ICMs

**PACEMAKERS**

**ICDs**

**CRT DEVICES**

**CRYOBALLOON**

**THE AF ADVANTAGES ACROSS OUR PORTFOLIO**

**ICMs**

- **Reveal LINQ™ ICM**
  - The world's smallest, most accurate ICM†
  - 8x fewer AF false positives than other app-based ICMs.2,3
  - Up to three-year longevity for long-term monitoring
  - 40% of high-risk patients had AF at 30 months.4
  - Stroke AF diagnoses based on ICMs.2,3

**PACEMAKERS**

- **Azure™ XT DR MRI pacemaker, Evera MRI™ DR ICD, Claria MRI™ CRT-D, and Percepta™ Quad CRT-P MRI**
  - Highest published detection accuracy8-12
  - Every 1% of unnecessary RV pacing is accompanied by a 1% greater AF risk.16
  - Adaptive CRT™ Algorithm 46% reduction in AF risk18

**ICDs**

- **Visia AF MRI™ VR ICD**
  - The only single chamber ICD that detects AF using the TruAF™ Detection Algorithm and a traditional lead
  - 34% of patients had AF detected at six months.14

**CRT DEVICES**

- **TruA™ AF Detection Algorithm**
  - that detects AF using the
  - The only single chamber ICD for paroxysmal atrial fibrillation.

**CRYOBALLOON**

- **MVP™** reduces unnecessary RV pacing by 99%15
  - Every 1% of unnecessary RV pacing is accompanied by a 1% greater AF risk.16
- **Reactive ATP™ Algorithm** reduces the duration of AT/AF17:
  - ≤ 1 day by 19%
  - ≤ 7 days by 36%
  - ≤ 30 days by 44%

**TREAT PAF**

With more than 12 years of clinical experience, a half-million procedures performed in over 60 countries, and more than 700 peer-reviewed articles,20 momentum is building for the Arctic Front family of cryoballoons — the safe21 and consistent2,5 way to treat paroxysmal AF (PAF).

- **Arctic Front Advance™ Cryoballoon**
  - 68.1% freedom from PAF at 36 months23
- **AdaptivCRT™ Algorithm**
  - 46% reduction in AF risk18
- **EffectivCRT During AF Algorithm**
  - up to 16% increase in effective CRT delivery19

**REFERENCES**

Brief Statement

ICM and Advanced IPG, 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 CRT-P systems are 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 for 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. • New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction ≤35% and a prolonged QRS duration • Left bundle branch block (LBBB) with a 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 MRI™ (Amplia MRI)™: only Some CRT-D systems 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-P 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, 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 bradycardia 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. Anti-tachycardia 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 symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia. MRI 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 system patients 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 unipolar pacing leads (Revo MRI™ only), concomitant implantation with another the Landa 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 underlying cardiac rhythm is atrial tachyarrhythmia. Reveel LINQ. There are no known contraindications for the implant of the Reveel LINQ ICM. However, the patient’s particular medical condition may dictate whether or not a substantial, chronically implanted device can be tolerated. 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 arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillator paddles directly over the device. Additional precautions for single chamber devices may not provide cardiac resynchronization. Use of the device should not be based on the results of this procedure. Indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com or www.mrisurescan.com.

Arcot Front and Arctic Front Advance™ Cardiac Cryoablation Catheter Systems

Indications: The Arctic Front and Arctic Front Advance 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 is contraindicated:

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 conditions where the manipulation of the catheter within the heart would be unsafe (e.g., intracardiac mural thrombus)

Warnings/Precautions: Do not re-stereilize this device for purpose of reuse. Only use the 12 Fr FlexCath™ Steerable Sheath family with the Arctic Front Advance cryoballoon because using another sheath may damage the catheter or balloon segment. Do not use both sheaths in the same patient at the same time. Do not inflate 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 pericardial nerve injury and pulmonary veins stenosis. Do not connect the cryoballoon to aradiofrequency (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. Do not use the catheter in the right atrium. Always inflate the balloon to the size specified in the instructions for use. When the balloon is inflated, it should be fully expanded within the atrium then position it at the pulmonary vein ostium to avoid vascular injury. Do not ablate in the tubular portion of the pulmonary vein. Use continuous pneumatic nerve pacing throughout each cryoablation application in the right pulmonary veins. To avoid nerve injury, place a hand on the abdomen in the location of the diaphragm to assess for changes in the strength of the diaphragmatic contraction or loss of capture. In case of no pneumatic nerve capture, frequently monitor diaphragmatic movement using fluoroscopy. Stop ablation immediately if phrenic nerve impairment is observed. The Arctic Front and Arctic Front Advance cryobalrons were not studied for safety of changes in cryoablation therapy in patients with paroxysmal atrial fibrillation. This equipment should be used only by or under the supervision of physicians trained in left atrial cryoballoon procedures. Cryoablation procedures should be performed only in a fully equipped facility. Potential Complications: Potential complications/adverse events from cardiac catheterization and/or intervention include, but are not limited to the following: Anemia; Anxiety; Atrophic 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 consult the Medtronic website at www.medtronic.com.

Caution: Federal Law (USA) restricts these devices to sale by or on the order of a physician.