Abbott

CARDIAC RHYTHM MANAGEMENT

POWERING HEARTS BEAT TO BEAT

Partnering with you to personalize care from diagnosis through treatment and ongoing management.

AT ABBOTT, THE CARDIAC RHYTHM MANAGEMENT (CRM) BUSINESS UNIT'S COLLECTIVE PURPOSE IS TO **GET PEOPLE'S HEARTS WORKING BETTER, SOONER.**

Abbott's CRM business is dedicated to improving lives by providing personalized therapies for cardiac rhythm disorders.

We've built a portfolio of life-changing leadless and transvenous pacemaker technologies, algorithm-rich implantable cardioverter defibrillators and cardiac resynchronization therapy devices, and intelligent insertable cardiac monitors – with enhanced connectivity. Together, our devices provide you with functional flexibility while you maintain your focus on care. We are dedicated to collaboration and enabling you to make life-changing technologies accessible through educational programs with training, technical support, and services that help you and allied health professionals improve outcomes.

PROVIDING BETTER OUTCOMES

COLLABORATION FOR IMPROVED OUTCOMES

We collaborate with you to improve lives. Enabling you to make life-changing technologies accessible through educational programs with training, technical support, and services that help you and allied health professionals improve outcomes.

PERSONALIZED PRODUCTS

We offer products personalized to your patients' needs. From diagnosis through treatment and ongoing management, we offer products to help you make clinically actionable decisions sooner, customize treatment plans, and tailor care for your patients.

LIFE-CHANGING TECHNOLOGY

We continually engineer life-changing technology. We're committed to innovative products that provide you with functional flexibility while you maintain focus on care.

INSERTABLE CARDIAC MONITORS (ICM)

Supported by myMerlin™ Mobile App, SyncUP™ Remote Monitoring Support, Merlin™ 3650 Patient Care System, and Merlin.net™ Patient Care Network.

Assert-IQ™ ICM

Advanced AI Algorithms. Longest-Lasting Bluetooth® ICM.* Clinically Actionable Data. IQ Insights. Remote Programmability.

This leading innovation features advanced AI algorithms that reduce false positives from AF and Pause episodes while maintaining high sensitivity. Extended monitoring with the longest-lasting Bluetooth® ICM with full functionality and no compromises.[1-8,27] The ICM system detects arrhythmias more accurately,[9,10] shows electrogram (EGM) details more clearly,†† and provides additional insights for more informed decision-making[†] – all with a 3-year or 6-year battery life with remote programming capabilities in most models.** This device allows patients to undergo a no wait 1.5T or 3T MRI scan.[†]

Actual sizes of devices represented.

Jot Dx™ ICM

View Three Key Episodes or All Episodes. Increase Control. Diagnose with Confidence.

Bluetooth®-enabled and designed to reduce data burden, Jot Dx ICM features technology that allows you to toggle between viewing all patient episodes or Three Key Episodes*** without compromising time to diagnosis. This device allows for no wait 1.5T or 3T MRI scans.[†]

**As of 12.31.24. Reveal LINQ† User Manual, LINQ II† User Manual, LUX-Dx† User Manual, LUX-Dx II/II+† User Manual, BIOMONITOR III† User Manual, BIOMONITOR IIIm† User Manual, and BIOMONITOR IV† User Manual.*

***Remote Programming available on DM5300/DM5500.*

****Key Episodes is a feature of Merlin.net™ Patient Care Network.*

†For additional information about specific MR Conditional systems and lead model numbers, including warnings, precautions, adverse conditions to MRI scanning and potential adverse events, please refer to the MRI-Ready Systems Manual.

††Compared to predicate devices.

LEARN MORE ABOUT OUR INSERTABLE CARDIAC MONITOR SOLUTIONS

IMPLANT TOOLS

The insertable cardiac monitor introducer and incision tool make insertion simpler for you and more comfortable for your patients. The incision tool features a revolutionary triple-edge blade that reduces the puncture force by a factor of 8 compared to its predecessor.[11,12] Plastic surgeons guided the design, and electrophysiologists verified an improved incision appearance, which may help reduce scarring.

INCISION TOOL

~8X **LESS** PUNCTURE FORCE

INSERTION TOOL

PACEMAKERS

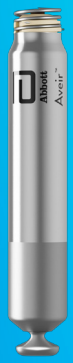
AVEIR™ DR Dual Chamber Leadless Pacemaker System

Supported by Merlin™ 3650 Patient Care System.

Beat-To-Beat Synchrony. Upgradeable System. Long-Term Retrieval.

The world's first dual chamber leadless pacemaker (LP) system with implant-to-implant (i2i™) communication between atrial and ventricular LPs that provides continuous beat-to-beat AV synchrony.[13,14] It offers the option to implant an atrial or ventricular device alone, or both for dual chamber support.[14] Upgrading from a single to dual chamber system is available anytime. This device is compatible with 1.5T and 3T MRI scans.

AVEIR™ AR2
Atrial Leadless Pacemaker



AVEIR™ VR
Ventricular Leadless Pacemaker

AVEIR™ AR2 Atrial Leadless Pacemaker

Supported by Merlin™ 3650 Patient Care System.

Leadless AAI(R) Pacing. Upgradable to a Dual Chamber System. Designed for Long-Term Retrieval.

Leadless pacing has been limited to the right ventricle, necessitating the use of conventional pacemakers. Now, more patients can experience the power of leadless pacing with the launch of Abbott's second-generation atrial leadless device — AVEIR AR2 Atrial LP — delivering increased battery life within the same device size.[13] This device is compatible with 1.5T and 3T MRI scans.

AVEIR™ VR Ventricular Leadless Pacemaker

Supported by Merlin™ 3650 Patient Care System.

Long-Term Retrieval. Long Lasting. Electrical Mapping Prior to Fixation.

A next-generation leadless pacemaker that has an active helical fixation designed for long-term retrieval,[15] a battery with at least 1.7x the projected capacity of other ventricular leadless pacemakers on the market,[16,17] and mapping capabilities designed to help reduce the number of repositioning attempts.[18] If patient needs change, the device is upgradeable to a dual chamber leadless system.[16] This device is compatible with 1.5T and 3T MRI scans.

Assurity MRI™ Pacemaker

Supported by Merlin@home™ Transmitter, MerlinOnDemand™ Capability Transmitter, Merlin™ 3650 Patient Care System, Merlin™ 2 Patient Care System, and Merlin.net™ Patient Care Network.

The longest-lasting compact MRI-ready pacemaker helps reduce infection risk and complications from implant and device replacements with a small pocket size.† No wait 1.5T and 3T MRI scan capability provides patients with the care they need, when they need it.††

LEARN MORE ABOUT OUR LOW VOLTAGE SOLUTIONS

**The average battery longevity among Leadless II phase 2 IDE patients at 1 year follow-up is estimated to be 17.6 years. 48% of the study patients have an estimated battery longevity of over 20 years.*

† For pacemakers less than 11cc as of 07.01.24.

††No minimum length of time requirement between implant and MRI scan. Stability of pacing capture thresholds is required prior to MRI scan. See MRI-Ready Systems Manual for device and lead combinations and associated MRI scan parameters.

PACING LEADS

UltiPace™ Pacing Lead

The UltiPace Pacing Lead is engineered for superior performance and approved by the FDA for left bundle branch area pacing (LBBAP). It provides a robust distal lead tip design, improved abrasion and crush resistance, SurGrip™ suture sleeve technology, and improved torque transmission.[19] Clinical evidence demonstrates safety and improved outcomes when used in LBBAP.[26] Allows patients to undergo a no wait 1.5T or 3T MRI scan when used in conjunction with Abbott MRI-ready† devices.

