Abbott

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

Longest Lasting Bluetooth® ICM.*
Clinically Actionable Data. IQ Insights.
Remote Programmability.

This leading innovation is the longest lasting Bluetooth® ICM with full functionality and no compromises in performance.[1-8] The ICM system detects arrhythmias more accurately,[9-11] shows electrogram (EGM) details more clearly,†† and gives 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.†

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 12.31.23. Reveal LINQ‡ User Manual, LUX-Dx‡ User Manual, LUX-Dx II/III+‡ 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.[12-13] 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

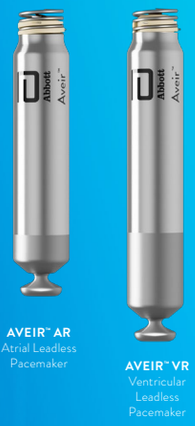
PACEMAKERS

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[14] with implant-to-implant (i2i™) communication between atrial and ventricular LPs that provides continuous beat-to-beat AV synchrony. The system is upgradeable[15] from single to dual chamber leadless pacing with mapping prior to fixation capabilities.[17] The devices are 1.5T and 3T MR Conditional.



AVEIR™ AR
Atrial Leadless Pacemaker

AVEIR™ VR
Ventricular Leadless Pacemaker

AVEIR™ AR Atrial Leadless Pacemaker

Supported by Merlin™ 3650 Patient Care System.

AAI(R) Pacing. Upgradeable System.

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 world's first atrial leadless pacemaker.[14] AVEIR AR Atrial LP offers a safe,[17] effective,[17] and upgradeable[15] pacing solution for patients with sinus node dysfunction and normal AV and intraventricular conduction systems.

AVEIR™ VR Ventricular Leadless Pacemaker

Supported by Merlin™ 3650 Patient Care System.

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

A next-generation leadless pacemaker that has an active helical fixation designed for long-term retrieval,[16] a battery with up to twice the projected capacity as other VR leadless pacemakers on the market,[18-19] and mapping capabilities designed to help reduce the number of repositioning attempts.[20] The device is 1.5T and 3T MR Conditional and upgradeable to a dual chamber leadless system.[18]

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.

Small and long lasting pacemaker that helps reduce infection risk and complications due to device replacement and pocket size. No-wait 1.5T and 3T MRI scan capability allows for patient management flexibility.†

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.*

†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 a newly engineered pacing lead 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.[22] 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 technology to provide a new level of secure fixation and advanced lead protection. It delivers the confidence you need with actively monitored, long-term data that shows a 92.21% lead survival rate at 134 months[23] while allowing patients to undergo a no-wait 1.5T or 3T MRI scan when used in conjunction with Abbott MRI-ready† devices. Now 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

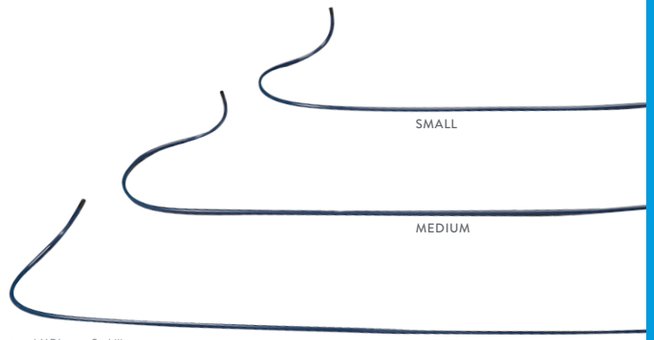
DELIVERY TOOLS

Helix Locking Tool

A novel accessory designed to aid with lead fixation by providing control over extension and retraction of the helix.[22] The Helix Locking Tool is a proven solution to lock an extended helix in place during tissue burrowing without retraction.

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. Compatible with 6 F stylet driven leads, such as UltiPace Pacing Leads.



†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 DF-4 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™ ICD

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 DeFT Response™ technology, which helps protect patients with a tailored waveform published rate of 100% 10J safety margin success.[24] These devices feature smartphone connectivity and 40 J max shock. In addition, these devices are no-wait 1.5T and 3T MR Conditional.†

Entrant™ ICD

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 LEAD

Durata™ Defibrillation Lead

A cardiac lead designed to offer high-performance handling, more control at implant, and a proven platform of long-term durability[24] with Optim™ lead insulation in a thin, 7 F sizing. More than 13 years of proven performance with 99% freedom from all-cause insulation abrasion at 12 years.[25] The DF-4 connector header has a single terminal pin connection, which decreases chances of lead-to-port mismatch. This lead allows patients to undergo a no-wait 1.5T or 3T MRI scan when used in conjunction with Abbott MRI-ready† ICDs and CRT-Ds.

