.

Potential Complications

Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis.

An additional complication for ICDs and CRT ICDs is the acceleration of ventricular tachycardia.

SureScan systems have been designed to minimize potential complications in the MRI environment. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

Reveal™ DX/XT Insertable Cardiac Monitor and Patient Assistants

Indications

9529 Reveal™ XT and 9528 Reveal™ DX Insertable Cardiac Monitors

The Reveal XT and Reveal DX Insertable Cardiac Monitors are implantable patient-activated and automatically-activated monitoring systems that record subcutaneous ECG and are 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

9539 Reveal™ XT and 9538 Reveal™ Patient Assistants

The Reveal XT and Reveal Patient Assistants are intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates one or more of the data management features in the Reveal Insertable Cardiac Monitor:

- To verify whether the implanted device has detected a suspected arrhythmia or device related event. (Model 9539 only)
- To initiate recording of cardiac event data in the implanted device memory

Contraindications

There are no known contraindications for the implant of the Reveal XT or Reveal DX Insertable Cardiac Monitors. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Warnings/Precautions

9529 Reveal XT and 9528 Reveal DX Insertable Cardiac Monitors

Patients with the Reveal XT or Reveal DX 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. MRI scans should be performed only in a specified MR environment under specified conditions as described in the device manual.

9539 Reveal XT and 9538 Reveal Patient Assistants

Operation of the Model 9539 or 9538 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.

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.

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 manuals 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 these devices to sale by or on the order of a physician.

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