ACTIVE

Tendril™ STS Pacing Lead

This clinically proven pacing lead has been enhanced with SurGrip suture sleeve technology to provide a new level of secure fixation and advanced lead protection. It delivers the confidence you need with long-term data that shows a 97.18% lead survival rate at 10 years[21] while allowing patients to undergo a no wait 1.5T or 3T MRI scan when used in conjunction with Abbott MRI-ready† devices. FDA approved for left bundle branch area pacing.

ACTIVE

IsoFlex™ Optim™ Pacing Lead

Allows patients to undergo a no wait 1.5T or 3T MRI scan when used in conjunction with Abbott MRI-ready† devices. It is available as a passive-fixation straight or J shape in multiple lengths to accommodate varying needs and patient anatomies.

PASSIVE

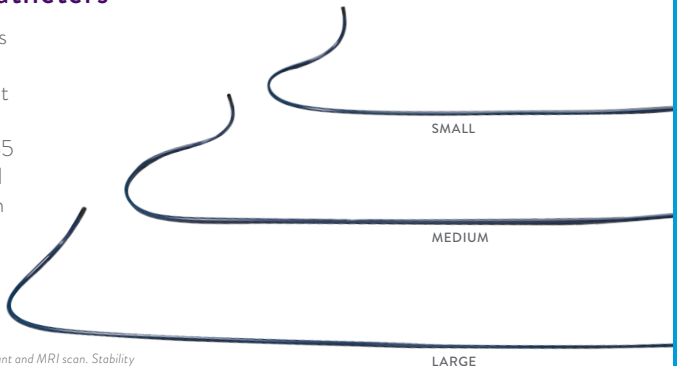
DELIVERY TOOLS

Helix Locking Tool

A novel accessory designed to aid with lead fixation by providing control over extension and retraction of the helix. The Helix Locking Tool is a proven solution to lock an extended helix in place during tissue burrowing without retraction. [20]

CPS Locator™ 3D Catheters

The CPS Locator 3D Catheters offer three unique distal curves to accommodate various patient anatomies. Medium and large curves are provided in 42 and 45 cm lengths to provide improved reach. They are compatible with 6 F stylet-driven leads, such as UltiPace Pacing Leads.



SMALL

MEDIUM

LARGE

†No minimum length of time requirement between implant and MRI scan. Stability of pacing capture thresholds is required prior to MRI scan. See MRI Ready Systems Manual for device and lead combinations and associated MRI scan parameters.

IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICD)

Available in DF4 and DF-1 configurations to improve quality of life for patients in all stages of therapy.

Supported by myMerlinPulse™ Mobile App, SyncUP™ Remote Monitoring Support, MerlinOnDemand™ Capability Transmitter, Merlin™ 3650 Patient Care System, Merlin™ 2 Patient Care System, and Merlin.net™ Patient Care Network.

Gallant™ ICDs

These small, lightweight devices are enhanced with VF Therapy Assurance, which is the only technology to provide an additional safety net for difficult-to-detect, ventricular arrhythmias, and *Precision Shock Technology*, which helps protect patients with a tailored waveform and a published rate of 100% 10 J safety margin success.[21] These devices feature smartphone connectivity and 40 J max shock. In addition, these devices are no wait 1.5T and 3T MR Conditional.†

Entrant™ ICDs

These devices offer smartphone connectivity and long-lasting therapy in a small, lightweight, contoured design with a 36 J max shock. In addition, these devices are no wait 1.5T and 3T MR Conditional.†

†No minimum length of time requirement between implant and MRI scan. Stability of pacing capture thresholds is required prior to MRI scan. See MRI-Ready Systems Manual for device and lead combinations and associated MRI scan parameters.

LEARN MORE ABOUT OUR ICD THERAPY SOLUTIONS

DEFIBRILLATION LEADS

Defibrillation leads featuring Optim™ lead insulation, now with over sixteen years and more than one million implants demonstrating proven performance.[22] These leads allow patients to undergo a no wait 1.5T or 3T MRI scan when used in conjunction with Abbott MRI-ready† ICDs and CRT-Ds.

Durata™ Defibrillation Lead

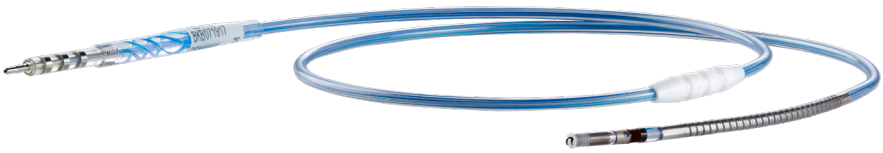
A cardiac lead designed to offer high-performance handling, more control at implant, and a proven platform of long-term durability featuring Optim lead insulation, in a thin, 7 F sizing. Experience proven performance with 99% freedom from all-cause insulation abrasion at 12 years.[23] The DF4 connector header has a single terminal pin connection, which decreases chances of lead-to-port mismatch.

ACTIVE

PASSIVE

Optisure™ Defibrillation Lead

Building on the proven Durata defibrillation lead design, the Optisure lead features additional Optim lead insulation at the proximal end of the lead and under the SVC coil. Two innovative designs are intended to help prevent tissue ingrowth: flat-wire technology provides a low profile for the defibrillation coils, and silicone backfilling completely fills the shock coil space.



†No minimum length of time requirement between implant and MRI scan. Stability of pacing capture thresholds is required prior to MRI scan. See MRI Ready Systems Manual for device and lead combinations and associated MRI scan parameters.

CARDIAC RESYNCHRONIZATION THERAPY (CRT)

Available in bipolar and quadripolar configurations to improve quality of life for patients at every stage of therapy.

Supported by myMerlinPulse™ Mobile App, SyncUP™ Remote Monitoring Support, MerlinOnDemand™ Capability Transmitter, Merlin™ 3650 Patient Care System, Merlin™ 2 Patient Care System, and Merlin.net™ Patient Care Network.

DEFIBRILLATORS (CRT-D)

Gallant™ HF CRT-D

With a small, contoured design, this device offers SyncAV™ *Plus* CRT and MultiPoint™ Pacing technology which provide options to achieve the narrowest QRS and give patients the best chance of survival. The device has 1.5T and 3T MRI-ready solutions to ensure no loss of CRT therapy for your patients during full-body scans and allows for programming of an MRI timeout.†

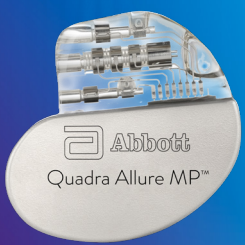
Entrant™ HF CRT-D

Featuring SyncAV CRT technology and designed to achieve narrower QRS 100% of the time,[25] this small, contoured device is no wait 1.5T and 3T MR Conditional.†

PACEMAKERS (CRT-P)

Quadra Allure MP™ CRT-P

This device offers SyncAV CRT technology to achieve a narrower QRS and MultiPoint Pacing technology to deliver multiple independent left ventricular (LV) pacing pulses from a single quadripolar lead. It is no wait 1.5T and 3T MRI-ready at implant.†



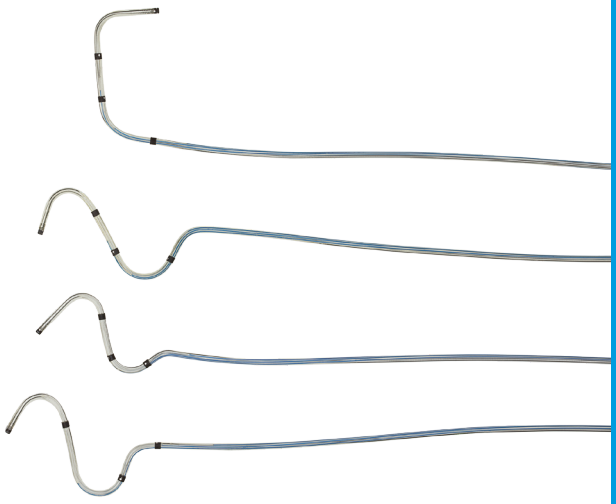
†No minimum length of time requirement between implant and MRI scan. Stability of pacing capture thresholds is required prior to MRI scan. See MRI-Ready Systems Manual for device and lead combinations and associated MRI scan parameters.

