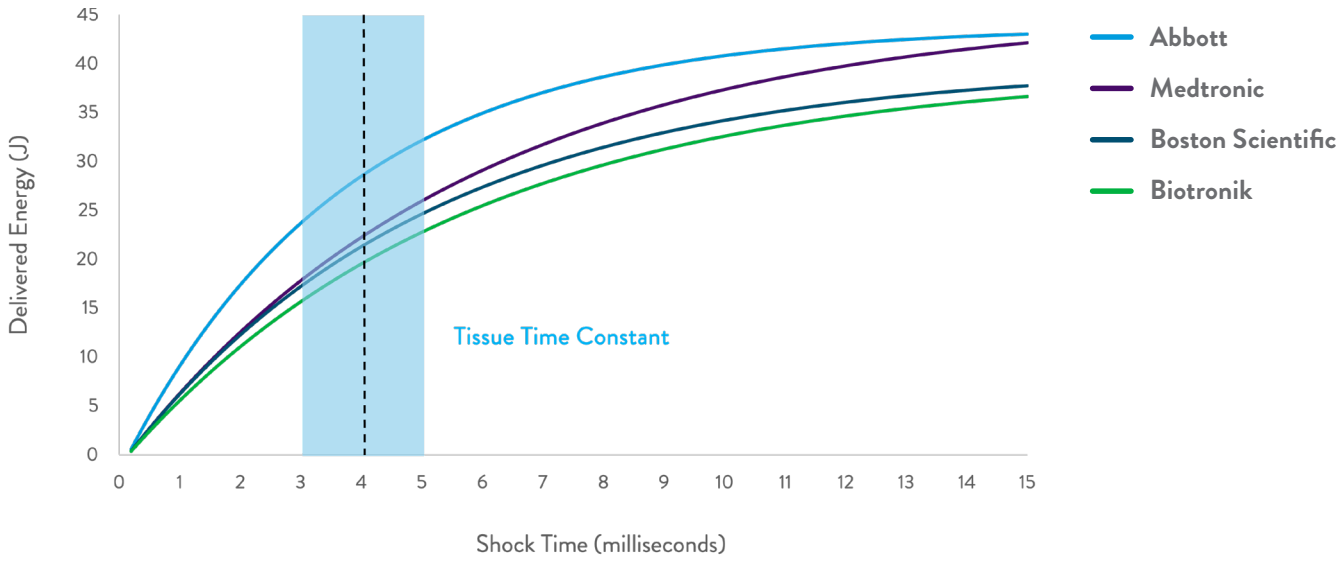
GALLANT™ AND ENTRANT™ ICDs & CRT-Ds

Precision Shock Technology

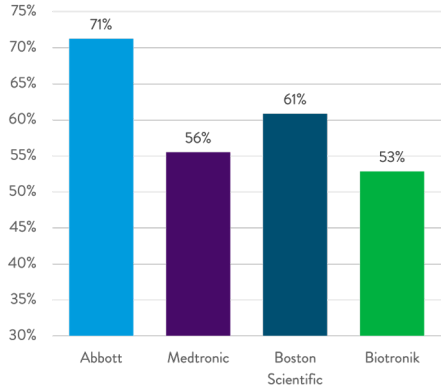
Right Energy. Right Time. For greater first-shock success.[1]

Timing is everything when shocking a patient out of VF. *Precision Shock Technology* delivers the right energy within the right time[2-9] for greater first-shock success.[1] Any energy outside this response window is wasted.

Delivered Energy vs. Time*



% of Effective Energy Delivered at 4 ms*



Precision Shock Technology is uniquely designed to optimize the energy delivery profile. Abbott devices deliver the highest voltage on the market[10] and discharge more energy earlier.

Abbott	Medtronic	Boston Scientific	Biotronik
894 V	728 V	728 V	684V

*Assumes standard 66.3 Ohm patient load at the maximum rated shock energy at Efficiency = Delivered to Stored Energy Ratio. These graphs are simulated using publicly available data from IFUs, Methods and data on file. Simulated model presents ~±6% variance on delivered energy. (Engineering Test Report 91111487 Rev. C)

Improved Shock Efficacy Using Optimized *Precision Shock Technology*[1]

295 PATIENTS

Optimized
Precision Shock Technology
vs. Out-of-the-box.[1]

Clinical data demonstrated patients programmed with optimized *Precision Shock Technology* significantly improved first-shock success by ***14%***.[1]

Optimizing *Precision Shock Technology* by programming patient-specific shock pulse widths achieved a ***100%**** success in first-shock conversion rates.[1]

To learn more about our **ICD & CRT-D Solutions**, please contact your local Abbott Sales Representative.

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

References:

1. Improved ICD Shock Efficacy using Programmable Pulse Width. Michael Katcher, MD; Kevin Davis, BS; Nima Badie, PhD; Luke C. McSpadden, PhD; Ulrika Birgersdotter-Green, MD; Jacqueline Joza, MD; Robert Schaller, MD; Gabriel Mouchawar, PhD. Heart Rhythm Society Conference. April 24-27, 2025.
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10. Abbott IFU (Gallant) (ARTEN600312644 A) , Medtronic IFU (Cobalt™): (M029527C001), Boston Scientific IFU(Resonate™, Perciva™, Charisma™, Viglant™, and Momentum™):, Biotronik technical manual (Rivacor™) (439133, Rev. C)

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
Abbott.com

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