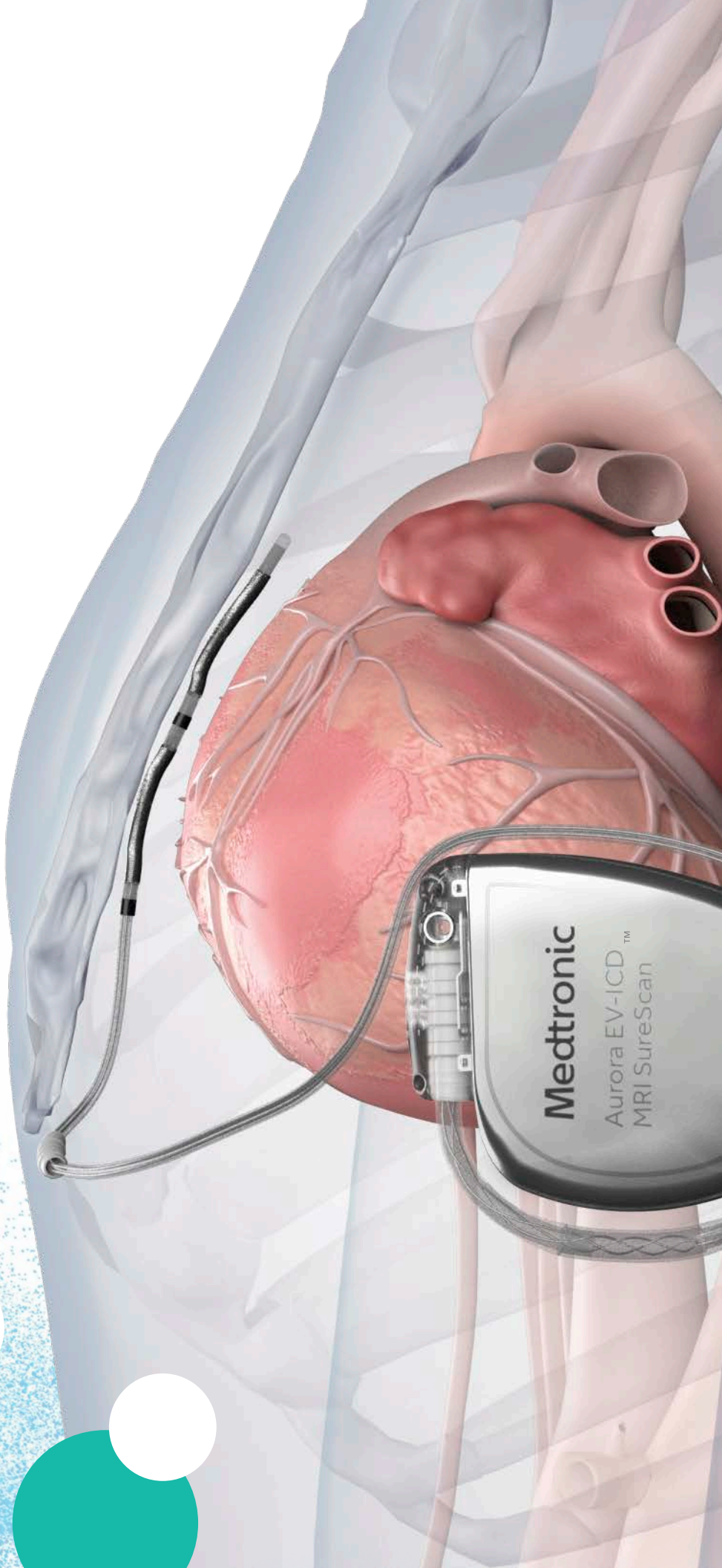
Medtronic

Aurora EV-ICD™ system

The extravascular system with transvenous ICD benefits[1]



Establishing the rhythm.
Pioneering what's possible.

Why Aurora EV-ICD?