LEARN MORE ABOUT OUR CARDIAC RESYNCHRONIZATION THERAPY SOLUTIONS

LEFT VENTRICULAR LEADS

Quartet™ Left-Heart Leads

With the most quadripolar lead options to match a patient's anatomy, this proven LV lead features more distal shape options for a low profile. The 4.7 F lead body diameter allows for maneuverability. Additional total electrode spacing options include 40, 47, and 60 mm.



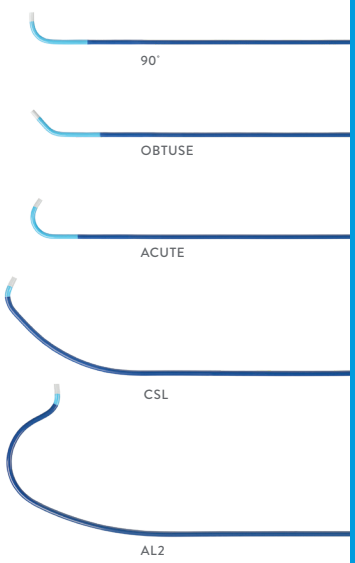
QuickFlex™ Lead

Featuring a steerable tip and flexible lead body, this low-profile bipolar LV lead offers deliverability and stability. It has a 4.3 F lead body diameter and ring-to-tip electrode spacing of 20 mm.

DELIVERY TOOLS

CPS™ Cardiac Positioning Products

This inter-compatible system of tools gives you more control – efficiently and predictably – to deliver to your vein of choice. Includes the CPS Aim Universal II Catheter, available in five curve shapes, and the CPS Universal II Slitter.



CONNECTIVITY SOLUTIONS

Merlin.net™ Patient Care Network (PCN)

This web application is used to review remote monitoring data and manage patients who have Abbott Cardiac Rhythm Management (CRM) devices. It allows you and other clinicians to monitor your patients' cardiac conditions, track their devices' performance, and manage their data transmission schedules.

Merlin™ 3650 Patient Care System (PCS)

This programmer is designed to interrogate, monitor, and program a patient's Abbott CRM device quickly and accurately during implant and follow-up. The Merlin 3650 PCS allows for simple patient management with a touch screen that clearly displays programming and diagnostics.

Merlin™ 2 Patient Care System (PCS)

This programmer features integrated Bluetooth® wireless technology and is a cyber-secure solution designed to streamline your workflow. The Merlin 2 PCS supports informed clinical decisions so you can deliver comprehensive care during implant and follow-up. The programmer has a rapid data processor and a super-responsive touch screen, allowing fast and efficient care management of patients.

SyncUP™ Remote Monitoring Support

SyncUP support experts guide your patients through installation of the myMerlin™ Mobile App for Abbott ICM devices and the myMerlinPulse™ Mobile App for Gallant™ and Entrant™ ICD and CRT-D devices. The SyncUP team connects directly with your patients to educate them about remote monitoring and help them set up their Abbott remote monitoring apps.

LEARN MORE ABOUT OUR CONNECTIVITY SOLUTIONS

AVEIR™ Patient Transmitter

AVEIR Patient Transmitter (Model LSRM01) with software Model LSRM1000 allows efficient remote transmission of data from patients implanted with an AVEIR Leadless Pacemaker device through scheduled, patient-initiated transmissions that support alert monitoring.

Merlin@home™ Transmitter

Capable of monitoring compatible Abbott CRM devices daily, this transmitter enables patients to send data to Merlin.net PCN from the comfort of their own home. The Merlin@home Transmitter can reduce the number of scheduled clinic visits a patient may need by automatically sending alert-initiated and scheduled data transmissions to Merlin.net PCN.

MerlinOnDemand™ Capability Transmitter

Merlin@home Transmitters with MerlinOnDemand capability can interrogate compatible Abbott CRM devices in a hospital or clinic setting and deliver data via email or fax without the need for an Abbott Representative to be on site.

myMerlin™ Mobile App

Patients implanted with Abbott Bluetooth®-enabled ICMs can use their iPhone‡ or Android‡ smartphone to send data from their heart monitor to Merlin.net PCN.* When paired with an inserted Abbott ICM, the myMerlin Mobile App makes monitoring your patient's heart easy, effective, and discreet while delivering data 20x faster than other ICMs.[25]

myMerlinPulse™ Mobile App

The myMerlinPulse Mobile App connects with the latest Bluetooth®-enabled ICD and CRT-D devices from Abbott: Gallant and Entrant. The app can be used with your patient's iPhone‡ or Android‡ smartphone.* When paired with your patient's implanted Gallant or Entrant device, the app empowers you and your patient with a remote monitoring solution that provides daily device monitoring and alert detection using the patient's own smartphone.

Refer to the myMerlin™ IFU and myMerlinPulse™ IFU for smartphone minimum requirements.
An Abbott mobile transmitter is available for patients without a compatible smartphone.

POWERING HEARTS BEAT TO BEAT

Partnering with you to personalize care from diagnosis through treatment and ongoing management.

Scan to learn more about our Cardiac Rhythm Management solutions.

ABOUT ABBOTT

A healthy heart is essential to good health. That's why we're committed to advancing treatments for people with cardiovascular disease. Our breakthrough medical technologies help restore people's health so they can get back to living their best lives, faster.

We focus on innovative technologies that can improve the way doctors treat people with heart arrhythmias or irregular heartbeats.

Our cardiac rhythm management devices keep the heart beating at a healthy pace with pacemakers, implantable cardiac defibrillators, and implantable cardiac monitors, all designed to get people's hearts working better, sooner.

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IMPORTANT SAFETY INFORMATION

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

™ Indicates a trademark of the Abbott group of companies.
‡ Indicates a third-party trademark, which is property of its respective owner. .

Abbott Insertable Cardiac Monitors (ICM)

Assert-IQ™ ICM, Jot Dx™ ICM

Indications for Use: Abbott ICMs are indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms that may be cardiac-related such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias such as bradycardia, tachycardia, and sinus pauses. Abbott ICMs are also indicated for patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF. Abbott ICMs are intended to be inserted subcutaneously in the left pectoral region, also described as the left anterior chest wall. Abbott ICMs have not been specifically tested for pediatric use.

Intended Use: Abbott ICMs are intended to help physicians and clinicians monitor, diagnose and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms by detecting arrhythmias and transmitting data for review.

Contraindications: There are no known contraindications for the insertion of Abbott ICMs. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

Potential Adverse Events: Possible adverse events (in alphabetical order) associated with the device, include the following: allergic reaction, bleeding, chronic nerve damage, erosion, excessive fibrotic tissue growth, extrusion, formation of hematomas or cysts, infection, keloid formation and migration.

Refer to the User's Manual for detailed indications for use, contraindications, warnings, precautions and potential adverse events.

An Abbott mobile transmitter is available for patients without their own compatible mobile device.

