

Medtronic

Aurora EV-ICD™ MRI SureScan™

Model DVEA3E4

Single chamber, extravascular ICD with:

- Antitachycardia pacing (ATP)
- Pause Prevention and Post-shock pacing
- 1.5T and 3T MRI access†
- PhysioCurve™ design
- EV4 connector

†When MR conditions for use are met.



Product specifications

Physical characteristics

Volume ^a	33 cm ³
Mass	77 g
H x W x D	64 mm x 51 mm x 13 mm
Surface area of device can	57 cm ²
Connector	
Type	EV4-LLHH
Length	30 mm
Functional diameter	3.2 mm
Radiopaque ID ^b	REX
Materials in contact with human tissue ^c	Titanium, polyurethane, silicone rubber adhesive, silicone rubber, liquid silicone rubber
Battery	Hybrid CFx lithium/silver vanadium oxide
Battery model	M970710A

^a Volume with connector ports unplugged.

^b The radiopaque ID, which includes a Medtronic identifier symbol, can be viewed in a fluoroscopic image of the device.

^c These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Replacement indicators

Recommended Replacement Time (RRT)	< 2.73 V on 3 consecutive daily automatic measurements
End of Service (EOS)	3 months after RRT

Projected service life

The service life projection for the device is 11.7 years.

Based on the following assumptions:

- Pacing at 0%.
- 2 high-voltage therapies per year.
- Pre-arrhythmia EGM storage programmed to On for 6 months, over life of device.
- Wireless telemetry:
 - 3 hours of telemetry enabled at implant.
 - 30 min of telemetry enabled for quarterly scheduled CareLink™ monitor remote sessions (if available).
 - 1 hour of in-office wireless telemetry enabled annually.
- Shelf storage life of 5 months, before implant.

Maximum energy levels and typical full energy charge times

Maximum programmed energy	40 J
Energy delivered at maximum programmed energy ^a	40 J
Stored energy at maximum programmed energy ^b	47 J
Typical charge time at Beginning of Service (BOS) ^c	9.4 s
Typical charge time at Recommended Replacement Time (RRT) ^c	14.8 s























^a Tolerance for delivered energy delivered into a 75 Ω load is 40 J ± 15%.









^b Energy stored at charge end on capacitor.

^c Charge time during a nonwireless telemetry session may be slightly higher.

Device parameters

Ventricular tachyarrhythmia detection parameters

Parameter	Programmable values
VF Detection ^a	On  ; OFF
VF Initial Beats to Detect	12/16; 18/24; 24/32; 30/40  ; 45/60; 60/80; 75/100; 90/120; 105/140; 120/160
VF Beats to Redetect	6/8; 9/12; 12/16  ; 18/24; 21/28; 24/32; 27/36; 30/40
VF: Ventricular Interval Rate ^b	240; 250 ... 320  ... 400 ms
FVT Detection	OFF  ; via VF
FVT: Ventricular Interval Rate ^b	200; 210 ... 240  ... 600 ms
VT Detection	On; OFF 
VT Interval Rate ^b	280; 290 ... 360  ... 650 ms
VT Initial Beats to Detect	12; 16  ... 52; 76; 100
VT Beats to Redetect	8; 12  ... 52
Monitor	Monitor  ; Off
Monitored VT Beats to Detect	16; 20; 24; 28; 32  ... 56; 80; 110; 130
Monitor: Ventricular Interval Rate ^b	280; 290 ... 450  ... 650 ms
Wavelet	
Wavelet	On  ; Off; Monitor
Template	[date]
Match Threshold	40; 43; 46 ... 61  ... 97%
Auto Collection	On  ; Off
Rapid AF	On  ; Off
Feature Match	On  ; Off
SVT V. Limit ^b	210; 220 ... 260  ... 650 ms
Other enhancements	
Stability ^b	Off  ; 30; 40 ... 100 ms
Onset	Off  ; On; Monitor
Percent	72; 75; 78; 81  ; 84; 88; 91; 94; 97%
















High Rate Timeout	Off; 0.25; 0.5; 0.75  ; 1; 1.25; 1.5; 1.75; 2; 2.5; 3; 3.5; 4; 4.5; 5 min
VF Zone Only (min)	Off  ; 0.5; 1; 1.5 ... 5; 6; 7 ... 20; 22; 24; 26; 28; 30 min
All Zones (min)	Off  ; 0.5; 1; 1.5 ... 5; 6; 7 ... 20; 22; 24; 26; 28; 30 min
T Wave	On  ; Off
Noise	
Sensed Noise	On  ; Off
Morphology Noise	On  ; Off
Sensed EMI	On  ; Off
Shared Noise Timeout ^c	Off; 0.25; 0.50; 0.75 ... 2.00; 2.50; 3.0  ... 4.00 min

^a Reset does not happen in the box. Table shows reset value when implanted.