Aurora EV-ICD offers the advantages of an extravascular system

- Avoids certain complications associated with transvenous leads†
- Preserves the vasculature and reduces potential for vascular injury

Aurora EV-ICD provides features available in transvenous ICD systems while outside the heart and vasculature

Antitachycardia pacing (ATP)

Small size (33 cm^3) and PhysioCurve™ design – same size and shape as Medtronic transvenous single-chamber ICDs

11.7-year projected longevity[2]

Pause Prevention pacing (backup bradycardia pacing)

Programmable VF detection intervals and multiple therapy zones

Monitor zone which allows for documentation of slow VTs, including nonsustained VTs

† The Aurora EV-ICD lead is not intended for implantation within the heart or vasculature, and, thus, Aurora is expected to avoid vascular complications associated with transvenous leads. There were no major intraprocedural complications observed in the EV ICD Pivotal clinical study.[1]

What makes the Aurora EV-ICD advantages possible?

Because the lead is placed close to the heart, the energy required for pacing and defibrillation is lower than if it were further away and separated from the heart by bone.[1,3]

As a result, the EV-ICD system is able to incorporate important features: ATP, Pause Prevention pacing (backup bradycardia pacing), and 40 joule defibrillation, all in a device the same size as transvenous ICDs and with similar projected longevity.

System safety

Specialized implant tools and techniques were developed for this procedure to help ensure the safety of the procedure and the performance of the system.[1,3-6]

The system has been evaluated in five clinical studies, involving more than 80 sites and more than 400 patient subjects.

The global, prospective EV ICD Pivotal clinical study exceeded its primary safety objective[1] and found the rate of EV-ICD freedom from major system- or procedure-related complications at six months to be in line with the rates observed in transvenous ICD studies[7-12] and the subcutaneous ICD (S-ICD) IDE study.[13] The EV-ICD system's safety was sustained through the duration of the study follow-up, which was an average of 29 months. There were 31 system- or procedure-related major complications in 29 patients throughout the study. Of these, the most common were revision for lead dislodgement and treatment for post-operative wound or pocket infection. No system changes were required for seven events.[14]

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Projected longevity

Projected longevity similar to other Medtronic single-chamber ICDs

11.0 years
Visia AF MRI™ single-chamber ICDs †,15

11.7 years
Aurora EV-ICD †,2

13.6 years
Cobalt™ & Crome™ VR family of single-chamber devices ‡,16

ALL WITHIN 11–13 YEARS

† Projected longevities for Visia AF MRI and Aurora EV-ICD are based on VVI with 0% pacing from the manuals of the models listed.
‡ Mean longevity projection based on median CareLink™ settings in the Cobalt manual. This value should not be interpreted as precise numbers. Individual patient results may vary based on their specific programming and experience.

Option for 40 J energy delivery on all shocks

(including the first shock)[2]

40 J Maximum **programmed** energy

40 J Energy **delivered** at maximum programmed energy

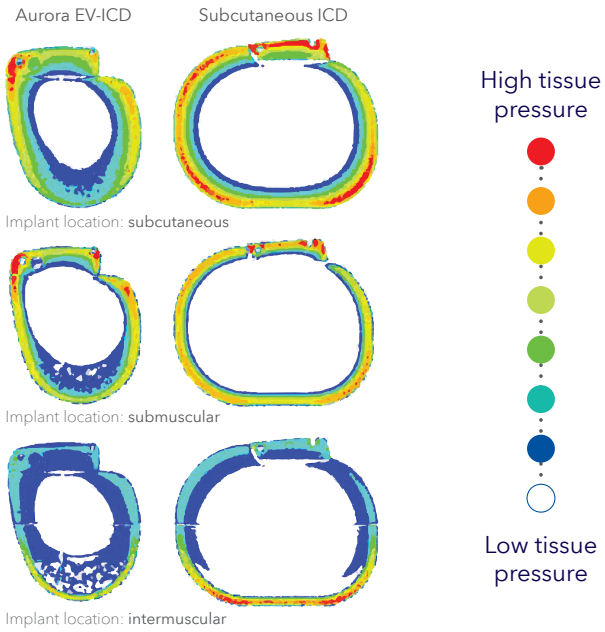
Effective defibrillation

at implantation in the EV ICD Pivotal clinical study[1] was greater than observed in historical transvenous ICD studies[17-20] and similar to S-ICD.[13]