Assurity MRI™ Pacemaker

Indications/Intended Use: Implantation is indicated in one or more of the following permanent conditions, or any combination of these symptoms: syncope, presyncope, fatigue, disorientation. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-chamber pacing is indicated for those patients exhibiting: sick sinus syndrome; chronic, symptomatic second-degree and third-degree AV block; recurrent Adams-Stokes syndrome; symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular pacing is indicated for patients with significant bradycardia and: normal sinus rhythm with only rare episodes of AV block or sinus arrest, chronic atrial fibrillation, severe physical disability. AF Suppression™ algorithm stimulation is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: Implanted cardioverter-defibrillator (ICD). Single-chamber pulse generators and dual-chamber pulse generators are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-adaptive pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression™ algorithm stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. Dual-chamber pacing, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-chamber atrial pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: air embolism; body rejection phenomena; cardiac tamponade or perforation; hematoma, bleeding hematoma, seroma; formation of fibrotic tissue, local tissue reaction; inability to interrogate or program a device due to programmer or device malfunction; infection; erosion; interruption of desired device pulse generator function due to electrical interference, either electromyogenic or electromagnetic; lead malfunction due to conductor fracture or insulation degradation; loss of capture or sensing due to lead dislodgement or reaction at the electrode/tissue interface; loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation); loss of normal device function due to battery failure or component malfunction; pacemaker migration or pocket erosion; pectoral muscle or diaphragmatic stimulation; phrenic nerve stimulation; pneumothorax/hemothorax; device migration and pocket erosion; endocarditis; excessive bleeding; induced atrial or ventricular arrhythmias; myocardial irritability; pericardial effusion; pericardial rub; pulmonary edema; rise in threshold and exit block; valve damage; death.

AVEIR™ Leadless Pacemaker System

Indications for Use: The AVEIR™ Leadless Pacemaker system is indicated for management of one or more of the following chronic clinical presentations: syncope, pre-syncope, fatigue, disorientation, and one or more of the indications which follow. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-chamber pacing is indicated for patients exhibiting one or more of the following conditions: sick sinus syndrome; chronic, symptomatic second- and third-degree AV block; recurrent Adams-Stokes syndrome; symptomatic bilateral bundle-branch block when tachyarrhythmia and other causes have been ruled out. Atrial pacing is indicated for patients with: sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular pacing is indicated for patients with significant bradycardia and: normal sinus rhythm with only rare episodes of AV block or sinus arrest, chronic atrial fibrillation. MR Conditional:

The AVEIR Leadless Pacemaker is conditionally safe for use in the MRI environment and according to the instructions in the MRI-Ready Leadless System Manual.

Intended Use: The AVEIR™ Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle and the right atrium. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy within the implanted chamber for the target treatment group. The LP is also intended to operate optionally with another co-implanted LP to provide dual-chamber pacing therapy.

The AVEIR™ Delivery Catheter is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation includes implanting an LP within the target chamber of the heart.

Contraindications: Use of the AVEIR™ Leadless Pacemaker is contraindicated in these cases:

Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.

Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing.

Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor driven rates.

Use is contraindicated in patients with an implanted vena cava filter or mechanical tricuspid valve because of interference between these devices and the delivery system during implantation.

Persons with known history of allergies to any of the components of this device may suffer an allergic reaction to this device. Prior to use on the patient, the patient should be counseled on the materials (listed in the Product Materials section of the IFU) contained in the device and a thorough history of allergies must be discussed.

Adverse Events: Potential complications associated with the use of the AVEIR™ Leadless Pacemaker system are the same as with the use of single or dual chamber pacemakers with active fixation pacing leads including, but not limited to: cardiac perforation; cardiac tamponade; pericardial effusion; pericarditis; endocarditis; thrombus formation; thromboembolism; valve damage or regurgitation; heart failure; pneumothorax/hemothorax; cardiac arrhythmias; diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation; palpitations; hypotension; syncope; cerebrovascular accident; infection; hypersensitivity reaction to device materials, contrast media, medications, or direct toxic effect of contrast media on kidney function; pacemaker syndrome; inability to interrogate or program the LP due to programmer or LP malfunction; intermittent or complete loss of capture, pacing or sensing (non-battery related); oversensing; increased capture threshold; inappropriate sensor response; corrupted, intermittent, or loss of i2i communications; interruption of desired LP function due to electrical interference, either electromyogenic or electromagnetic; battery malfunction/premature battery depletion; device-related complications (premature deployment, device dislodgement/embolization of foreign material, inability to release/re-dock of the LP from catheter, helix distortion); additional surgery or intervention; death. As with any percutaneous catheterization procedure, potential complications include, but are not limited to: vascular access complications, such as perforation, dissection, puncture, groin pain; bleeding or hematoma; thrombus formation; thromboembolism; air embolism; local and systemic infection; peripheral nerve damage; general surgery risks and complications from comorbidities; such as dyspnea, respiratory failure, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions, and adverse events.

CPS Aim™ Universal II Catheter

Indications: The CPS Aim™ Universal II slittable inner catheter (subselector/cannulator) is designed for intracardiac access of the coronary sinus and subselection of the venous system of the heart, and to serve as a conduit during implantation for delivery of contrast medium and Abbott Medical devices (such as guidewires and implantable left heart leads). In addition, the CPS Aim™ Universal II slittable inner catheter (subselector/cannulator) can work with outer guide catheters as a system.

Intended Use: The CPS™ delivery tools help provide access to the venous system and aid in the delivery of the left ventricular lead during Cardiac Resynchronization Therapy (CRT) procedures. The CRT devices are intended for patients with heart failure, who require resynchronization of the right and left ventricles.

Complications: As with any catheterization procedure, potential complications include thromboembolism, local and systemic infection, bleeding or hematoma at the puncture site, vascular dissection or perforation, cardiac perforation, and cardiac tamponade.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions, and potential adverse events.

CPS Locator™ 3D Catheters

Indications for Use: The Delivery Catheter is indicated for the introduction of various types of catheters and pacing or defibrillator leads.

Contraindications:

- Obstructed or inadequate vasculature for venous access
- Review contraindications associated with ancillary devices used with the Delivery Catheter

Complications: Possible complications associated with the Delivery Catheter include: Vessel trauma, Endocardial trauma, Blood loss, Lead Dislodgement, Embolization (material, air), Allergic reaction, Infection, Device incompatibility. Possible complications associated with the use of ancillary devices with the Delivery Catheter include: Air embolism, Bleeding, Bradycardia, Cardiac perforation, Cardiac tamponade, Chronic nerve damage, Death, Extracardiac stimulation (muscle/nerve stimulation), Hematoma, Heart block, Hemothorax, Incisional pain, Infection including endocarditis, Lead dislodgement, Myocardial infarction, Myocardial trauma, Pericarditis, Pneumothorax, Stroke, Tachyarrhythmias, Thrombosis/thromboemboli, Valve damage, Venous occlusion, Venous trauma (e.g., perforation, dissection, erosion).

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions, and potential adverse events.

Manufactured by:
CenterPoint Systems LLC
3338 Parkway Blvd West Valley City, UT 84119, U.S.A.
Tel: +1-877-848-0828
Info@centerpoint-systems.com

Distributed by:
Abbott Medical
15900 Valley View Court Sylmar, CA 91342 USA
+1-818-362-6822

Duarta™ Defibrillation Leads (Models 7120, 7121, 7122)

Indications: The Durata™ defibrillation leads are indicated for use in combination with implantable cardioverter defibrillators (ICDs) or cardiac resynchronization therapy-defibrillators (CRT-Ds) to provide sensing, pacing and cardioversion/defibrillation therapy for the treatment of bradyarrhythmia's and life-threatening tachyarrhythmias in patients who are at risk from sudden cardiac death. They are implanted transvenously in the right ventricle.

Intended Use: The Durata™ leads are implantable defibrillation leads intended for use with a compatible pulse generator to provide long-term cardiac sensing, pacing, and delivery of cardioversion/defibrillation therapy to treat life threatening ventricular arrhythmias in the right ventricle.

Contraindications: Durata™ Models 7120, 7121, and 7122 leads are contraindicated in the following: Patients with tricuspid valvular disease or a mechanical tricuspid valve. Patients with ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated.

