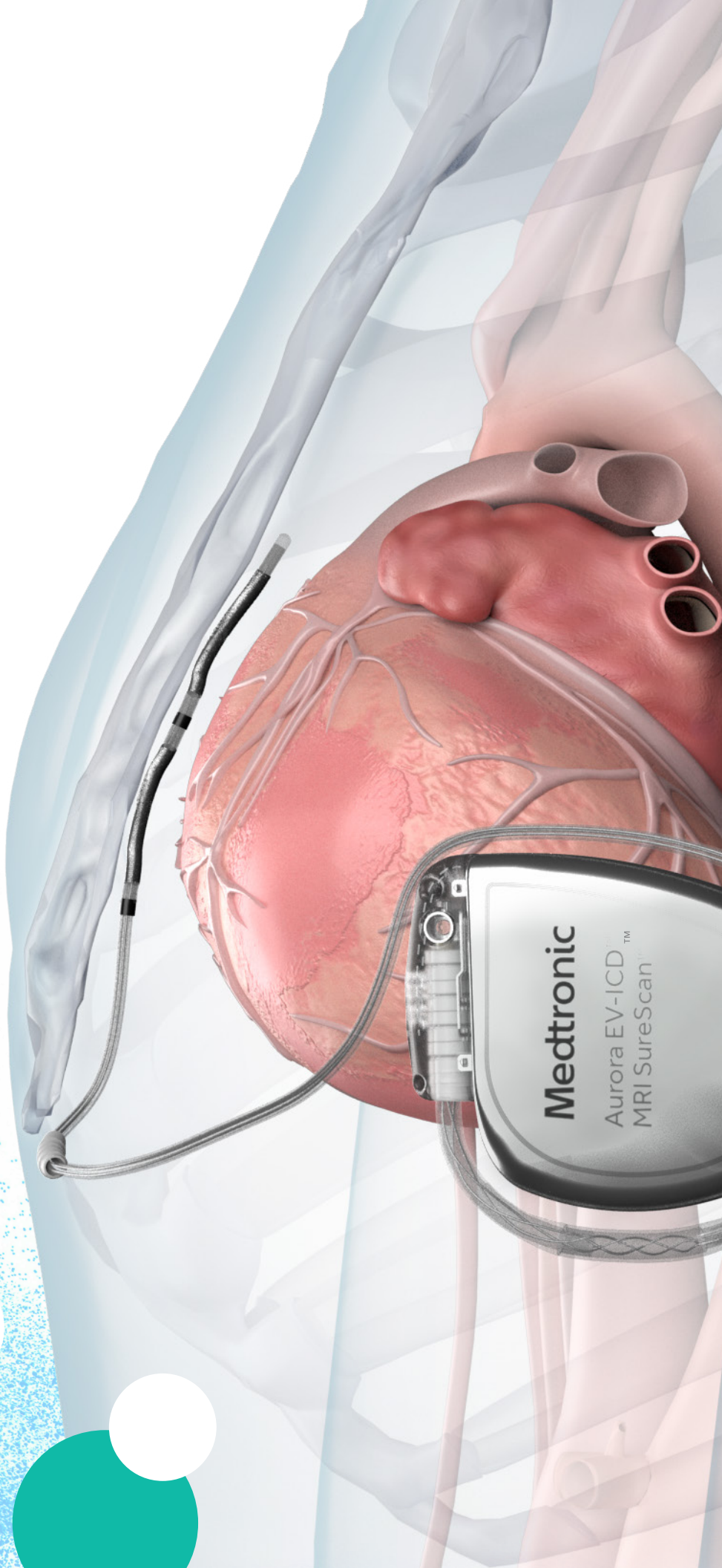
Medtronic

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[26]

Aurora EV-ICD provides features available in transvenous ICD systems

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 non-sustained VTs[26]

†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 S-ICD IDE study.[13] The study's investigators observed 25 major complications in 23 patients at 6 months. Procedure-related complications included revision for lead dislodgement and treatment of postoperative wound infection.[1] No system changes were required for seven events.

