NEUTRINO™ NxT ICD

Abbott

POWERFUL
THERAPY ASSURANCE

The Neutrino™ NxT ICD harnesses smartphone connectivity with long- lasting therapy and features you can intuitively program to meet your patients' changing needs.

40J MAX SHOCK

ENHANCED DETECTION AND TREATMENT

of challenging ventricular arrhythmias with Abbott's unique discriminator – VF Therapy Assurance.

DECREASE TIME TO TREATMENT

for arrhythmias in patients who are likely to be hemodynamically unstable.

>800

patients annually with challenging arrhythmias could have their lives saved because of VF Therapy Assurance.[1]

SAFER MANAGEMENT OF CARE

with DeFT Response™ technology – the industry's most flexible option for the management of DFTs.

CUSTOMIZE MATCHING

of shock waveform to patients' cellular response time to lower DFTs.[2]

100%

success in preserving a 10J safety margin with DeFT Response™ technology vs. 83% achievement of 10J safety margin in fixed-tilt group of patients with competitive devices.[2]

REDUCE INAPPROPRIATE THERAPY

with ShockGuard™ technology's optimized ICD arrhythmia detection.

98.4%

of patients did not receive inappropriate shocks at 1 year (CI: 97.2 -99.2, $p<0.0001$).[3]

MR **1.5T AND 3T MRI READY SOLUTIONS***

NEUTRINO™ NxT ICD

EMPOWERING YOU.
EMPOWERING YOUR PATIENTS.
POWERED BY ABBOTT.

The myMerlinPulse™ app pairs with the Neutrino™ NxT ICD to streamline remote monitoring and support patient compliance.

97%

of patients using Abbott's app-based remote monitoring were compliant.[4]

*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.

References

1. Data on file. 60101422 Internal Validation Report. Total 2019 global high-voltage implants, all manufacturers, estimated to be 440,434 units (Source: Abbott Market Research).
2. Gabriels J, Budzikowski AS, Kassotis JT. Defibrillation waveform duration adjustment increases the proportion of acceptable defibrillation thresholds in patients implanted with single-coil defibrillation leads. Cardiology. 2013;124(2):71-75.
3. Veltmann C, Wöhrle A, Busch M, et al. Reduction of inappropriate shocks of ICDs with enhanced SVT discriminators. EUROPACE presentation; 2017.
4. Piorkowski C, et al. Early real-world adoption of mobile remote monitoring using the Confirm Rx Insertable Cardiac Monitor. Poster presented at: APHRS; 2018.

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Rx Only

Brief Summary: This product is intended for use by or under the direction of a Physician. 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) 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.

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