ACTIVE

PASSIVE

SINGLE COIL

DUAL COIL

†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 DF-4 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, Merlin@home™ Transmitter, 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 technology and MultiPoint™ Pacing that provides options to achieve the narrowest QRS and gives 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.†

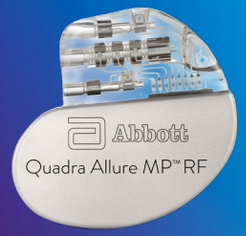
Entrant™ HF CRT-D

Featuring SyncAV CRT technology and designed to achieve narrower QRS 100% of the time,[26] 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. MRI compatible to 1.5T.†



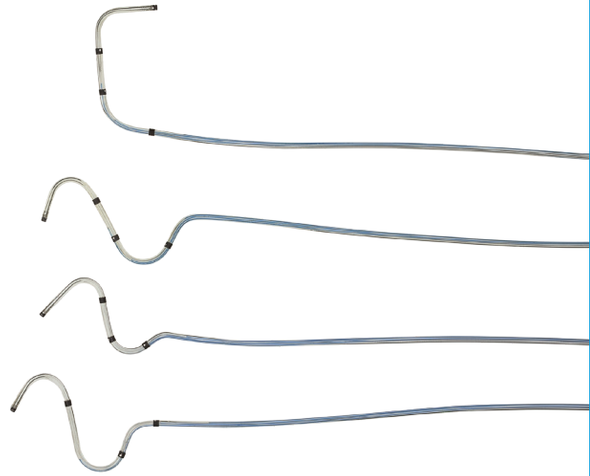
†No minimum length of time requirement between implant and MRI scan. Stability of pacing capture thresholds is required prior to MRI scan. See MRI-Ready Systems Manual for device and lead combinations and associated MRI scan parameters.

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. 4.7 F lead body diameter for maneuverability. More total electrode spacing options include 40, 47, and 60 mm.



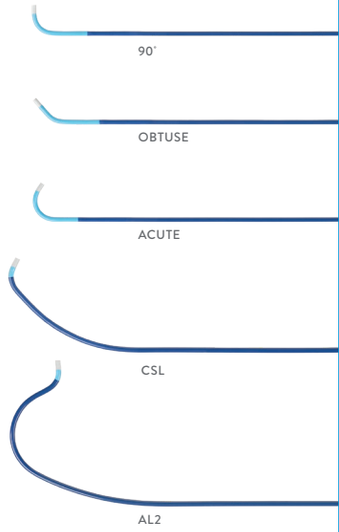
QuickFlex™ Lead

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

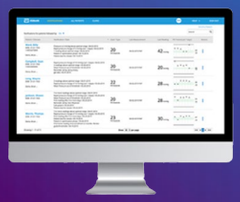
DELIVERY TOOLS

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 CPS™ Universal II Slitter and CPS Aim™ Universal II Catheter available in five curve shapes.



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. 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. Merlin 2 PCS supports informed clinical decisions so you can deliver comprehensive care. 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

Merlin@home™ Transmitter

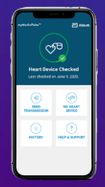
Capable of monitoring compatible Abbott CRM devices daily, this transmitter enables patients to send data to Merlin.net from the comfort of their own home. The Merlin@home transmitter can reduce the number of scheduled clinic visits a patient may need by automatically sending alert-initiated and scheduled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

MerlinOnDemand™ Capability Transmitter

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 insertable cardiac monitors can use their iPhone‡ or Android‡ smartphone to send data from their heart device to Merlin.net.* 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.[27]



myMerlinPulse™ Mobile App

The myMerlinPulse Mobile App connects with the latest Bluetooth®-enabled ICDs and CRT-Ds from Abbott: Gallant™, Entrant™. The app can be used with your patient's compatible 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 compatible 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

Abbott ICM

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.

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.

Assert-IQ™ ICM

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.

Indications for Use: The Assert-IQ™ ICM is 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.

The Assert-IQ ICM is also indicated for patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF. The Assert-IQ ICM is intended to be inserted subcutaneously in the left pectoral region, also described as the left anterior chest wall. The Assert-IQ ICM has not been specifically tested for pediatric use.

Intended Use: The Assert-IQ ICM is 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 the Assert-IQ ICM. 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. ™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Bluetooth and Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

Assurity™ MRI Pacemaker

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.

Indications: Implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. 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 A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. AF Suppression algorithm is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: 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™ 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: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue/local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, 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, device migration, pocket erosion or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, palpitations with high-rate pacing.

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

AVEIR™ Leadless Pacemaker System

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.

Indications: The AVEIR™ Leadless Pacemaker system is indicated for management of one or more of the following permanent conditions: Syncope, Pre-syncope, 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 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. 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/or 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, 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 the 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.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

CPS Aim™ Universal II Catheter

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.

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

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.

Indications: 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.

Complications: Possible complications include, but are not limited to, the following: exposure to x-ray radiation, adverse or allergic reaction to contrast agents, infection, hematoma, pneumothorax, embolization, vessel thrombosis, dissection, acute occlusion, clot formation, hemorrhage, vessel rupture, arrhythmia or heart block, hemodynamic changes, myocardial infarction, perforation of the heart, cardiac tamponade, stroke, and death.

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

Durata™ Family of Defibrillation Leads

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.

Indications and Usage: The Durata lead is intended for permanent sensing and pacing of the right ventricle and the delivery of cardioversion/defibrillation therapy when used with a compatible Abbott pulse generator.

