



**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 & Cardiac Resynchronization Therapy Devices and intelligent Insertable Cardiac Monitors – with enhanced connectivity. Together, they 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 patient.



## 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, Merlin™ Patient Care System, SyncUP™ Remote Monitoring Support 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. The ICM System detects arrhythmias more accurately,<sup>1-3</sup> shows electrogram (EGM) details more clearly<sup>††</sup> and gives additional insights for more informed decision making<sup>‡</sup> – all with a 3-year or 6-year battery-life device with remote programming capabilities in most models. This device allows patients to undergo a no wait 1.5T or 3T MRI scan.<sup>‡</sup>



## 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.<sup>‡</sup>



\*As of 12.31.22. Reveal LINQ<sup>2</sup> User Manual, LINQ II<sup>2</sup> User Manual, Lux Dx<sup>2</sup> User Manual, Biomonitor III<sup>2</sup> User Manual, Biomonitor III<sup>m</sup> User Manual.

\*\*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 implantation device 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. This transformational blade made with Japanese steel and asymmetric blade design gives you the sharpness and efficiency you need.<sup>5,6</sup> Plastic surgeons guided the design and Electrophysiologists verified an improved incision appearance which may help reduce scarring.



# PACEMAKERS

## AVEIR™ DR Dual Chamber Leadless Pacemaker System

Supported by Merlin™ Patient Care System

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

The world's first dual chamber leadless pacemaker (LP) system<sup>7</sup> with implant-to-implant (i2i™) communication between atrial and ventricular LPs that provides continuous beat-to-beat AV synchrony. The system is upgradeable<sup>8</sup> with long-term retrieval<sup>9</sup> and mapping prior to fixation capabilities.<sup>10</sup> Devices are 1.5T and 3T MR Conditional.



## AVEIR™ VR Leadless Pacemaker

Supported by Merlin™ Patient Care System

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

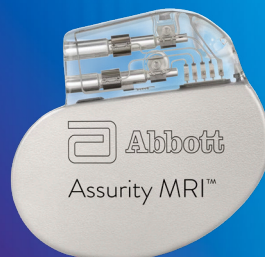
A next-generation leadless pacemaker that has an active helical fixation designed for long-term retrieval,<sup>9</sup> a battery projected to last up to twice as long as other VR leadless pacemakers in the market based on ISO standard settings<sup>11-12\*\*</sup> and mapping capabilities designed to help reduce the number of repositioning attempts.<sup>13-14</sup> Device is 1.5T and 3T MR Conditional.



## Assurity MRI™ Pacemaker

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

Small and long lasting pacemaker 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.†



\*\*ISO standard settings: VVIR, 60bpm, 2.5V @0.4 ms, 600 Q, 100% pacing.

†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  
LOW VOLTAGE SOLUTIONS



# PACING LEADS

## Tendril™ STS

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<sup>15</sup> while allowing patients to undergo a no-wait 1.5T or 3T MRI scan when used in conjunction with Abbott MRI-Ready† devices.



## IsoFlex™ OPTIM™

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 straight or J-shape in multiple lengths to accommodate varying needs and patient anatomies.



# DELIVERY TOOLS

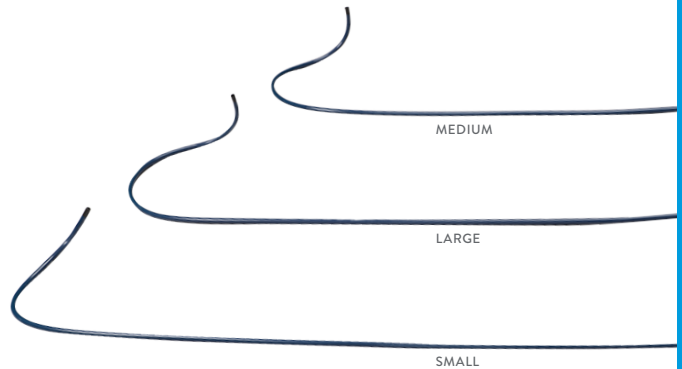
## HELIX LOCKING TOOL

The Helix Locking Tool is designed to aid with lead fixation by providing control over the extension and retraction of the helix.



