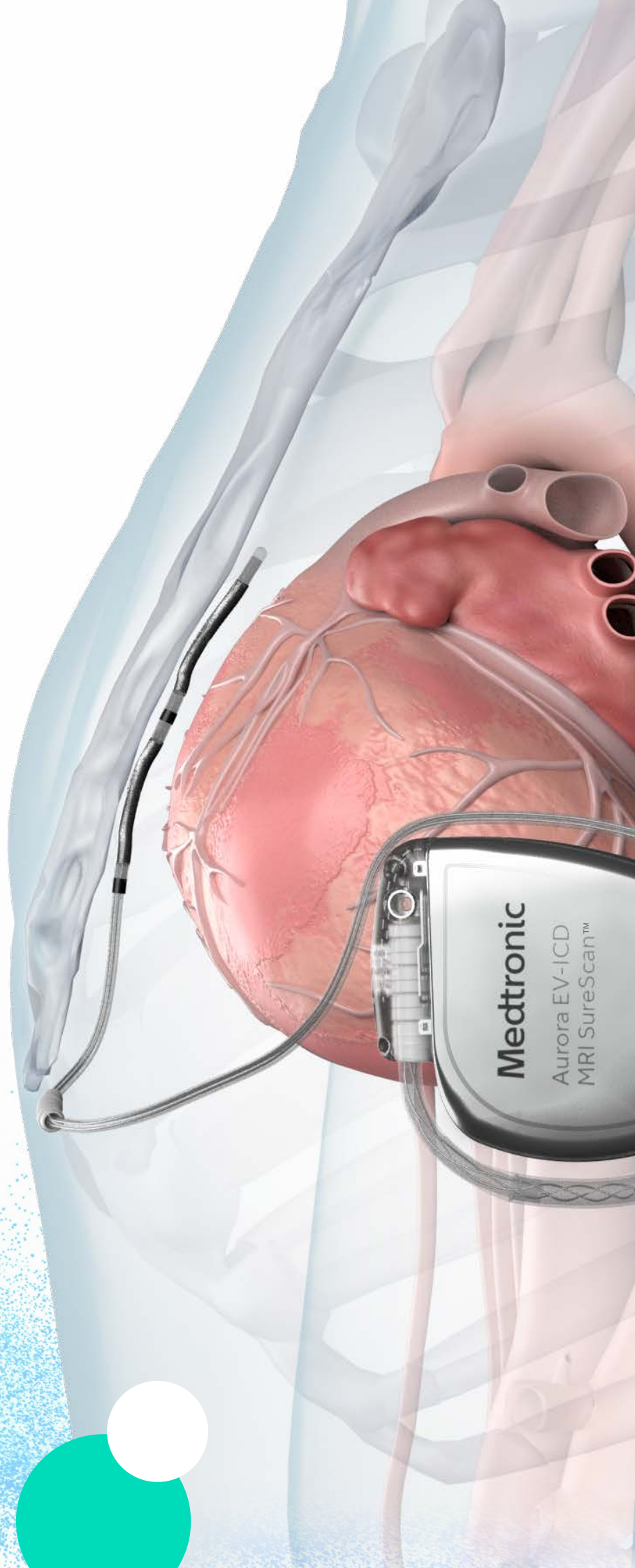


Medtronic

Aurora EV-ICD™ system

The extravascular system with
transvenous ICD features¹



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 cm³) and PhysioCurve™ design – same size and shape as Medtronic transvenous single-chamber ICDs



11.7-year projected longevity²



Pause Prevention pacing (backup bradycardia pacing)



Programmable VF detection intervals and multiple therapy zones



Monitor zone which allows for documentation of slow VTs, including non-sustained 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 objective¹ 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 studies⁷⁻¹² 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