Designed for patient comfort

With its PhysioCurve design, Aurora EV-ICD showed a 27% average reduction in tissue pressure relative to the subcutaneous ICD across the three implant locations modeled.[21]

- Tapered at the head and bottom of device to reduce tissue pressure and promote patient comfort
- Smaller footprint for a smaller incision

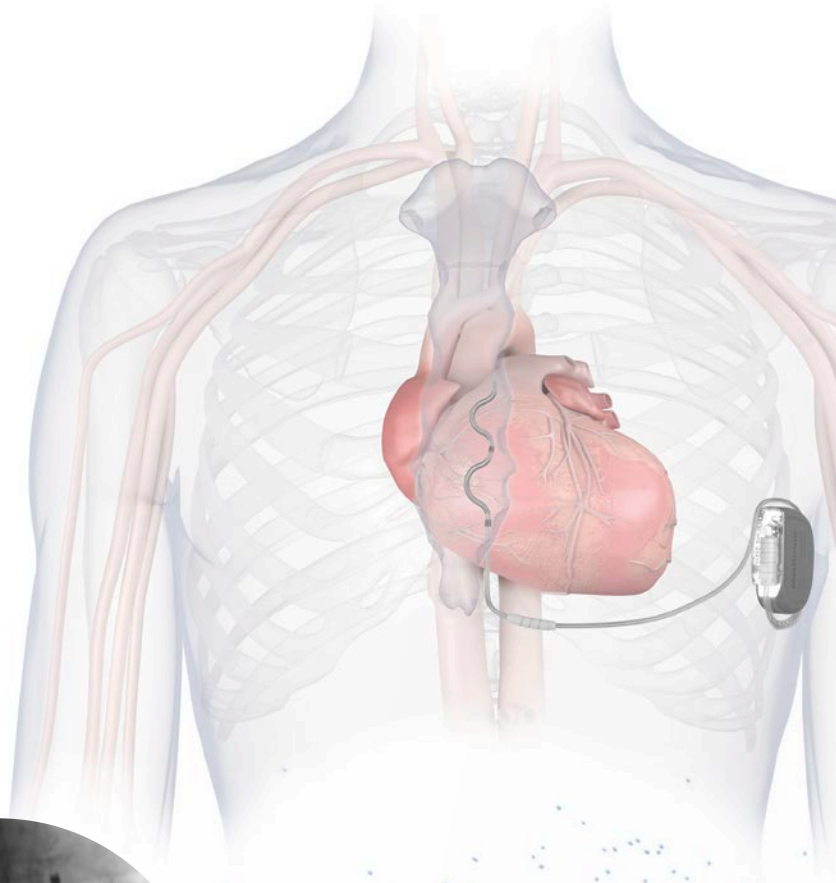


ATP

The only extravascular ICD to offer ATP

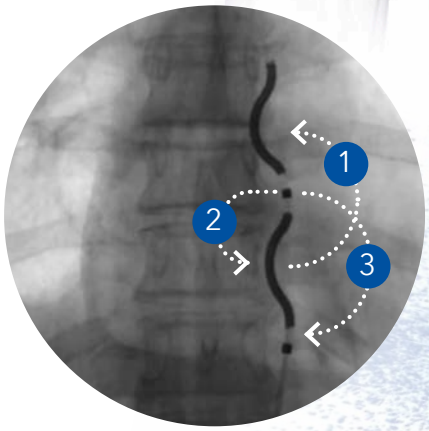
As with Medtronic transvenous ICDs, ATP therapy in Aurora EV-ICD includes Burst and Ramp pacing pulses, each with a programmable number of sequences.