## CPS Locator™ 3D CATHETERS

The CPS Locator 3D catheters offer three unique distal curves to accommodate various anatomies. They are designed to accept 6 Fr stylet-driven leads, such as the Tendril STS, which provides more control during lead delivery to your right ventricular location of choice.



†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)

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

## Gallant™ ICD

This small, lightweight device is 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 at a published rate of 10J Safety Margin Success.<sup>16</sup> These devices feature smartphone connectivity and 40J max shock. Device is 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 36J 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™

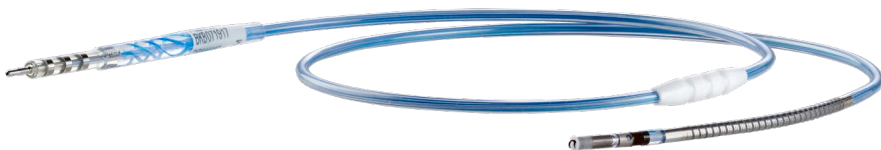
A cardiac lead designed to offer high-performance handling, more control at implant and a proven platform of long-term durability<sup>16</sup> with Optim™ lead insulation in a thin, 7 Fr sizing. More than 13 years of proven performance with 99% of freedom from all-cause insulation abrasion at 12 years.<sup>17</sup> The DF4 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 an 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

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

## 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. Device is no-wait 1.5T and 3T MR Conditional.†



### Entrant™ HF CRT-D

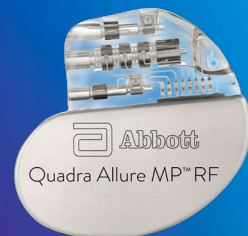
Featuring SyncAV™ CRT technology and designed to achieve narrower QRS 100% of the time,<sup>19</sup> this small, contoured device is no-wait 1.5T and 3T MR Conditional.†



## PACEMAKERS (CRT-P)

### Quadra Allure MP™ CRT-P

This device offers SyncAV™ CRT technology to achieve 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.

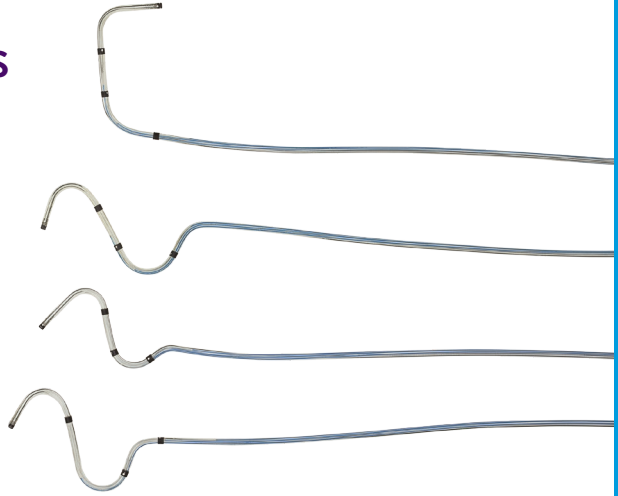


LEARN MORE ABOUT OUR CARDIAC RESYNCHRONIZATION THERAPY SOLUTIONS

# LEFT VENTRICULAR LEADS

## Quartet™ FAMILY 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 includes 40, 47 and 60 mm.



## QuickFlex™

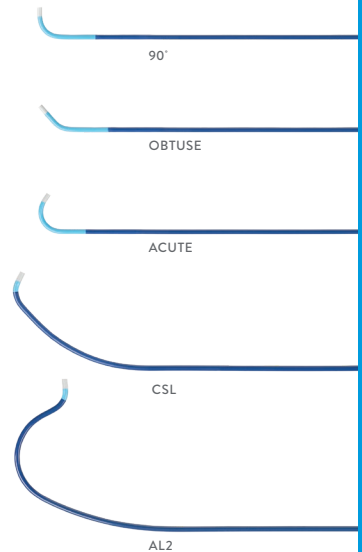
Featuring a steerable tip and flexible lead body, this low-profile LV lead offers deliverability and stability. 4.3 F lead body diameter. Ring-to-tip electrode spacing of 20 mm.