^b The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

^c Therapy can be withheld by noise oversensing enhancements for up to the total timeout period.

Ventricular tachyarrhythmia therapy parameters

Parameter	Programmable values
VF Therapies	
VF Therapy Status	On  ; Off
Energy	Rx1-Rx2: 0.4; 0.6; 0.8 J (±0.25 J) 1; 1.2 J (+0.25 J/-30%) 1.4; 1.6; 1.8; 2; 3; 4 J (+20%/-30%) 5; 6 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J (± 20%) 40  J (± 15%) Rx3-Rx6: 10; 11 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J (± 20%) 40  J (± 15%)
Pathway ^a	STD  ; REV
VT/FVT Therapies	
VT Therapy Status	Rx1-Rx6: On; Off 
Therapy Type	Rx1: CV; Burst  ; Ramp Rx2-Rx6: CV  ; Burst; Ramp
Energy ^b	Rx1-Rx6: 0.4; 0.6; 0.8 J (± 0.25 J) 1; 1.2 J (+0.25 J/-30%) 1.4; 1.6; 1.8; 2; 3; 4 J (+20%/-30%) 5; 6; ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J (± 20%) 40  J (±15%)
Pathway ^a	STD  ; REV
Burst therapy parameters	
Initial # Pulses	1; 2 ... 8  ... 15
R-S1 Interval = (% RR)	50; 53; 56; 59; 63; 66 ... 84; 88  ; 91; 94; 97%
Interval Dec	0; 10  ... 40 ms
# Sequences	1; 2 ... 10 VT therapies: 3  FVT therapies: 1 
Smart Mode ^c	On; Off 

Ventricular tachyarrhythmia therapy parameters, cont'd.

Parameter	Programmable values
Ramp therapy parameters	
Initial # Pulses	1; 2 ... 8 \diamond ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88; 91 \diamond ; 94; 97%
Interval Dec	0; 10 \diamond ... 40 ms
# Sequences	1; 2 ... 10 VT therapies: 3 \diamond FVT therapies: 1 \diamond
Smart Mode ^c	On; Off \diamond
Shared Settings	
Shared V. ATP	
V-V Minimum ATP Interval	150; 160 ... 200 \diamond ... 400 ms (\pm 12 ms ^d / \pm 60 ms ^e)
V. Amplitude	1; 2 ... 8; 10; 13; 16; 20; 30 V
V. Pulse Width	1 ^h ; 2 ^{g,h} ; 3 ^h ; 4 ^{g,h} ; 6 ^g ; 8 ^g ms
V. Pace Blanking	150; 160 ... 250 \diamond ... 450 ms (\pm 5 ms)
ATP Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1

^a STD = Coils to Can;
REV = Can to Coils.

^b This parameter is for CV (cardioversion).

^c Smart Mode is available only for Rx1–Rx4.

^d At \leq 8 V amplitude.

^e At \geq 10 V amplitude.

^f The tolerance for measurements performed per ISO 14708-2 is listed in Section 5.2.2.

^g Ring 1 to Ring 2 or Ring 1 to Coil 2.

^h Coil 2 to Coil 1.

Delivered energy conditions and tolerances

	30 Ω	50 Ω	75 Ω	200 Ω	250 Ω
22 °C:	-35%/	-30%/	-30%/	-30%/	-50%/
0.4 J - 35 J ^a	+20%	+20%	+20%	+20%	+50%
22 °C:	-30%/	-30%/	-30%/	-30%/	-50%/
40 J	+20%	+20%	+20%	+20%	+50%
37 °C:	-30%/	-30%/	-30%/	-30%/	-50%/
0.4 J - 4 J ^a	+20%	+20%	+20%	+20%	+50%
37 °C:	-30%/	-20%/	-20%/	-30%/	-50%/
5 J - 35 J	+20%	+20%	+20%	+20%	+50%
37 °C:	-30%/	-15%/	-15%/	-30%/	-50%/
40 J	+20%	+15%	+15%	+20%	+50%
45 °C:	-30%/	-30%/	-30%/	-30%/	-50%/
0.4 J - 40 J ^a	+20%	+20%	+20%	+20%	+50%

^a Tolerance is \pm 0.25 J for energy levels for which \pm 0.25 J is greater than the listed tolerance range.

