THE AF ADVANTAGES ACROSS OUR PORTFOLIO

- Increase the accurate and timely diagnosis of AF
- Improve AF patient outcomes
- May reduce AF-related utilization of healthcare resources

April 2018

ICMs

PACEMAKERS

ICDs

CRT DEVICES

CRYOBALLOON

**Detect**

**Reveal LINQ™ ICM**
The world’s smallest, most accurate ICM
- 8x fewer AF false positives than other app-based ICMs
Up to three-year longevity for long-term monitoring
- 30% of cryptogenic stroke AF diagnoses occur after two years
- 40% of high-risk patients had AF at 30 months

**Azure™ XT DR MRI pacemaker, Evera MRI™ DR ICD, Claria MRI™ CRT-D, and Percepta™ Quad CRT-P MRI**
95-96% AT/AF episode PPV

**Reduce**

**MVP™** reduces unnecessary RV pacing by 99%
- Every 1% of unnecessary RV pacing is accompanied by a 1% greater AF risk

**Reactive ATP™ Algorithm** reduces the duration of AT/AF:
- ≥ 1 day by 21%
- ≥ 7 days by 40%
- ≥ 30 days by 49%

**AdaptivCRT™ Algorithm** 46% reduction in AF risk

**Respond**

**EffectivCRT™ During AF Algorithm**
up to 16% increase in effective CRT delivery

**Unmatched MRI Access — 1.5T and 3T Full Body Scanning**

References


*For SureScan® devices when MR conditions for use are met.

The cryoballoon is indicated for the treatment of drug refractory paroxysmal AF.

April 2018
**brief statement**

ICM and Transvenous IGP, ICD, CRT-D, CRT-P, MRI

**indications:** The SureScan™ MRI transvenous pacing systems are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Dual chamber SureScan pacing is indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. The SureScan MRI defibrillation systems are indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. In addition, the dual chamber devices are indicated for use in the above patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. The SureScan MRI CRT-D systems 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. 

**Warnings and Precautions:**

Changes in 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 transvenous defibrillation paddles directly over the device. Additional precautions for dual chamber device operations may not provide cardiac resynchronization. Use of the device should not change the application of established anticoagulation protocols.

SureScan transvenous 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, device migration, infection, or erosion through the skin. Potential complications associated with cardiac rhythm devices include muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachycardia, and surgical complications such as hematoma, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibration, thrombosis, thrombotic and air embolism, cardiac perforation, heart wall rupture, cardiac tamponade, pericardial rub, myocardial irritability, and pneumothorax. Other potential complications related to the device include lead fracture, insulation failure, threshold elevation, or exit block. Potential MRI complications include, but are not limited to, electrode heating and tissue damage resulting in loss of sensing or capture or both, or MRI-induced stimulation on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse. Potential complications of the Reveal LINQ device include, but are not limited to, lead dislodgements, lead migration, lead infection, lead erosion through the skin, and lead thrombosis. See the appropriate product MRI SureScan Technical Manual for further information.

**Arctic Front™ and Arctic Front Advance™ Cardiac Cryoablation Catheter Systems Indications:**

The Arctic Front and Arctic Front Advance cardiac cryoablation catheter systems are indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation.

**Contraindications:**

Use of either Arctic Front or Arctic Front Advance cryoballoon systems is contraindicated in the following patients:

1. In the vicinity because of the danger of catheter entrapment in the chordae tendineae
2. In patients with one or more pulmonary vein stents
3. In patients with cryoglobulinemia
4. In patients with active systemic infections
5. In situations where the manipulation of the catheter within the heart would be unsafe (e.g., intracardiac mural thrombus)

**Warnings/Precautions:**

Do not re-sterilize this device for purpose of reuse. Use only the 12 Fr FlexCath™ Steerable Sheath family with the Arctic Front Advance cryoballoon because using another sheath may damage the catheter or balloon section. Do not infuse liquid within the sheath. Always verify with fluoroscopy or by using the proximal shaft visual marker that the balloon is fully outside the sheath before inflation to avoid catheter damage. Do not position the cryoballoon catheter within the tubular portion of the pulmonary vein to minimize phrenic nerve injury and pulmonary veins stenosis. Do not connect the cryoballoon to a radiofrequency (RF) generator or use it to deliver RF energy because this may cause catheter malfunction or patient harm. The catheter contains pressurized refrigerant during operation; release of this gas into the circulatory system due to equipment failure or misuse could result in gas embolism, which can occlude vessels and lead to tissue infarction with serious consequences. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism. Do not pull on the catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue; this may lead to tissue injury. Do not advance the balloon beyond the guide wire to reduce the risk of tissue damage. Do not pass the catheter through a prosthetic heart valve (mechanical or tissue) to avoid damage to the valve. Avoid placing occlusion devices, such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia.

**MR Conditions of Use:** Medtronic SureScan systems are MR conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use. Transvenous SureScan systems may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging. When 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 pacing 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 http://www.mrisurescan.com/ Any other combination may result in a hazard to the patient during an MRI scan.

**Contraindications:** The SureScan transvenous pacing and CRT-P systems are contraindicated for implantation with unicameral pacing leads (Revo MRI™) only, concomitant implantation with another cardiac device or an implantable cardioverter defibrillator. SureScan defibrillation and CRT-D systems are contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes, or patients with incessant VT or VF. For dual chamber and CRT-D devices, the device is contraindicated for patients whose primary arrhythmia is chronic atrial tachyarrhythmias with no concomitant VT or VF. For single chamber devices, the device is contraindicated for patients whose primary arrhythmia is atrial tachyarrhythmia. Reveal LINQ: There are no known contraindications for the implant of the device. Some CRT-D system are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias. The SureScan CRT-D systems are indicated for: NYHA Functional Class II or IV and who have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration ≤ 130 ms, left ventricular ejection fraction ≤ 30% and NYHA Functional Class II. NYHA Functional Class III or IV and who have left ventricular ejection fraction ≤ 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. Claria/Amplia only: Some CRT-D system are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias. The SureScan CRT-D systems are indicated for: NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have a LVEF ≤ 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF ≤ 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. Rate adaptive pacing is provided for those patients developing a bradyarrhythmia indication who might benefit from increased pacing rates concurrent with increases in activity. Dual chamber and atrial tracking modes are indicated for patients who may benefit from maintenance of AV synchrony. Atrial tachyarrhythmia pacing ATPS is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications. The Reveal LINQ™ insertable cardiac monitor (ICM) is an implantable patient-activated and automatically activated monitoring system that records subcutaneous ECG and is indicated for patients with clinical syndromes or situations at increased risk of cardiac arrhythmias, or patients who experience transient syncope such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia.

**potential complications/adverse events from cardiac cryoablation procedures.**

Cardiac cryoablation procedures may include, but are not limited to the following: Anemia; Anxiety; Atrial flutter; Back pain; Bleeding from puncture sites; Blurred vision; Bradycardia; Bronchitis; Bruising; Cardiac tamponade; Cardiopulmonary arrest; Cerebral vascular accident; Chest discomfort/pain/pressure; Cold feeling; Cough; Death; Diarrhea; Dizziness; Esophageal damage (including esophageal fistula); Fatigue; Fever; Headache; Hemoptysis; Hypotension/Hypertension; Light headedness; Myocardial infarction; Nausea/vomiting; Nerve injury; Pericardial effusion; Pulmonary vein stenosis; Shivering; Shortness of breath; Sore throat; Tachycardia; Transient ischemic attack; Urinary infection; Vasovagal reaction; Visual changes. Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com.

**medtronic.com**

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