Potential Adverse Events: The following lists potential adverse effects and their categories as applicable when using a high voltage lead. Arrhythmia (Arrhythmia acceleration, Induced atrial ectopy or arrhythmias, Induced atrioventricular or bundle branch block, Induced ventricular ectopy or arrhythmias, Myocardial irritability), Cardiac perforation (Cardiac tamponade, Perforation of the myocardium, Pericardial effusion), Death, Embolism (Air embolism, Intravascular foreign body, Dislodgement of intracardiac thrombus), Extra cardiac stimulation (Diaphragmatic stimulation, Stimulation of phrenic nerve), Heart failure (Cardiogenic shock, Right ventricular decompensation, Pacing induced cardiomyopathy, Tricuspid valve dysfunction), Hemorrhage (Acute hemorrhage/bleeding), Hypersensitivity (Hypersensitivity, including local tissue reaction or allergic reaction), Infection (Endocarditis, Pericarditis), Lead revision or reprogramming (Electrical malfunction of the lead, Lead dislodgement, Lead dysfunction (sensing/threshold issue), Mechanical malfunction of the lead, Inappropriate defibrillation therapy), Pleural perforation (Hemothorax, Pneumothorax), Pocket Erosion (Erosion of the skin, Extrusion), Prolonged exposure to fluoroscopic radiation, Seroma (Fluid accumulation), Tissue necrosis, Tricuspid valve perforation, Vascular perforation (Arteriovenous fistula, Arterial perforation, Coronary sinus or coronary vein perforation, Hematoma, Venous perforation), Vascular Thrombosis (Venous thrombosis and/or obstruction, Venous occlusion). The physician should discuss the patient's potential adverse events with them.

Duarta™ Defibrillation Leads (Models 7120Q, 7121Q, 7122Q)

Indications/Intended Use: The Durata™ Models 7120Q, 7121Q, and 7122Q leads are 7 French, transvenous, steroid eluting, bipolar, DF4 compatible (single connector with four electrical terminals), active fixation leads intended for permanent sensing and pacing of the right ventricle and the delivery of cardioversion/defibrillation therapy when used with a compatible Abbott Medical pulse generator with a DF4-LLHH lead receptacle designation.

Contraindications: Durata™ Models 7120Q, 7121Q, and 7122Q leads are contraindicated in the following: Patients with tricuspid valvular disease or a mechanical tricuspid valve. Patients with ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. For use with extra firm (red color knob) stylets.

Potential Adverse Events: Possible adverse events associated with the use of transvenous lead systems include, but are not limited to, those summarized in as follows. Refer to the appropriate pulse generator manual for additional complications and precautions specific to the pulse generator.

Dislodgement, breaching of the lead insulation, connector fracture, poor connection to the pulse generator, electrode fracture, or conductor is continuity (Intermittent or continuous loss of sensing, possibly resulting immunodetection of arrhythmia; oversensing of artifact, possibly causing inappropriate delivery of therapy from the pulse generator; intermittent or continuous loss of defibrillation, cardioversion, or pacing therapy; possible muscle or nerve stimulation in the pocket area; intermittent or continuous loss of cardioversion/defibrillation therapy, sensing, or pacing therapies.), Cardiac perforation (Intermittent or continuous loss of sensing, cardiac tamponade, hemorrhage, pneumothorax, or loss of contractility), Venous perforation (Acute hemorrhage (may not be readily apparent), hemothorax, pneumothorax, or cardiac tamponade), Myocardial irritability (Premature ventricular contractions, supraventricular and ventricular tachyarrhythmias, postoperative heart failure), Transvenous implantation procedure (Air embolism), Chronic (> 3 months) implantation (Venous thrombosis and/or obstruction, tissue necrosis, skin erosion, tricuspid valve dysfunction, chronic mechanical stimulation of the heart), Contamination (Infection requiring removal of lead system, pulse generator, or both), Post-shock rhythm disturbances (Post-shock bradycardia or supraventricular arrhythmias, conduction disturbances), Threshold elevation or exit block (Loss of efficacy of defibrillation, cardioversion, or pacing therapy), Shunting or insulating of current during defibrillation with internal or external paddles (Increased external defibrillation energy and/or repositioning of paddles required).

Durata™ Defibrillation Leads (Models 7170, 7171)

Indications/Intended Use: The Durata™ Models 7170 and 7171 transvenous leads are indicated for use with compatible pulse generators (refer to the applicable defibrillator manual for system indications). They provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart.

Contraindications: Durata™ Models 7170 and 7171 leads are contraindicated in the following:

• Patients with tricuspid valvular disease or a mechanical tricuspid valve.

• Patients with ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

• Patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated.

Potential Adverse Events: Possible adverse events associated with the use of transvenous lead systems include, but are not limited to Dislodgement, breaching of the lead insulation, connector fracture, poor connection to the pulse generator, electrode (Intermittent or continuous loss of sensing, possibly resulting in nondetection of arrhythmia; oversensing of artifact, possibly causing inappropriate delivery of therapy from the pulse generator; intermittent or continuous loss of defibrillation, cardioversion, or pacing therapy; possible); fracture, or conductor discontinuity (muscle or nerve stimulation in the pocket area; intermittent or continuous loss of cardioversion/defibrillation therapy, sensing, or pacing therapies.); Cardiac perforation (Intermittent or continuous loss of sensing, cardiac tamponade, hemorrhage, pneumothorax, or loss of contractility); Venous perforation (Acute hemorrhage (may not be readily apparent), hemothorax, pneumothorax, or cardiac tamponade); Myocardial irritability (Premature ventricular contractions, supraventricular and ventricular tachyarrhythmias, postoperative heart failure); Transvenous implantation procedure (Air embolism); Chronic (> 3 months) implantation (Venous thrombosis and/or obstruction, tissue necrosis, skin erosion, tricuspid valve dysfunction, chronic mechanical stimulation of the heart); Contamination (Infection requiring removal of lead system, pulse generator, or both); Post-shock rhythm disturbances (Post-shock bradycardia or supraventricular arrhythmias, conduction disturbances); Threshold elevation or exit block (Loss of efficacy of defibrillation, cardioversion, or pacing therapy); Shunting or insulating of current during defibrillation with internal or external paddles (Increased external defibrillation energy and/or repositioning of paddles required).

Durata™ Defibrillation Leads (Models 7170Q, 7171Q, 7172Q)

Indications/Intended Use: Durata™ Models 7170Q, 7171Q, and 7172Q leads are 7 French, transvenous, steroid eluting, bipolar, DF4 compatible (single connector with four electrical terminals), passive fixation leads intended for permanent sensing and pacing of the right ventricle and the delivery of cardioversion/defibrillation therapy when used with a compatible Abbott Medical pulse generator with a DF4-LLHH lead receptacle designation.

Contraindications: Durata™ Models 7170Q, 7171Q, and 7172Q leads are contraindicated in the following:

• Patients with tricuspid valvular disease or a mechanical tricuspid valve.

• Patients with ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

• Patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated.

Potential Adverse Events: Dislodgement, breaching of the lead insulation, connector fracture, poor connection to the pulse generator, electrode fracture, or conductor discontinuity. (Intermittent or continuous loss of sensing, possibly resulting in nondetection of arrhythmia oversensing of artifact, possibly causing inappropriate delivery of therapy from the pulse generator; intermittent or continuous loss of defibrillation, cardioversion, or pacing therapy; possible muscle or nerve stimulation in the pocket area; intermittent or continuous loss of cardioversion/defibrillation therapy, sensing, or pacing therapies.); Cardiac perforation (Intermittent or continuous loss of sensing, cardiac tamponade, hemorrhage, pneumothorax, or loss of contractility); Venous perforation (Acute hemorrhage (may not be readily apparent), hemothorax, pneumothorax, or cardiac tamponade); Myocardial irritability (Premature ventricular contractions, supraventricular and ventricular tachyarrhythmias, postoperative heart failure); Transvenous implantation procedure (Air embolism); Chronic (> 3 months) implantation (Venous thrombosis and/or obstruction, tissue necrosis, skin erosion, tricuspid valve dysfunction, chronic mechanical stimulation of the heart); Contamination (Infection requiring removal of lead system, pulse generator, or both); Post-shock rhythm disturbances (Post-shock bradycardia or supraventricular arrhythmias, conduction disturbances); Threshold elevation or exit block (Loss of efficacy of defibrillation, cardioversion, or pacing therapy); Shunting or insulating of current during defibrillation with internal or external paddles(Increased external defibrillation energy and/or repositioning of paddles required)

Entrant™ and Gallant™ HF CRT-D

Intended Use: The Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing and ventricular cardioversion/defibrillation. In addition, these devices can detect and treat: chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle; various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium. CRT-D devices sense cardiac activity and provide pacing to resynchronize the right and left ventricles.

