

# REACTIVE ATP: NEW DATA DEMONSTRATES BENEFIT ACROSS IPG, ICD, AND CRT DEVICES

Atrial Fibrillation can spontaneously organize to atrial flutter or sinus tachycardia. Reactive ATP™ (rATP) provides an opportunity to terminate an ongoing AF episode by delivering atrial antitachycardia pacing (ATP) during those times when the rhythm has organized and/or slowed. The rATP algorithm is available on current Medtronic dual chamber pacemakers and ICDs, as well as CRT devices.

## WHAT EVIDENCE HAS PREVIOUSLY BEEN GENERATED ON THE EFFICACY OF REACTIVE ATP?

The randomized, controlled MINERVA trial evaluated the effects of rATP in dual chamber pacemaker patients (n = 1,166). All patients had a documented history of AT/AF within 12 months prior to enrollment.

- Key finding: rATP + MVP™ + Atrial Intervention was associated with a **48% relative risk reduction in progression to persistent or permanent AF** over 2 years.<sup>1</sup>
- Secondary finding: rATP + MVP + Atrial Intervention was associated with a 52% reduction in AF-related hospitalizations and ER visits.

## WHAT IS THE NEW EVIDENCE ON REACTIVE ATP?

An analysis of 8,032 U.S. patients in the Medtronic CareLink™ database assessed the impact of rATP across pacemakers, ICDs, and CRT devices.<sup>2</sup>

- Key finding: rATP was associated with a reduction in the progression of AF to  $\geq 1$  day,  $\geq 7$  days, and  $\geq 30$  days across all device types ( $p < 0.001$ )<sup>2</sup>
- This retrospective analysis is the first to **demonstrate rATP's benefit across device types**, and in a **real-world** setting.

## RISK OF AT/AF BETWEEN MATCHED PATIENT GROUPS†

Event	Number of Subjects with Event (2-year Kaplan-Meier Event Rate)		Cox Proportional Hazard Model†	
	Reactive ATP Group (N = 4,016)	Control Group (N = 4,016)	% Relative Risk Reduction	P-Value
AT/AF $\geq 1$ day	1,123 (38.4%)	1,370 (43.0%)	21%	< 0.0001
AT/AF $\geq 7$ days	537 (20.4%)	857 (28.9%)	40%	< 0.0001
AT/AF $\geq 30$ days	306 (12.2%)	584 (20.1%)	49%	< 0.0001

†Model components included group, age, sex, baseline AF, and device type.

Frailty model results were consistent with those from Cox proportional hazard models ( $P > 0.0001$  for all).

<sup>1</sup> Padeletti L, Pürerfellner H, Mont L, et al. New-generation atrial antitachycardia pacing (Reactive ATP) is associated with reduced risk of persistent or permanent atrial fibrillation in patients with bradycardia: Results from the MINERVA randomized multicenter international trial. *Heart Rhythm*. August 2015;12(8):1717-1725.

<sup>2</sup> Hudnall, Harrison. Reactive Atrial-based Antitachycardia Pacing Therapy to Slow Progression of Atrial Fibrillation. August 2017. Medtronic data on file.

## Brief Statement: General Transvenous IPG, CRT-P, ICD, and CRT-D with MRI

### Indications

**Transvenous Implantable Pulse Generators (IPGs)** are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Dual chamber SureScan™ pacing systems are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony.

**Cardiac Resynchronization Therapy (CRT) IPGs** are indicated for NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have a LVEF  $\leq$  35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF  $\leq$  50%, are on stable, optimal heart failure medical therapy if indicated and have atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant.

**Implantable cardioverter defibrillators (ICDs)** are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Some ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

**CRT ICDs** are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications: New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction  $\leq$  35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration  $\geq$  130 ms, left ventricular ejection fraction  $\leq$  30%, and NYHA Functional Class II. NYHA Functional Class I, II, or III and who have left ventricular ejection fraction  $\leq$  50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant. Some CRT ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

### MRI SureScan IPGs, CRT IPGs, ICDs, and CRT ICDs only:

Medtronic SureScan systems are MR Conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use. Patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging. When SureScan systems are programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. A complete SureScan system, which is a SureScan device with appropriate SureScan lead(s), is required for use in the MR environment. To verify that components are part of a SureScan system, visit [www.mrisurescan.com](http://www.mrisurescan.com). Any other combination may result in a hazard to the patient during an MRI scan.

### Contraindications

**Transvenous IPGs and CRT-Ps** are contraindicated for concomitant implantation with another bradycardia device or an implantable cardioverter defibrillator.

**ICDs and CRT-Ds** are contraindicated in patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis; patients who have a unipolar pacemaker implanted, patients with incessant ventricular tachycardia (VT) or ventricular fibrillation (VF), and patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

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### Warnings and Precautions

Changes in a patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset or device damage. Do not place transthoracic defibrillation paddles directly over the device.

Additionally, for CRT-Ds and CRT-Ps, certain programming and device operations may not provide cardiac resynchronization. Also for CRT-Ps, Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and/or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set. Use of the device should not change the application of established anticoagulation protocols.

MRI SureScan systems: Patients and their implanted systems must be screened to meet the following requirements for MRI: no lead extenders, lead adaptors or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history and the system must be implanted in the left or right pectoral region.

### Potential Adverse Events

Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis. An additional complication for ICDs and CRT ICDs is the acceleration of ventricular tachycardia.

MRI SureScan systems: Potential MRI complications for the SureScan system include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or MRI induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse; spontaneous tachyarrhythmia occurring during the scan that is not detected and treated because tachyarrhythmia detection is suspended while MRI SureScan is programmed to On; potential for VT/VF induction when the patient is programmed to an asynchronous pacing mode during MRI SureScan; device heating resulting in tissue damage in the implant pocket or patient discomfort or both; or damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer. See the MRI SureScan Technical Manual before performing an MRI Scan.

*See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult [www.medtronic.com](http://www.medtronic.com).*

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