Post-shock pacing parameters

Parameter	Programmable values
Post Shock Pacing Enable	On; Off
Amplitude	1 2; ... 8 V ^{a,b} 10; 13; 16; 20; 30 V ^{b,c}
Pulse Width	2; 4; 6; 8 ms ^{a,b} 1; 2 ... 10 ms ^{b,c}
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1
Lower Rate ^{d,e,f,g}	40 bpm (1,500 ms) (\pm 1.3 bpm (\pm 50 ms) \leq 8 V; \pm 2.7 bpm (\pm 100 ms) \geq 10 V)
Therapy Duration ^d	30 s

^a For \leq 8 V amplitude, Ring 1 to Ring 2 or Ring 1 to Coil 2.

^b The tolerance for measurements performed per ISO 14708-2 is listed in Section 5.2.2.

^c For \geq 10 V amplitude, Coil 2 to Coil 1.

^d This parameter is nonprogrammable.

^e Escape interval is 1,500 ms.

^f The corresponding pacing interval or escape interval can be calculated as follows: interval (in ms) = 60 000/Lower Rate (in bpm).

^g The tolerance for the escape interval is \pm 30/–2 ms.

Pause Prevention Detection – detection and pacing parameters

Parameter	Programmable values
Setting	
Pause Prevention Detection Enable	On; Off; Monitor
Pause Prevention Detection Interval	5; 6 ... 15 s
Amplitude	1; 2; ... 8 V ^{a,b} 10; 13 V ^{b,c}
Pulse Width	2; 4; 6; 8 ms ^{a,b} 1; 2 ... 10 ms ^{b,c}
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1
Lower Rate ^{d,e,f,g}	40 bpm (1,500 ms) (\pm 1.3 bpm (\pm 50 ms) \leq 8 V; \pm 2.7 bpm (\pm 100 ms) \geq 10 V)
Therapy Duration ^d	30 s

^a For \leq 8 V amplitude, Ring 1 to Ring 2 or Ring 1 to Coil 2.

^b The tolerance for measurements performed per ISO 14708-2 is listed in Section 5.2.2.

^c For \geq 10 V amplitude, Coil 2 to Coil 1.

^d This parameter is nonprogrammable.

^e Escape interval is 1,500 ms.

^f The corresponding pacing interval or escape interval can be calculated as follows: interval (in ms) = 60 000/Lower Rate (in bpm).

^g The tolerance for the escape interval is \pm 30/–2 ms.

Sensing parameters

Parameter	Programmable values
Sensitivity ^{a,b,c}	0.075; 0.100; 0.150 (± 75%); 0.200; 0.300; 0.450; 0.600 (± 50%); 0.900; 1.200 mV (± 30%)
Sense Polarity	Ring 1 to Ring 2; Ring 1 to Can; Ring 2 to Can
Blank after Sense	140; 150 ... 200 ms
Sensing Threshold Decay Delay	210; 260 ... 360 ... 650 ms
Sensing Threshold Drop Time	500; 680; 1,000; 1,100 ... 1,500 ; 1,600 ... 2,000; 2,500 ms
Blank after Pace	200; 210 ... 250 ... 450 ms
Oversensing Prevention	Low - 1; 2; Medium - 3 ; 4; 5; High - 6

^a Warning: Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to a more sensitive setting. When susceptibility to modulated interference is tested under the conditions specified in ISO 14708-6, ISO 14117, or EN 45502-2-2, the device is more susceptible to electromagnetic interference. The device will meet standard requirements when the sensitivity threshold is programmed to 0.3 mV or higher.

^b There is no nominal value for this parameter.

^c Programming Sense Polarity to a unipolar setting (Ring 1 to Can or Ring 2 to Can) will result in increased susceptibility to EMI. Consider programming Sense Polarity to a bipolar setting whenever possible.