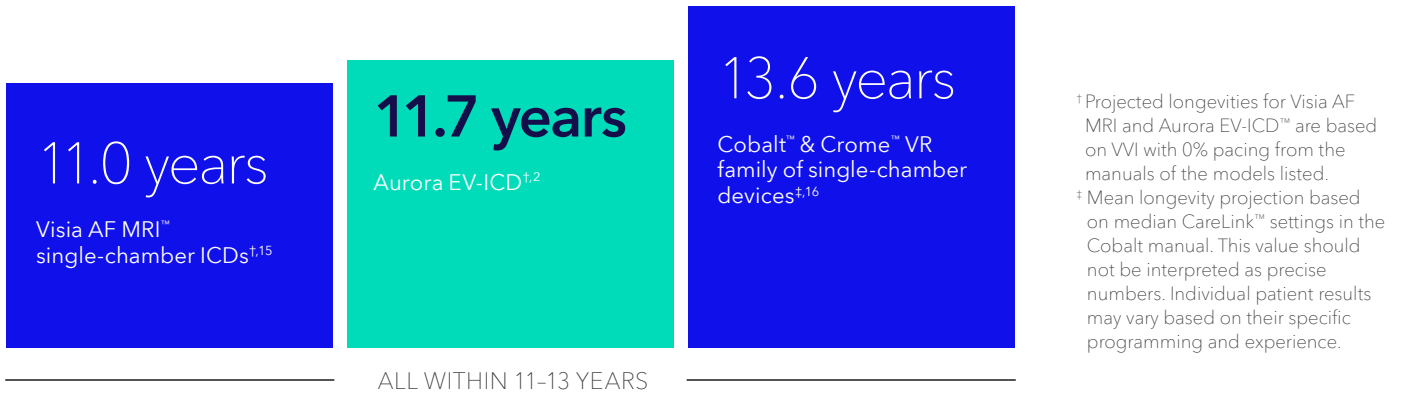
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FEATURES

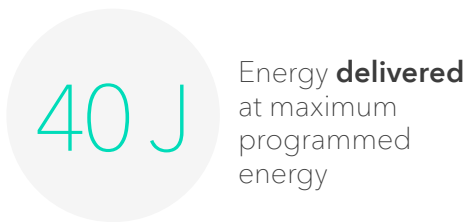
Projected longevity

Projected longevity similar to other Medtronic single-chamber ICDs



Option for 40 J energy delivery on all shocks

(including the first shock)²



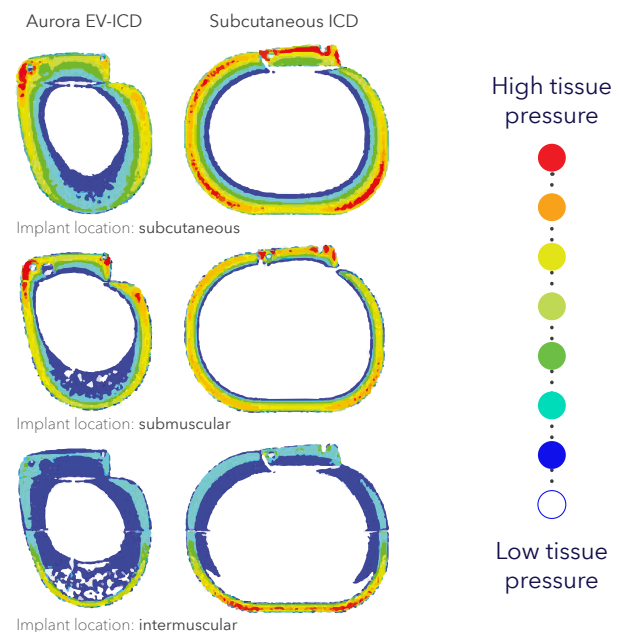
Effective defibrillation

at implantation in the EV ICD Pivotal clinical study¹ was greater than observed in historical transvenous ICD studies¹⁷⁻²⁰ 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