In the EV ICD Pivotal clinical study, ATP successfully terminated 77% of episodes (37 of 48).[14] This is in the range of the ATP efficacy reported in transvenous ICD publications, 52% to 87%.[22-25]



Aurora EV-ICD has three pacing vector options for ATP

1. Coil 2 to coil 1
2. Ring 1 to coil 2
3. Ring 1 to ring 2



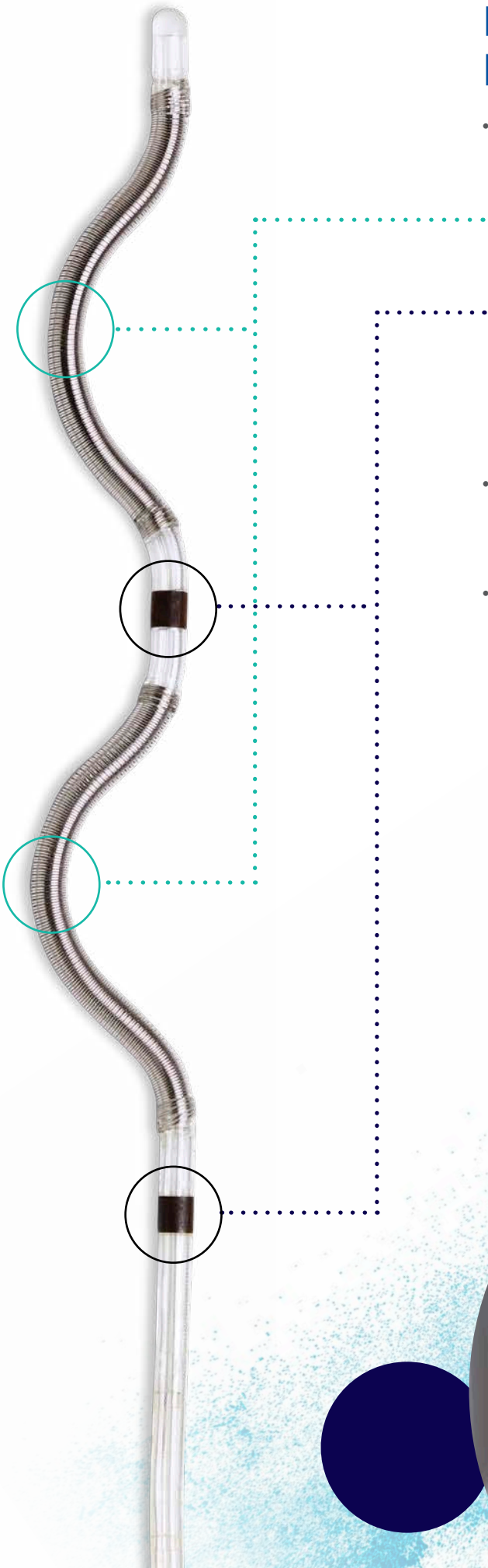
Pause Prevention pacing

Pause Prevention is a pacing feature that monitors the heart for significant pauses and responds by providing temporary bradycardia pacing support.

The device records data about episodes that meet the programmed pause detection criteria when Pause Prevention is programmed to On or Monitor. This data is useful for analyzing Pause Prevention episodes and the events leading up to them.

Post-shock pacing

Aurora EV-ICD can be programmed to deliver temporary post-shock pacing following a defibrillation or cardioversion therapy, as there may be a temporary bradycardia or asystole after the heart receives a high-voltage therapy.