MRI SureScan parameters

Parameter	Programmable values
MRI SureScan	On; Off
Timeout ^a	6 hr
Mode ^a	OVO
Detection/Therapies ^a	Off

^a This parameter is nonprogrammable when the MRI SureScan feature is programmed to On.

Medtronic CareAlert™ parameters

Clinical management alerts

Parameter	Programmable values
Number of Shocks Delivered in an Episode ^a	
Device Tone	
Alert Enable – Urgency	Off ; On-Low; On-High
Number of Shocks Threshold ^b	1 ; 2; 3; 4; 5; 6
Patient Home Monitor ^c	
Alert Enable	Off ; On
Number of Shocks Threshold ^b	1 ; 2; 3; 4; 5; 6
All Therapies in a Zone Exhausted for an Episode	
Device Tone	
Alert Enable – Urgency	Off ; On-Low; On-High
Patient Home Monitor	
Alert Enable	Off ; On
Number of Pause Prevention Episodes	

Device Tone	
Alert Enable – Urgency	Off ; On-Low; On-High
Number of Pause Prevention Episodes Threshold ^b	1; 2; 3; 4; 5
Patient Home Monitor	
Alert Enable	Off; On
Number of Pause Prevention Episodes Threshold ^b	1; 2; 3; 4; 5
Alert Time (all others)	00:00; 00:10 ... 08:00 ... 23:50

^a Note that VF, VT, and FVT therapies could be delivered during a single episode (from initial detection until episode termination).

^b This parameter is displayed only when its related alert is enabled; a single parameter is shared between the Device Tone and Patient Home Monitor alerts.

^c Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

Lead/device integrity alerts

Parameter	Programmable values
Lead Impedance Out of Range	
Device Tone	
Alert Urgency ^a	Low; High
Lead Impedance Enable	
Ring 1 to Ring 2	On; Off (Observation only)
Ring 1 to Coil 2	On; Off (Observation only)
High Voltage	On; Off (Observation only)
Patient Home Monitor	
Lead Impedance Enable ^b	
Ring 1 to Ring 2	On; Off
Ring 1 to Coil 2	On; Off
High Voltage	On; Off
Low Battery Voltage RRT	
Device Tone	
Alert Enable – Urgency	Off; On-Low; On-High
Patient Home Monitor	
Alert Enable ^b	Off; On
Excessive Charge Time EOS	
Device Tone	
Alert Enable – Urgency	Off; On-Low; On-High
Patient Home Monitor	
Alert Enable ^b	Off; On
VF Detection Off, 3+ VF or 3+ FVT Rx Off	
Device Tone	
Alert Enable	Off; On-High
Patient Home Monitor	
Alert Enable ^b	Off; On

^a This parameter is displayed only if an associated alert has been enabled.

^b Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

Shared parameters

Parameter	Programmable values
Patient Home Monitor	Yes; No
Alert Time ^a	00:00; 00:10 ... 08:00 ... 23:50

^a This parameter is displayed only if an associated alert has been enabled.

Data collection parameters

Data collection parameters

Parameter	Programmable values
LECG Source ^a	Ring 1 to Ring 2; Ring 2 to Can ; Coil 2 to Ring 2
LECG Range	±1; ±2; ±4; ±8 ; ±12; ±16; ±32 mV
EGM 1 Source	Ring 1 to Ring 2 ; Ring 1 to Can; Ring 2 to Can; Coil 2 to Coil 1
EGM 1 Range	±2; ±4; ±8 ; ±12; ±16; ±32 mV
EGM 2 (Wavelet) Source	Ring 1 to Ring 2; Ring 1 to Coil 1; Ring 1 to Coil 2; Coil 2 to Can ; Coil 1 to Can; Ring 1 to Can; Ring 2 to Can; Coil 2 to Coil 1
EGM 2 (Wavelet) Range	±1; ±2; ±4; ±8 ; ±12; ±16; ±32 mV
EGM 3 Source	Coil 2 to Coil 1 ; Ring 1 to Ring 2; Coil 2 to Ring 2
EGM 3 Range	±1; ±2; ±4; ±8 ; ±12; ±16; ±32 mV
Stored (Ventricular)	EGM1 and EGM2 ; EGM1 and EGM3; EGM1 and LECG; EGM2 and EGM3; EGM2 and LECG; EGM3 and LECG
Pre-arrhythmia EGM	Off ; On - 1 month; On - 3 months; On Continuous
Device Date/Time ^b	(Enter time and date)
Holter Telemetry	Off ; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr

^a LECG: This EGM channel displays morphology channel signals.