The myMerlinPulse™ mobile application is intended for use by people who have an Abbott Medical implanted heart device and access to a mobile device. The app provides remote monitoring capability of the implanted heart device by transmitting information from the patient's implanted heart device to the patient's healthcare provider.

Indications: Cardiac Resynchronization Therapy (CRT) devices are indicated for reduction of symptoms in patients who have congestive heart failure, a reduced left ventricular ejection fraction (LVEF) and a prolonged QRS duration. CRT-D devices are indicated in patients who meet the CRT indications and have already survived a cardiac arrest or are at a high risk of Sudden Cardiac Death (SCD) due to VT (ventricular tachycardia) or VF (ventricular fibrillation). The device is most commonly implanted within a device pocket in the pectoral region.

The myMerlinPulse mobile application is indicated for use by patients with supported Abbott Medical implanted heart devices.

Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

The myMerlinPulse mobile application is contraindicated for use with any implanted medical device other than supported Abbott Medical implanted heart devices.

Adverse Events: Possible adverse events associated with the implantation of the pulse generator system include the following: Arrhythmia (for example, accelerated or induced), Bradycardia, Cardiac or venous perforation, Cardiac tamponade, Cardiogenic shock, Death, Discomfort, Embolism, Endocarditis, Erosion, Exacerbation of heart failure, Excessive fibrotic tissue growth, Extracardiac stimulation (phrenic nerve, diaphragm, pectoral muscle), Extrusion, Fluid accumulation within the device pocket, Formation of hematomas, cysts, or seromas, Heart block, Hemorrhage, Hemothorax, Hypersensitivity, including local tissue reaction or allergic reaction, Infection, Keloid formation, Myocardial damage, Nerve damage, Occlusion/Thrombus, Pericardial effusion, Pericarditis, Pneumothorax, Pulmonary edema, Syncope, Thrombosis, Valve damage. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and rarely, death. Among the psychological effects of device implantation are imagined pulsing, depression, dependency, fear of premature battery depletion, device malfunction, inappropriate pulsing, shocking while conscious or losing pulse capability. Possible adverse device effects include complications due to the following: Abnormal battery depletion, Conductor fracture, Device-programmer communication failure, Elevated or rise in defibrillation/cardioversion threshold, Inability to defibrillate or pace, Inability to interrogate or program due to programmer or device malfunction, Incomplete lead connection with pulse generator, Inhibited therapy including defibrillation and pacing, Inappropriate therapy (for example, shocks and antitachycardia pacing [ATP] where applicable, pacing), Interruption of function due to electrical or magnetic interference, Intolerance to high rate pacing (for example dyspnea or discomfort), Lead abrasion, Lead fracture, Lead insulation damage, Lead migration or lead dislodgement, Loss of device functionality due to component failure, Pulse generator migration, Rise in DFT threshold, Rise in pacing threshold and exit block, Shunting of energy from defibrillation paddles, System failure due to ionizing radiation. Additionally, potential adverse events associated with the implantation of a coronary venous lead system include the following: Allergic reaction to contrast media, Breakage or failure of implant instruments, Prolonged exposure to fluoroscopic radiation, Renal failure from contrast media used to visualize coronary veins.

No potential adverse events have been identified with use of the myMerlinPulse™ mobile application.

Entrant™ and Gallant™ ICD

Intended Use: The Implantable Cardioverter Defibrillator (ICD) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing and ventricular cardioversion/defibrillation. In addition, these devices can detect and treat: chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle; various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.

The myMerlinPulse™ mobile application is intended for use by people who have an Abbott Medical implanted heart device and access to a mobile device. The app provides remote monitoring capability of the implanted heart device by transmitting information from the patient's implanted heart device to the patient's healthcare provider.

Indications: The ICD devices are indicated in patients who have already survived a cardiac arrest or are at a high risk of Sudden Cardiac Death (SCD) due to VT (ventricular tachycardia) or VF (ventricular fibrillation). The device is most commonly implanted within a device pocket in the pectoral region.

The myMerlinPulse™ mobile application is indicated for use by patients with supported Abbott Medical implanted heart devices.

Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

The myMerlinPulse™ mobile application is contraindicated for use with any implanted medical device other than supported Abbott Medical implanted heart devices.

Adverse Events: Possible adverse events associated with the implantation of the pulse generator system include the following: Arrhythmia (for example, accelerated or induced), Bradycardia, Cardiac or venous perforation, Cardiac tamponade, Cardiogenic shock, Death, Discomfort, Embolism, Endocarditis, Erosion, Exacerbation of heart failure, Excessive fibrotic tissue growth, Extracardiac stimulation (phrenic nerve, diaphragm, pectoral muscle), Extrusion, Fluid accumulation within the device pocket, Formation of hematomas, cysts, or seromas, Heart block, Hemorrhage, Hemothorax, Hypersensitivity, including local tissue reaction or allergic reaction, Infection, Keloid formation, Myocardial damage, Nerve damage, Occlusion/Thrombus, Pericardial effusion, Pericarditis, Pneumothorax, Pulmonary edema, Syncope, Thrombosis, Valve damage. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and rarely, death. Among the psychological effects of device implantation are imagined pulsing, depression, dependency, fear of premature battery depletion, device malfunction, inappropriate pulsing, shocking while conscious, or losing pulse capability. Possible adverse device effects include complications due to the following: , Abnormal battery depletion, Conductor fracture, Device-programmer communication failure, Elevated or rise in defibrillation/cardioversion threshold, Inability to defibrillate or pace, Inability to interrogate or program due to programmer or device malfunction, Incomplete lead connection with pulse generator, Inhibited therapy including defibrillation and pacing, Inappropriate therapy (for example, shocks and antitachycardia pacing [ATP] where applicable, pacing), Interruption of function due to electrical or magnetic interference, Intolerance to high rate pacing (for example dyspnea or discomfort), Lead abrasion, Lead fracture, Lead insulation damage, Lead migration or lead dislodgement, Loss of device functionality due to component failure, Pulse generator migration, Rise in DFT threshold, Rise in pacing threshold and exit block, Shunting of energy from defibrillation paddles, System failure due to ionizing radiation. Additionally, potential adverse events associated with the implantation of a coronary venous lead system include the following: Allergic reaction to contrast media, Breakage or failure of implant instruments, Prolonged exposure to fluoroscopic radiation, Renal failure from contrast media used to visualize coronary veins.

No potential adverse events have been identified with use of the myMerlinPulse™ mobile application.

IsoFlex™ Optim™ Pacing Lead

Indications/Intended Use: IsoFlex™ Model 1948 leads are 7 F, steroid eluting, passive fixation (tined) straight body leads designed for use with compatible pulse generators to provide permanent pacing and sensing in either the right atrium or right ventricle. IsoFlex Model 1944 leads are 7 F, steroid eluting, passive fixation (tined) J-shaped leads designed for use with compatible pulse generators to provide permanent pacing and sensing in the right atrium.

Contraindications: The use of IsoFlex™ leads is contraindicated in patients who are expected to be hypersensitive to a single dose of 1.0 milligram of dexamethasone sodium phosphate. The use of the Model 1948 is also contraindicated in the presence of tricuspid atresia and in patients with mechanical tricuspid valves (if the lead is to be positioned in the ventricle).