Epsila EV™ defibrillation lead key features

- Epsilon-shaped distal section is intended to optimize the electrodes' locations relative to the heart and the device
  - Defibrillation coils positioned toward the patient's right side for a wider defibrillation vector between the coils and the device
  - Pacing/sensing ring electrodes positioned toward the patient's left side so they are closer to the heart
  - Curvature intended to help stabilize the lead in the mediastinal tissue
- Four electrodes, consisting of two coils and two rings, to support three different pacing vector options and three sensing vector options
- Isodiametric 8.7 Fr lead body and four conductor cables extending to the distal tip of the lead to provide high tensile strength for extractability

Scan to learn more about the Aurora EV-ICD system

Diagnostics and programmability

- Programmable VF detection intervals from 12/16 to 120/160 allow for tailoring the timing of therapy delivery
- Multiple therapy zones provide more programming flexibility
- Monitor zone allows for documentation of slow VTs, including nonsustained VTs
- EGM storage of VT/VF, VT monitor, and SVT episodes, including slow VT episodes, provides additional clinical information

MRI access at 1.5T and 3T

How MRI SureScan™ technology works

- SureScan devices are specifically engineered for the MRI environment, with enhancements for patient safety during an MRI scan
- 1.5T and 3T MRI access when MR conditions for use are met
- MRI scanning conditions are straightforward: no anatomical exclusion zone, no patient height restriction, 1.5T and 3T MR Conditional[26]

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16. Medtronic Cobalt™ XT VR ICD MRI SureScan™ Model DVPA2D4 device manual.
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26. Medtronic Aurora EV-ICD™ MRI SureScan™ DVEA3E4 MRI technical manual.

Brief Statement
Aurora EV-ICD™ MRI SureScan™ System and Associated Tunneling Tools

Indications
Device: The Aurora EV-ICD™ MRI SureScan™ Model DVEA3E4 device is indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias through the delivery of antitachycardia pacing, cardioversion, and defibrillation therapies. Medical conditions that may indicate a patient for an EV-ICD for primary or secondary prevention of sudden cardiac death due to life-threatening ventricular tachyarrhythmias include: previous ventricular tachyarrhythmias, coronary disease with left ventricular dysfunction, cardiomyopathy, inherited primary arrhythmia syndromes, and congenital heart disease.

Note: For patient-specific recommendations regarding indications for primary and secondary prevention of sudden cardiac death, refer to current clinical guidelines from the European Society of Cardiology (ESC), American Heart Association (AHA), American College of Cardiology (ACC), and Heart Rhythm Society (HRS).

Lead: The Epsila EV™ MRI SureScan™ Model EV2401 extravascular lead is indicated for use in the anterior mediastinum for pacing therapies, cardioversion, and defibrillation when an extravascular implantable cardioverter defibrillator is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias.

Tunneling Tools: The Epsila EV™ Model EAZ101 sternal tunneling tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

The Epsila EV™ Model EAZ201 transverse tunneling tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

MR Conditions for Use

The Aurora EV-ICD MRI SureScan system is MR Conditional and, as such, is designed to allow patients to be safely scanned by an MRI machine when used according to the specified MR conditions for use. A complete SureScan system is required for use in the MR environment. Before performing an MR scan, refer to the MRI technical manual for MRI-specific warnings and precautions. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned. A complete SureScan system includes a SureScan extravascular ICD device (Model DVEA3E4) with a SureScan extravascular lead (Model EV2401). 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 Aurora EV-ICD MRI SureScan Model DVEA3E4 device is contraindicated for use in the following situations:

- If implanted with a unipolar pacemaker, a device delivering dual-chamber or triple-chamber pacing, and/or a device delivering antitachyarrhythmia therapies
- If incessant ventricular tachycardia (VT) or ventricular fibrillation (VF) exists
- If the patient's primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF
- If symptomatic bradycardia exists
- If tachyarrhythmias with transient or reversible causes exist

The Epsila EV MRI SureScan Model EV2401 lead is contraindicated for any application that is not specified in the Indications.

The Epsila EV Model EAZ101 sternal tunneling tool is contraindicated for use in patients with a prior sternotomy.

The Epsila EV Model EAZ201 transverse tunneling tool is contraindicated for any application that is not specified in the Indications.