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Projected longevity

Projected longevity similar to other Medtronic single-chamber ICDs

11.0 years
Visia AF MRI™# single-chamber ICDs†[14]

11.7 years
Aurora EV-ICD†[2]

13.6 years
Cobalt™§ & Crome™¶ VR family of single-chamber devices ‡[15]

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

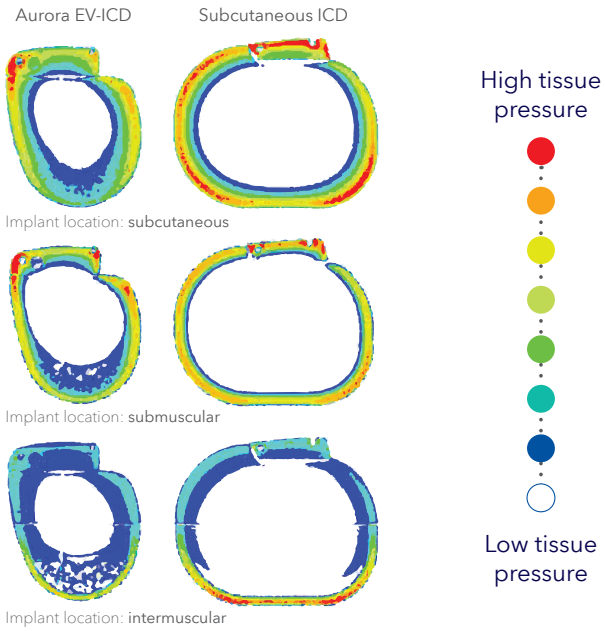
at implantation in the EV ICD Pivotal clinical study[1] was greater than observed in historical transvenous ICD studies[16-19] and similar to S-ICD.[13]

§The commercial name is Cobalt XT VR MRI SureScan
¶The commercial name is Crome VR MRI SureScan
#The commercial name is Visia AF MRI XT VR SureScan

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.[20]

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

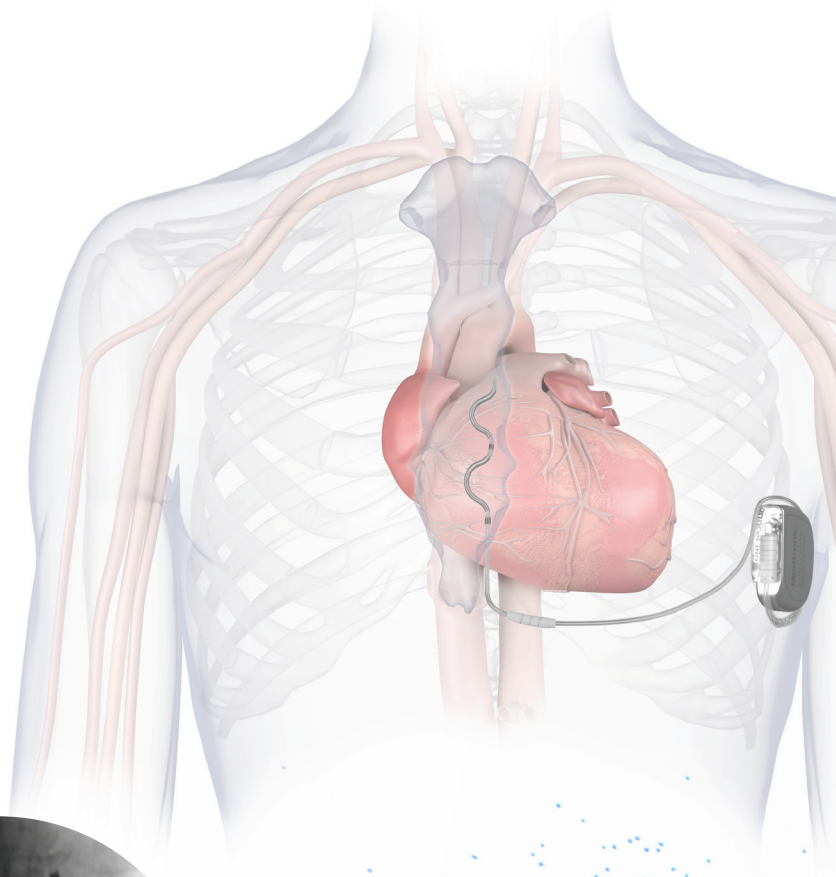


ATP

The only extravascular ICD to offer ATP[26]

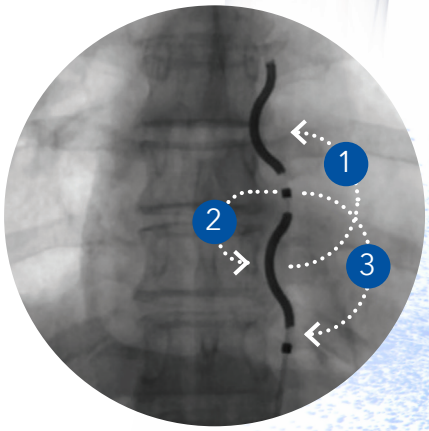
As with Medtronic transvenous ICDs, ATP therapy in Aurora EV-ICD includes Burst and Ramp pacing pulses, each with a programmable number of sequences.