^b The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

System test parameters

System test parameters

Parameter	Selectable values
Tests – Sensing	
Mode	
Test Value	OVO
Permanent	OVO

Tests – Pacing Threshold

Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1
Mode	
Test Value	VVI
Permanent	OVO
Lower Rate	30; 35 ... 60; 70; 75 ... 150 bpm
Amplitude	Ring 1 to Ring 2, Ring 1 to Coil 2: 1.00; 1.50 ... 8.00 V Coil 2 to Coil 1: 10; 13; 16; 20; 30 V
Pulse Width	Ring 1 to Ring 2, Ring 1 to Coil 2: 2.00; 4.00; 6.00; 8.00 ms Coil 2 to Coil 1: 0.50; 1.00; 2.00 ... 10.00 ms

Additional Settings

V. Pace Blanking	150; 160 ... 450 ms
Tests – Wavelet	
Wavelet enable	Off; On ; Monitor
Match Threshold	40; 43 ... 61 ... 97
Auto Collection	On ; Off
Mode	OVO

EP study parameters

T-Shock parameters

Parameter	Selectable values
Enable	(checked); (unchecked)
#S1	2; 3; 4; 5 ; 6 ... 15
S1S1	300; 310 ... 400 ... 2,000 ms
S1 Pathway	Ring 1 to Coil 2 ; Coil 2 to Coil 1
Delay	120; 130 ... 300 ... 600 ms
T Energy	1 ; 1.2; 1.4 ... 2; 3 ... 16; 18; 20 J
Waveform ^a	Monophasic

^a This parameter is nonprogrammable.

Burst induction parameter

Parameter	Selectable values
Enable	(checked); (unchecked)

PES parameters

Parameter	Selectable values
Enable	(checked); (unchecked)
#S1	1; 2 ... 8 ; 9 ... 15
S1S1	150; 160 ... 600 ; 610 ... 2,000 ms
S1S2	150; 160 ... 400 ; 410 ... 600 ms

PES parameters, cont'd.

Parameter	Selectable values
S2S3	150; 160 ... 400 ^a ; 410 ... 600 ms ^a
S3S4	150; 160 ... 400 ^a ; 410 ... 600 ms ^a
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1
Amplitude	Ring 1 to Ring 2, Ring 1 to Coil 2: 8 V Coil 2 to Coil 1: 10; 13; 16; 20; 30 V
Pulse Width	Ring 1 to Ring 2, Ring 1 to Coil 2: 2; 4; 6; 8 ms Coil 2 to Coil 1: 1; 2; 3; 4 ms

^a Default value when parameter is On is 400 ms.

Defibrillator parameters

Parameter	Selectable values
Enable	(checked); (unchecked) ^a
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40 ^a J
Waveform ^a	Biphasic
Pathway	STD ^a ; REV

^a This parameter is nonprogrammable.

Cardioversion parameters

Parameter	Selectable values
Enable	(checked); (unchecked) ^a
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40 ^a J
Pathway	STD ^a ; REV

Burst ATP parameters

Parameter	Selectable values
Enable	(checked); (unchecked) ^a
# Pulses	1; 2 ... 8 ^a ... 15
% RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88 ^a ; 91; 94; 97%
Minimum Interval	150; 160 ... 400 ms
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1
Amplitude ^a	Ring 1 to Ring 2, Ring 1 to Coil 2: 8 V Coil 2 to Coil 1: 10; 13; 16; 20; 30 V
Pulse Width	Ring 1 to Ring 2, Ring 1 to Coil 2: 2; 4; 6; 8 ms Coil 2 to Coil 1: 1; 2; 3; 4 ms

^a This value is nonprogrammable.

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
- Acute coronary disease
- Left ventricular dysfunction
- Cardiomyopathy
- Inherited primary arrhythmia syndromes
- Congenital heart disease
- Inflammatory, rheumatic and valvular heart disease

Note: For patient-specific recommendations such as primary and secondary preventions, 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.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

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