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 | |
| VF Zone Only (min) | 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 |
| 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%)<br>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<br>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<br>VT therapies: 3 ◆<br>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◈ … 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<br>VT therapies: 3◈<br>FVT therapies: 1◈ |
| Smart Mode[c] | On; Off◈ |
| Shared Settings | |
| Shared V. ATP | |
| V-V Minimum ATP Interval | 150; 160 … 200◈ … 400 ms (± 12 ms[d]/± 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◈ … 450 ms (±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 ≤ 8 V amplitude.
[e] At ≥ 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: 0.4 J - 35 J[a] | -35%/ +20% | -30%/ +20% | -30%/ +20% | -30%/ +20% | -50%/ +50% |
| 22 °C: 40 J | -30%/ +20% | -30%/ +20% | -30%/ +20% | -30%/ +20% | -50%/ +50% |
| 37 °C: 0.4 J - 4 J[a] | -30%/ +20% | -30%/ +20% | -30%/ +20% | -30%/ +20% | -50%/ +50% |
| 37 °C: 5 J - 35 J | -30%/ +20% | -20%/ +20% | -20%/ +20% | -30%/ +20% | -50%/ +50% |
| 37 °C: 40 J | -30%/ +20% | -15%/ +15% | -15%/ +15% | -30%/ +20% | -50%/ +50% |
| 45 °C: 0.4 J - 40 J[a] | -30%/ +20% | -30%/ +20% | -30%/ +20% | -30%/ +20% | -50%/ +50% |

[a] Tolerance is ± 0.25 J for energy levels for which ± 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]<br>10; 13; 16; 20; 30 V[b,c] |
| Pulse Width | 2; 4; 6; 8 ms[a,b]<br>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)<br>(± 1.3 bpm (± 50 ms) ≤ 8 V;<br>± 2.7 bpm (± 100 ms) ≥10 V) |
| Therapy Duration[d] | 30 s |

[a] For ≤ 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 ≥ 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 +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]<br>10; 13 V[b,c] |
| Pulse Width | 2; 4; 6; 8 ms[a,b]<br>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)<br>(± 1.3 bpm (± 50 ms) ≤ 8 V;<br>± 2.7 bpm (± 100 ms) ≥10 V) |
| Therapy Duration[d] | 30 s |

[a] For ≤ 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 ≥ 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 +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<br>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<br>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 ◆; 410 … 600 ms[a] |
| S3S4 | 150; 160 … 400 ◆; 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<br>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<br>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) ◆ |
| Energy | 0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40 ◆ J |
| Waveform[a] | Biphasic |
| Pathway | STD ◆; REV |

[a] This parameter is nonprogrammable.

## Cardioversion parameters

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

## Burst ATP parameters

| Parameter | Selectable values |
|---|---|
| Enable | (checked); (unchecked) ◆ |
| # Pulses | 1; 2 … 8 ◆ … 15 |
| % RR Interval | 50; 53; 56; 59; 63; 66 … 84; 88 ◆; 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<br>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<br>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, 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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