Potential Adverse Events: Potential complications associated with the use of the IsoFlex™ family of leads are the same as with the use of any lead and include: cardiac perforation; cardiac tamponade; damage to vessels; embolism; excessive bleeding; hypersensitivity, including local tissue reaction or allergic reaction; induced atrial or ventricular arrhythmias; infection; loss of pacing and or sensing due to dislodgement or mechanical malfunction of the lead; phrenic nerve stimulation; tissue necrosis; thrombosis; valve damage. Phrenic nerve or direct diaphragmatic stimulation may also be a result of lead position. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and, rarely, death. The physician should discuss the patient's potential adverse events with them.

Refer to the device manual for additional complications and precautions specific to the pulse generator.

Merlin™ 2 PCS Programmer

Indications: The Merlin™ 2 PCS (Merlin 2 PCS Programmer, Model MER3700, and Merlin 2 PCS Software, Model MER3400) is a portable, dedicated system that is indicated for the interrogation, diagnostic evaluation, and programming of compatible Abbott Medical cardiac implantable devices in patients. These are patients who have been diagnosed with cardiac arrhythmias, such as bradycardia, tachycardia or heart failure, and who are undergoing implantation, lead or device revision, explant, or device follow-up of Abbott Medical cardiac implantable devices.

Intended Use: The Merlin™ 2 PCS (Merlin 2 PCS Programmer, Model MER3700, and Merlin 2 PCS Programmer Software, Model MER3400) is intended to interrogate, program, display data, and test cardiac implantable devices and leads to help physicians and clinicians monitor, diagnose, record heart rhythms, and program devices, which include pacemakers, implantable cardioverter-defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, and implantable cardiac monitors (ICMs), during implant, revision, explant, or follow-up sessions.

Potential Adverse Events: Possible adverse events include:
Arrhythmia
Electric Shock
Prolonged Surgery
Discomfort
Infection
Injury (for example, Burn)

Merlin™ 3650 Patient Care System Programmer

Intended Use: The St. Jude Medical Merlin™ PCS Model 3650 is a portable, dedicated system designed to interrogate, program, display data from, and test St. Jude Medical implantable devices during implant and follow up. At time of implant, it is intended to assess the pacing and sensing performance of the lead after it is connected to the pulse generator.

Indications: The Merlin™ PCS Model 3650 programmer is indicated for use for patients with bradyarrhythmias, tachyarrhythmias or heart failure undergoing implantation, lead revision, explant or device follow-up of a cardiac monitor, pacemaker, implantable cardioverter defibrillator, or cardiac resynchronization therapy system.

Optisure™ Defibrillation Lead

Indications: The Optisure™ defibrillation leads are indicated for use in combination with implantable cardioverter defibrillators (ICDs) or cardiac resynchronization therapy-defibrillators (CRT-Ds) to provide sensing, pacing and cardioversion/defibrillation therapy for the treatment of bradyarrhythmia's and life-threatening tachyarrhythmias in patients who are at risk from sudden cardiac death. They are implanted transvenously in the right ventricle.

Intended Use: The Optisure™ leads are bipolar, steroid-eluting implantable defibrillation leads intended for use with a compatible pulse generator to provide long-term cardiac sensing, pacing, and delivery of cardioversion/defibrillation therapy to treat life-threatening ventricular arrhythmias in the right ventricle.

Contraindications: Optisure™ Models LDA220, LDA230, LDA210, LDA220Q, LDA230Q, LDA210Q, LDP220, LDP230, LDP220Q, and LDP230Q leads are contraindicated in the following: Patients with tricuspid valvular disease or a mechanical tricuspid valve. Patients with ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated.

Potential Adverse Events: Possible adverse events associated with the use of transvenous lead systems include, but are not limited to, the following. Refer to the appropriate pulse generator manual for additional complications and precautions specific to the pulse generator.

Arrhythmia (Arrhythmia acceleration, Induced atrial ectopy or arrhythmias, Induced atrioventricular or bundle branch block, Induced ventricular ectopy or arrhythmias, Myocardial irritability), Cardiac perforation (Cardiac tamponade, Perforation of the myocardium, Pericardial effusion), Death, Embolism (Air embolism, Intravascular foreign body, Dislodgement of intracardiac thrombus), Extra-cardiac stimulation (Diaphragmatic stimulation, Stimulation of phrenic nerve), Heart failure (Cardiogenic shock, Right ventricular decompensation, Pacing-induced cardiomyopathy, Tricuspid valve dysfunction), Hemorrhage (Acute hemorrhage/bleeding), Hypersensitivity (Hypersensitivity, including local tissue reaction or allergic reaction), Infection (Endocarditis, Pericarditis), Lead revision or reprogramming (Electrical malfunction of the lead, Lead dislodgement, Lead dysfunction (sensing/threshold issue), Mechanical malfunction of the lead, Inappropriate defibrillation therapy), Pleural perforation (Hemothorax, Pneumothorax), Pocket Erosion (Erosion of the skin, Extrusion), Prolonged exposure to fluoroscopic radiation, Seroma (Fluid accumulation), Tissue necrosis, Tricuspid valve perforation, Vascular perforation (Arteriovenous fistula, Arterial perforation, Coronary sinus or coronary vein

perforation, Hematoma, Venous perforation), Vascular Thrombosis (Venous thrombosis and/or obstruction, Venous occlusion). The physician should discuss the patient's potential adverse events with them.

Quadra Allure MP™ Cardiac Resynchronization Therapy Pacemaker

Indications/Intended Use: Implantation of a CRT-P is indicated for: maintaining synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic atrial fibrillation and have NYHA Class II or III heart failure; the reduction of the symptoms of moderate to severe heart failure (NYHA Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration. Implantation of a single chamber pulse generator, dual-chamber pulse generator, or CRT-P is indicated in one or more of the following permanent conditions, or any combination of these symptoms: syncope, presyncope, fatigue, disorientation. Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-Chamber Pacing is indicated for those patients exhibiting: sick sinus syndrome; chronic, symptomatic second- and third-degree AV block; recurrent Adams-Stokes syndrome; symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial Pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular Pacing is indicated for patients with significant bradycardia and: normal sinus rhythm with only rare episodes of AV block or sinus arrest; chronic atrial fibrillation; severe physical disability. AF Suppression™ algorithm stimulation is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: Implanted Cardioverter-Defibrillator (ICD). CRT-Ps are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression algorithm stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. Dual-chamber Pacing, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. Single-chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-chamber Atrial Pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction. For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: air embolism; body rejection phenomena; cardiac tamponade or perforation; hematoma, bleeding hematoma, seroma; formation of fibrotic tissue, local tissue reaction; inability to interrogate or program due to programmer or device malfunction; infection; erosion; interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic; lead malfunction due to conductor fracture or insulation degradation; loss of capture or sensing due to lead dislodgement or reaction at the electrode/ tissue interface; loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation); loss of normal device function due to battery failure or component malfunction; pacemaker migration or pocket erosion; pectoral muscle or diaphragmatic stimulation; phrenic nerve stimulation; pneumothorax/hemothorax; endocarditis; excessive bleeding; induced atrial or ventricular arrhythmias; myocardial irritability; pericardial effusion; pericardial rub; pulmonary edema; rise in threshold and exit block; valve damage; cardiac/coronary sinus dissection; cardiac/coronary sinus perforation; coronary sinus or cardiac vein thrombosis; death.

Quartet™ LV Lead

Indications and Usage: The Quartet™ leads are 5.1 French, transvenous, steroid eluting, quadripolar, IS4 compatible (single connector with four electrical terminals), passive fixation leads intended for permanent sensing and pacing of the left ventricle when used with a compatible Abbott Medical biventricular system with an IS4-LLLL lead receptacle designation.

