Abbott

GALLANT™ ICDs & CRT-Ds

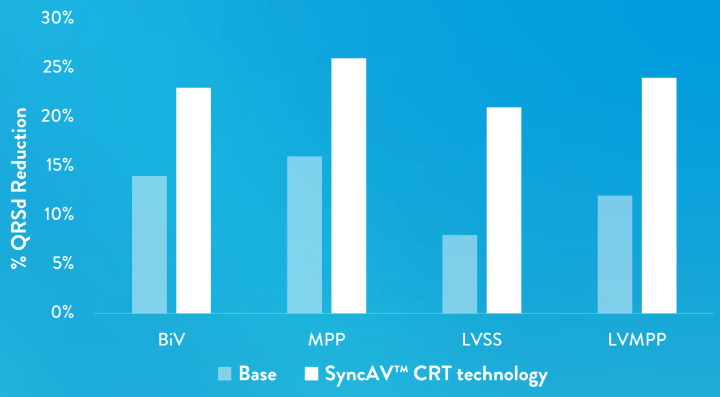
Right Energy, Right Time with ***Precision Shock Technology***

Right Energy. Right Time. For greater first-shock success.[1]

Precision Shock Technology delivers the right energy within the right time for greater first-shock success.[1-9] Clinical data demonstrated patients programmed with optimized *Precision Shock Technology* significantly improved first-shock success by **14%**.[1]

Proven to Provide Narrower QRS and Reduce HF Hospitalizations.[10, 11]

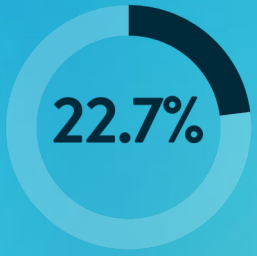
SyncAV™ CRT technology delivers near 2x the median acute QRSd improvement compared to off-the-shelf AV delays, regardless of pacing mode.[10] HF hospitalization rates significantly reduce by 22% at 2 years with SyncAV CRT technology ON vs OFF.[11]



MR Conditional with LBB Lead**

MR conditional with UltiPace™ Pacing Lead in the left bundle branch (LBB) area when used in the LV IS-1 port.**

With Abbott-exclusive **No Wait 1.5T and 3T MRI**, ensure your patients can get the scans they need, when they need it.†



of MRI scans are urgent or emergent.[13]

IMPLANT TODAY, 1.5T AND 3T MRI READY TOMORROW.†

Abbott's 1.5T and 3T MRI-ready solutions ensure no loss of CRT therapy for your patients during full-body scans and allows for programming of an MRI timeout.***

READY TO MAKE A CHANGE?

Scan to learn more at
cardiovascular.abbott/builtforpatients

† No minimum length of time requirement between implant and MRI scan. Stability of pacing capture thresholds is required prior to MRI scan.

*Median % of shock success evaluated paired, intra-patient differences in shock success rate and delivered energy were evaluated.

** MR conditional with our UltiPace™ Pacing Lead in the left bundle branch area (LBBA) using LV IS-1 port with Gallant™ and Entrant™ CRT-D models. For additional information about specific MR Conditional ICDs, leads, including scan parameters, warnings, precautions, adverse conditions to MRI scanning, and potential adverse events, please refer to Abbott MRI-Ready Systems Manual at manuals.eifu.abbott.

*** No Loss of CRT therapy only applicable for select Gallant™ CRT-D models.

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

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

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

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

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

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

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

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

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

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