Contraindications: Durata 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.

Adverse Events: Potential adverse events include: cardiac tamponade, hemorrhage, pneumothorax, air embolism, venous thrombosis and/or obstruction, tissue necrosis, tricuspid valve dysfunction, infection.

Entrant™ and Gallant™ HF CRT-D

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.

Intended Use: The Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are intended to provide ventricular antitachycardia pacing and ventricular cardioversion/defibrillation. The CRT-D devices are also intended 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: The CRT-D devices are indicated for automated treatment of life-threatening ventricular arrhythmias. CRT-D devices are also indicated to treat symptoms in patients who have congestive heart failure with ventricular dyssynchrony.

In addition, CRT-D devices with the AT/AF detection algorithm are indicated in patients with atrial tachyarrhythmias or those patients who are at significant risk of developing atrial tachyarrhythmias.

MR Conditional CRT-Ds are conditionally safe for use in the MRI environment when used in a complete MR Conditional system and according to instructions in the MRI-Ready Systems manual. Scanning under different conditions may result in severe patient injury, death or device malfunction.

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

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

Entrant™ and Gallant™ ICD

Rx Only

Intended Use: The Implantable Cardioverter Defibrillator (ICD) devices are intended to provide ventricular antitachycardia pacing and ventricular cardioversion/defibrillation.

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 for automated treatment of life-threatening ventricular arrhythmias.

In addition, dual chamber ICD devices with the AT/AF detection algorithm are indicated in patients with atrial tachyarrhythmias or those patients who are at significant risk of developing atrial tachyarrhythmias.

MR Conditional ICDs are conditionally safe for use in the MRI environment when used in a complete MR Conditional system and according to instructions in the MRI-Ready Systems manual. Scanning under different conditions may result in severe patient injury, death or device malfunction.

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

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

Gallant™ ICD and CRT-Ds with DF-1 Headers

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.

Intended Use: The Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are intended to provide ventricular antitachycardiapacing and ventricular cardioversion/defibrillation. The CRT-D devices are also intended 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: The ICD and CRT-D devices are indicated for automated treatment of life-threatening ventricular arrhythmias. CRT-D devices are also indicated to treat symptoms in patients who have congestive heart failure with ventricular dyssynchrony.

In addition, dual chamber ICD and CRT-D devices with the AT/AF detection algorithm are indicated in patients with atrial tachyarrhythmias or those patients who are at significant risk of developing atrial tachyarrhythmias. MR Conditional ICDs and CRT-Ds are conditionally safe for use in the MRI environment when used in a complete MR Conditional system and according to instructions in the MRI-Ready Systems manual. Scanning under different conditions may result in severe patient injury, death or device malfunction. 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 antitachycardiapacing [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. Refer to the User's Manual for detailed intended use, indications, contraindications, warnings, precautions and potential adverse events. No potential adverse events have been identified with use of the myMerlinPulse™ mobile application.

† Competition defined as LV Only and BiV Simultaneous pacing modes. Modes 1 and IV of the referenced JAHA data. Numbers were rounded up for graphic representation.

§ Fixed-tilt group of patients with competitive devices only achieved 83% success for maintaining a 10J safety margin.

* For additional information about specific MR Conditional ICDs and leads, including scan parameters, warnings, precautions, adverse conditions to MRI scanning, and potential adverse events, please refer to the Abbott MRI-Ready Systems Manual at medical.abbott/manuals.

** No Loss of CRT therapy only applicable for model numbers CDHFA500Q, CDHFA500T, CDHFA300Q, and CDHFA300T.

IsoFlex™ Optim™ Pacing Lead

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.

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.

Quadra Allure MP™ Cardiac Resynchronization Therapy Pacemaker

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. Devices depicted may not be available in all countries. Check with your Abbott representative for product availability in your country.

Indications: Implantation of Quadra Allure MP device 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): devices 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.

Quartet™ LV Lead

Rx Only

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

Indications and Usage: The Quartet LV lead is intended for permanent sensing and pacing of the left ventricle when used with a compatible Abbott biventricular system.

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: 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, myocardial irritability, myopotential sensing, pectoral/diaphragmatic/phrenic nerve stimulation, pericardial effusion, pericardial rub, pneumothorax/hemothorax, pulmonary edema, thrombolytic or air embolism, valve damage.

QuickFlex™ Left Heart Leads

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.

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

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.

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 associated with the use of Tendril™ leads are the same as with the use of other active fixation leads and 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. The physician should discuss the patient's potential adverse events with them.

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

UltiPace™ Pacing Leads

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.

Indications: UltiPace™ leads are indicated for use in combination with a compatible pacemakers, implantable cardioverter defibrillator (ICDs) or cardiac resynchronization therapy (CRT-P/CRT-D) to provide sensing and pacing for the management of chronic symptomatic bradycardia and various atrioventricular conduction abnormalities in patients who experience syncope, presyncope, fatigue, 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™ 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 associated with the use of UltiPace™ leads are the same as with the use of other active fixation leads and 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. The physician should discuss the patient's potential adverse events with them.

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

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