# DELIVERY TOOLS

## CPS™ CARDIAC POSITIONING FAMILY

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 remotely monitor 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 transmission schedules.



## Merlin™ PATIENT CARE SYSTEM (PCS)

This portable system designed to interrogate, monitor and program a patient's device quickly and accurately during implant and follow up allows for faster patient management with a touch screen that clearly displays programming and diagnostics.



## Merlin™ 2 PATIENT CARE SYSTEM (PCS)

This programmer features Bluetooth® wireless technology and is a cyber secure solution designed to streamline your workflow, which supports informed clinical decisions and delivers 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 Abbott devices. They connect directly with your patients to set up their Abbott remote monitoring apps.



LEARN MORE ABOUT OUR  
CONNECTIVITY SOLUTIONS



### Merlin@home™ TRANSMITTER

Allowing your patient to have their device checked from the comfort of their own home, this transmitter reduces the number of scheduled clinic visits and is also able to monitor your patient's device daily between scheduled follow-ups while alerting your clinic if it detects important events.



### MerlinOnDemand™ CAPABILITY TRANSMITTER

Transmitters with this capability enabled can promptly interrogate your patient's implanted cardiac device in a hospital setting and deliver printed reports without an Abbott representative on site.



### myMerlin™ MOBILE APP

This accompanies Abbott's Bluetooth®-enabled insertable cardiac monitors and is compatible with your patient's iPhone<sup>†</sup> or Android<sup>‡</sup> smartphone.\* 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.<sup>19</sup>



### myMerlinPulse™ MOBILE APP

The myMerlinPulse™ mobile app accompanies the latest Bluetooth®-enabled ICDs and CRT-Ds from Abbott, Gallant™ and Entrant™\*. The app is compatible with your patient's iPhone<sup>†</sup> or Android<sup>‡</sup> smartphone. When paired with your patient's implanted Gallant or Entrant device, the app empowers you and your patient with a mobile solution that encourages continuous, reliable engagement with remote monitoring.

*\*Refer to the myMerlin™ 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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™ Indicates a trademark of the Abbott group of companies.

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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:** Abbott Insertable Cardiac Monitors (ICMs) are indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. Abbott ICMs are also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation. Abbott ICMs have not been specifically tested for pediatric use.

**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.

**Adverse Events:** Possible adverse events (in alphabetical order) associated with these devices, 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, contraindications, warnings, precautions and potential adverse events.

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

### 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.

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## 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

**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.

## **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  $\leq 35\%$  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.

## Tendril Family of 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:** The Tendril STS™ Model 2088TC and Tendril MRI™ Model LPA1200M leads are designed for permanent sensing and pacing in either the right atrium or the right ventricle, in combination with a compatible device. Active leads such as the Tendril STS Model 2088TC and Tendril MRI Model LPA1200M leads may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of the screw-in leads such as Tendril STS Model 2088TC and Tendril MRI Model LPA1200M leads may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

**Contraindications:** The Tendril STS Model 2088TC and Tendril MRI Model LPA1200M leads are contraindicated: in the presence of tricuspid atresia, for patients with mechanical tricuspid valves, in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

**Adverse Events:** Potential complications associated with the use of Tendril STS Model 2088TC and Tendril MRI Model LPA1200M leads are the same as with the use of other active fixation leads and include: cardiac tamponade, diaphragmatic stimulation, embolism, excessive bleeding, induced ventricular ectopy, infection, loss of pacing and/or sensing due to dislodgement or mechanical malfunction of the pacing lead, phrenic nerve stimulation, thrombosis.

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



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