Warnings and Precautions

Device and Lead: It is important to read the Aurora EV-ICD MRI Technical Manual before conducting an MRI scan on a patient with an implanted SureScan system. The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine. When programmed to On, MRI SureScan operation disables arrhythmia detection and all user-defined diagnostics. Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode On may result in patient harm or damage to the SureScan system.

Patients and their implanted systems must be screened to meet the following requirements for MRI: no implanted 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 Sure Scan device must be operating within the projected service life; the device does not provide pacing therapy when SureScan mode is programmed On. Do not scan pacemaker-dependent patients. MRI scans during the lead maturation period have not been prospectively studied by Medtronic and are not recommended. If scanning a patient with multiple devices, ensure all devices meet the MRI labeling conditions.

Use only the Epsila EV MRI SureScan Model EV2401 extravascular lead with a Medtronic EV4 implantable cardioverter defibrillator system. The known potential adverse consequences of using any other combination may include undersensing of cardiac activity, failure to deliver necessary therapy, or an intermittent electrical connection. All can present serious risks for adverse events to the patient. The EV4 connector is a Medtronic proprietary design, not an industry standard. No claims of safety and efficacy can be made with regard to devices that are not labeled as EV4 by Medtronic.

Pre-implant consideration for concomitant implant with a neurostimulator and cardiac device implants: Some patients have medical conditions that require the implant of both a neurostimulator and a cardiac device (for example, a pacemaker, a defibrillator, or a monitor). In this case, physicians involved with either device should contact Medtronic Technical Services or their Medtronic representative before implanting the patient with the second device. Based on the particular devices that the physicians have prescribed, Medtronic can provide the necessary precautions and warnings related to the implant procedure.

Use of the DVEA3E4 device has not been evaluated in patients who have undergone a prior sternotomy.

The DVEA3E4 device has not been tested specifically for pediatric use.

Use of the EV2401 lead has not been evaluated in patients who have undergone a prior sternotomy. Performing a sternotomy on a patient with an implanted lead has not been evaluated.

Do not implant the EV2401 lead using any tools other than the Medtronic tunneling tools designed for implanting the extravascular ICD system.

Tunneling Tools: The tunneling tools have not been tested for use with non-Medtronic products or for pediatric use.

Use of the EAZ201 transverse tunneling tool have not been evaluated in patients who have undergone a prior sternotomy.

Potential Adverse Events

Implant and usage of this system may result in adverse events, which may lead to injury, death, or other serious adverse reactions. Potential adverse events include, but are not limited to acute tissue trauma, allergic reaction, bradyarrhythmia, cardiac arrest, cardiac inflammation, cardiac perforation, cardiac tamponade, death, device migration, discomfort, dizziness, dyspnea, erosion, extracardiac stimulation, fever, hematoma, hemorrhage, hemothorax, hiccups, hospitalization, inappropriate shock, infection, insulation failure, lead abrasion, lead fracture, lead migration or dislodgement, lethargy, mental anguish, organ damage (liver, mammary arteries, diaphragmatic arteries), pain, palpitations, pericardial effusion, pericarditis, pneumothorax, return of cardiac symptoms, seroma, syncope, tachyarrhythmia, toxic reaction, and wound dehiscence.

Potential MRI adverse events include the following: lead electrode heating resulting in tissue damage near the lead electrodes or patient discomfort or both; spontaneous tachyarrhythmia occurring during the scan that is not detected and treated because tachyarrhythmia detection is suspended while MRI SureScan mode is programmed to On; device heating resulting in tissue damage in the implant pocket or patient discomfort or both; MR-induced muscle stimulation resulting in patient discomfort; damage to the device or lead causing the system to fail to detect or treat irregular heartbeats or causing the system to treat the patient's condition incorrectly; damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer; and movement or vibration of the device or leads resulting in dislodgment.

See the Aurora EV-ICD MRI SureScan technical manual before performing an MRI Scan, and the device, lead and tunneling tools manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. Refer to the Medtronic Manual Library website www.medtronic.com/manuals. *For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at* www.medtronic.com *or* www.mrisurescan.com.

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

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