Contraindications: The use of the Quartet LV lead is contraindicated in patients who:
- Are expected to be hypersensitive to a single dose of 1.0 mg of dexamethasone sodium phosphate.
- Are unable to undergo an emergency thoracotomy procedure.
- Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

Adverse Events: Potential adverse events associated with the use of left ventricular leads include: Allergic reaction to contrast media, Body rejection phenomena, Cardiac/coronary sinus dissection , Cardiac/coronary sinus perforation, Cardiac tamponade, Coronary sinus or cardiac vein thrombosis, Death, Endocarditis, Excessive bleeding, Hematoma/seroma, Induced atrial or ventricular arrhythmias, Infection, Lead dislodgment, Local tissue reaction; formation of fibrotic tissue, Loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead, Myocardial irritability, Myopotential sensing, Pectoral/diaphragmatic/ phrenic nerve stimulation, Pericardial effusion, Pericardial rub, Pneumothorax/hemothorax, Prolonged exposure to fluoroscopic radiation, Pulmonary edema Renal failure from contrast media used to visualize coronary veins, Rise in threshold and exit block, Thrombolytic or air embolism, Valve damage Performance of a coronary sinus venogram is unique to lead placement in the cardiac venous system, and carries risks. Potential complications reported with direct subclavian venipuncture include hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage, and rarely, death.

QuickFlex™ Left Heart Leads

Indications/Intended Use: The QuickFlex™ µ Model 1258T leads are 4.7 French, transvenous, steroid eluting, bipolar, IS-1 compatible, S-shaped curve, passive fixation leads intended for permanent sensing and pacing of the left ventricle when used with a compatible Abbott Medical biventricular system.

Contradictions: The use of QuickFlex™ µ lead is contraindicated in patients who:

- Are expected to be hypersensitive to a single dose of 1.0 milligram of dexamethasone sodium phosphate
- Are unable to undergo an emergency thoracotomy procedure
- Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

Potential Adverse Events: Potential adverse events associated with the use of the QuickFlex™ µ Model 1258T include: Allergic reaction to contrast media, body rejection phenomena, cardiac/coronary sinus dissection, cardiac/coronary sinus perforation, cardiac tamponade, coronary sinus or cardiac vein thrombosis, death, endocarditis, excessive bleeding, hematoma/seroma, induced atrial or ventricular arrhythmias, infection, lead dislodgement, local tissue reaction; formation of fibrotic tissue, loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead, myocardial irritability, myopotential sensing, pectoral/diaphragmatic/phrenic nerve stimulation, pericardial effusion, pericardial rub, pneumothorax/hemothorax, pulmonary edema, renal failure from contrast media used to visualize coronary veins, rise in threshold and exit block, thrombolytic or air embolus, valve damage. Performance of a coronary sinus venogram is unique to lead placement in the cardiac venous system, and carries risks. Potential complications reported with direct subclavian venipuncture include hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage, and rarely, death.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions, and potential adverse events.

Tendril™ STS Pacing Leads

Intended Use: Tendril™ STS Model leads are bipolar, steroid eluting, active fixation implantable leads intended for use with an implantable pulse generator to provide long-term cardiac pacing and sensing in either the right atrium, and/or the right ventricle. They are also intended for long-term sensing and pacing in the left ventricular bundle branch area as an alternative to right ventricular pacing.

Indications: Tendril™ STS leads are indicated for use in combination with a compatible pacemaker, implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT-P/CRT-D) device to provide sensing and pacing for the management of chronic symptomatic bradycardia and various atrioventricular conduction abnormalities in patients who experience syncope, presyncope, fatigue, or disorientation due to arrhythmia/bradycardia, or any combination of these symptoms. The Tendril STS leads are implanted transvenously in either the right atrium, the right ventricle or the left bundle branch area.

Contraindications: Tendril™ STS Model 2088TC leads are contraindicated: in the presence of tricuspid atresia (if the lead is to be positioned in the right ventricle or left bundle branch area), for patients with mechanical tricuspid valves (if the lead is to be positioned in the right ventricle or left bundle branch area), in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Adverse Effects: Potential adverse effects and their categories as applicable when using an Tendril™ STS lead include: Arrhythmia (Accelerated arrhythmia, Induced atrial ectopy or arrhythmias, Induced atrioventricular or bundle branch block, Induced ventricular ectopy or asystole, Myocardial irritability), Cardiac perforation (Cardiac tamponade, Pericardial Effusion, Pericarditis, Septal perforation), Death, Embolism (Air embolus, Dislodgement of intracardiac thrombus, intravascular foreign body), Extra-cardiac stimulation, Heart failure (Right ventricular decompensation, Tricuspid valve dysfunction/Tricuspid valve regurgitation/ insufficiency), Hypersensitivity (Hypersensitivity, including local tissue reaction or allergic reaction), Infection (Endocarditis), Lead revision or reprogramming resulting from, but not limited to, loss of pacing and/ or sensing (Electrical malfunction of the lead, Lead dislodgement, Lead dysfunction (sensing/threshold Issue), Mechanical malfunction of the lead), Lung perforation (Hemothorax, Pneumothorax), Pulmonary edema, Prolonged exposure to fluoroscopic radiation, Respiratory compromise, Tricuspid value perforation, Vascular injury (Arterial perforation, Arteriovenous fistula, Coronary sinus or coronary vein perforation/dissection, Hemorrhage/ Hematoma at device site, Venous perforation, Septal hematoma), Vascular thrombosis/ stenosis/ occlusion.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

UltiPace™ Pacing Leads

Intended Use: UltiPace™ leads are bipolar, steroid eluting, active fixation implantable leads intended for use with an implantable pulse generator to provide long-term cardiac pacing and sensing in either the right atrium, and/or the right ventricle. They are also intended for long-term sensing and pacing in the left ventricular bundle branch area as an alternative to right ventricular pacing.

Indications: UltiPace™ leads are indicated for use in combination with a compatible pacemaker, implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT-P/CRT-D) device to provide sensing and pacing for the management of chronic symptomatic bradycardia and various atrioventricular conduction abnormalities in patients who experience syncope, presyncope, fatigue, or disorientation due to arrhythmia/bradycardia, or any combination of these symptoms. The UltiPace leads are implanted transvenously in either the right atrium, the right ventricle or the left bundle branch area.

Contraindications: UltiPace™ Model LPA1231 leads are contraindicated: in the presence of tricuspid atresia (if the lead is to be positioned in the right ventricle or left bundle branch area); for patients with mechanical tricuspid valves (if the lead is to be positioned in the right ventricle or left bundle branch area); in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Potential Adverse Effects: Potential adverse effects and their categories as applicable when using an UltiPace™ lead include: Arrhythmia (Accelerated arrhythmia, Induced atrial ectopy or arrhythmias, Induced atrioventricular or bundle branch block, Induced ventricular ectopy or asystole, Myocardial irritability), Cardiac perforation (Cardiac tamponade, Pericardial Effusion, Pericarditis, Septal perforation), Death, Embolism (Air embolus, Dislodgement of intracardiac thrombus, intravascular foreign body), Extra-cardiac stimulation, Heart failure (Right ventricular decompensation, Tricuspid valve dysfunction/Tricuspid valve regurgitation/ insufficiency), Hypersensitivity (Hypersensitivity, including local tissue reaction or allergic reaction), Infection (Endocarditis), Lead revision or reprogramming resulting from, but not limited to, loss of pacing and/ or sensing (Electrical malfunction of the lead, Lead dislodgement, Lead dysfunction (sensing/threshold Issue), Mechanical malfunction of the lead), Lung perforation (Hemothorax, Pneumothorax), Pulmonary edema, Prolonged exposure to fluoroscopic radiation, Respiratory compromise, Tricuspid value perforation, Vascular injury (Arterial perforation, Arteriovenous fistula, Coronary sinus or coronary vein perforation/dissection, Hemorrhage/ Hematoma at device site, Venous perforation, Septal hematoma), Vascular thrombosis/ stenosis/ occlusion.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Abbott
15900 Valley View Court, Sylmar, CA 91342
Tel: +1 818 362 6822
Cardiovascular.Abbott

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