PACING CAPABILITIES

ATP

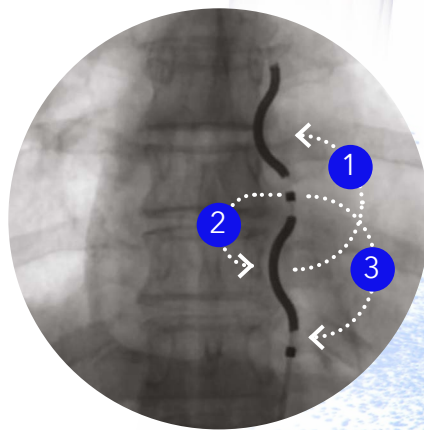
The only extravascular ICD to offer ATP

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



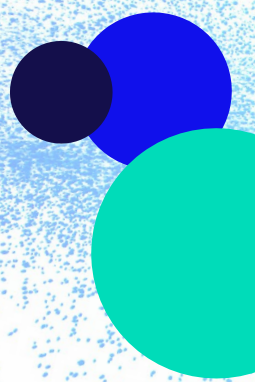
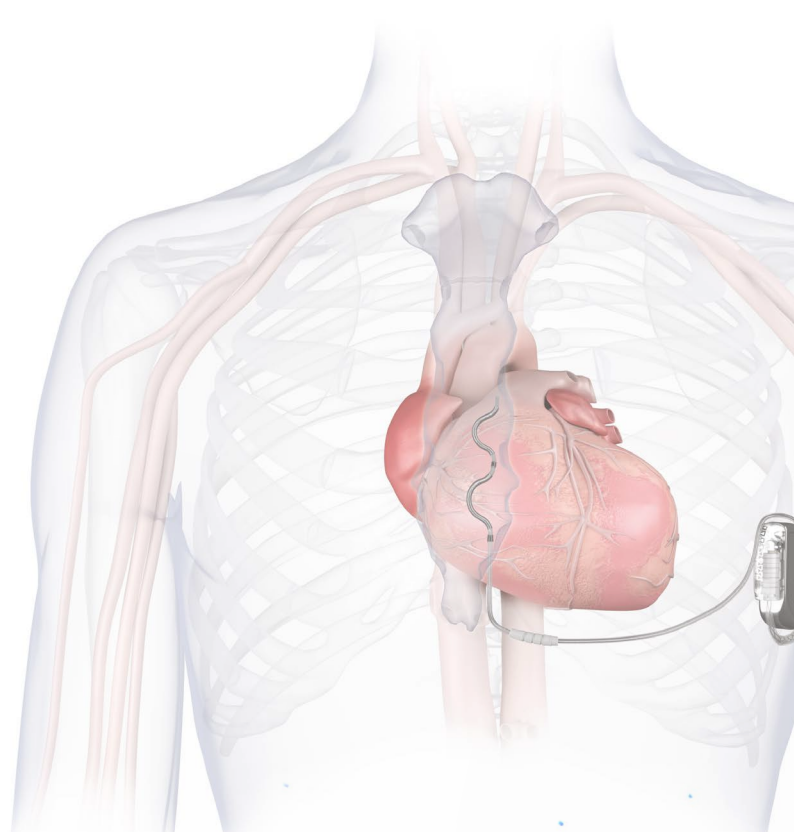
Pause Prevention pacing

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

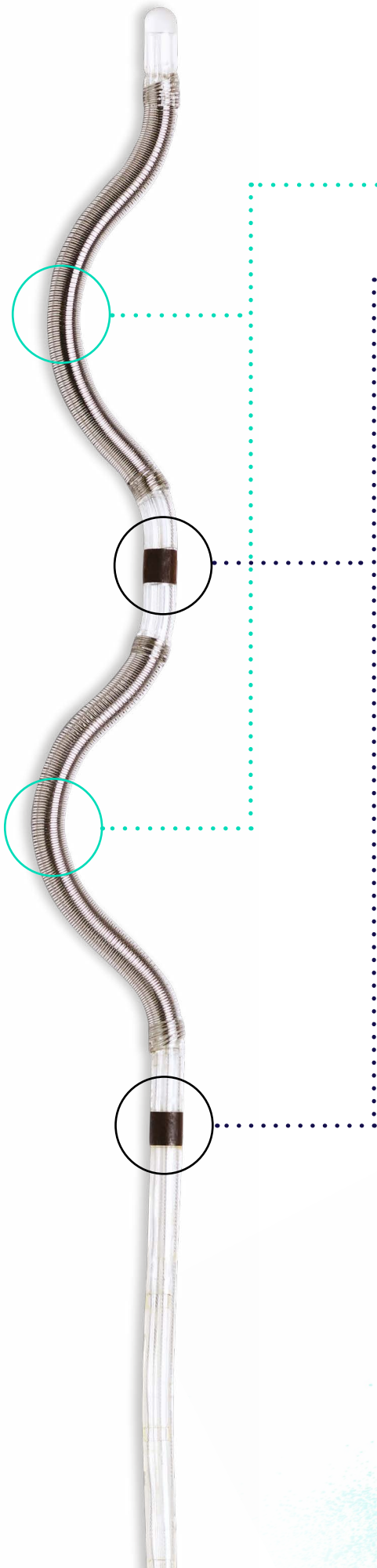
- Pacing/sensing ring electrodes positioned toward the patient's left side so they are closer to the heart

- 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 Conditional²⁶



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This material should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s). Please note that the intended use of a product may vary depending on geographical approvals.

See the device manual(s) for detailed information regarding the intended use, the (implant) procedure, indications, contraindications, warnings, precautions, and potential adverse events.

For a MRI compatible device(s), consult the MRI information in the device manual(s) before performing a MRI.

If a device is eligible for eIFU usage, instructions for use can be found at Medtronic's website manuals.medtronic.com.

Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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