In the EV ICD Pivotal clinical study, ATP successfully terminated 70% of episodes (32 of 46).[1] This is in the range of the ATP efficacy reported in transvenous ICD publications, 52% to 87%.[21-24]



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
  - Chronic lead extraction was prospectively studied in sheep. Chronic removal of 19 leads from the substernal space was successfully performed between one and three years post-implant using traction and simple tools.[25]

†The commercial name is Epsila EV MRI SureScan Lead

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 non-sustained 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, 1.5 and 3T compatibility[2]

References

[1] Friedman P, Murgatroyd F, Boersma LVA, et al. Efficacy and Safety of an Extravascular Implantable Cardioverter-Defibrillator. *N Engl J Med*. October 6, 2022;387(14):1292-1302.
[2] Medtronic Aurora EV-ICD™ MRI SureScan™ DVEA3E4 device manual.
[3] Crozier I, Haqqani H, Kotschet E, et al. First-in-Human Chronic Implant Experience of the Substernal Extravascular Implantable Cardioverter-Defibrillator. *JACC Clin Electrophysiol*. November 2020;6(12):1525-1536.
[4] Chan JYS, Lelakowski J, Murgatroyd FD, et al. Novel Extravascular Defibrillation Configuration With a Coil in the Substernal Space: The ASD Clinical Study. *JACC Clin Electrophysiol*. August 2017;3(8):905-910.
[5] Sholevar DP, Tung S, Kuriachan V, et al. Feasibility of extravascular pacing with a novel substernal electrode configuration: The Substernal Pacing Acute Clinical Evaluation Study. *Heart Rhythm*. April 2018;15(4):536-542.
[6] Boersma LVA, Merkely B, Neuzil P, et al. Therapy From a Novel Substernal Lead: The ASD2 Study. *JACC Clin Electrophysiol*. February 2019;5(2):186-196.
[7] Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an Implantable Cardioverter–Defibrillator for Congestive Heart Failure. *N Engl J Med*. January 20, 2005;352(3):225-237.
[8] Sweeney MO, Ellenbogen KA, Tang ASL, et al. Atrial pacing or ventricular backup–only pacing in implantable cardioverter-defibrillator patients. *Heart Rhythm*. November 2010;7(11):1552-1560.
[9] Curtis AB, Worley SJ, Adamson PB, et al. Biventricular pacing for Atrioventricular Block and Systolic Dysfunction. *N Engl J Med*. April 25, 2013;368(17):1585-1593.
[10] Linde C, Abraham WT, Gold MR, Sutton MSJ, Ghio S, Daubert C. Randomized Trial of Cardiac Resynchronization in Mildly Symptomatic Heart Failure Patients and in Asymptomatic Patients With Left Ventricular Dysfunction and Previous Heart Failure Symptoms. *J Am Coll Cardiol*. December 2, 2008;52(23):1834-1843.
[11] Gold MR, Sommer T, Schwitter J, et al. Full-Body MRI in Patients With an Implantable Cardioverter-Defibrillator: Primary Results of a Randomized Study. *J Am Coll Cardiol*. June 23, 2015;65(24):2581-2588.
[12] Auricchio A, Schloss EJ, Kurita T, et al. Low inappropriate shock rates in patients with single- and dual/triple-chamber implantable cardioverter-defibrillators using a novel suite of detection algorithms: PainFree SST trial primary results. *Heart Rhythm*. May 2015;12(5):926-936.
[13] Weiss R, Knight BP, Gold MR, et al. Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator. *Circulation*. August 27, 2013;128(9):944-953.
[14] Medtronic Visia AF MRI XT VR SureScan Model DVFB2D4 Device Manual. Available at http://manuals.medtronic.com/manuals/main/region.
[15] Medtronic Cobalt XT VR MRI SureScan Model DVPA2D4 and Crome VR MRI SureScan Model DVPC3D4 Device Manual. Available at http://manuals.medtronic.com/manuals/main/region.
[16] Michowitz Y, Lellouche N, Contractor T, et al. Defibrillation threshold testing fails to show clinical benefit during long-term follow-up of patients undergoing cardiac resynchronization therapy defibrillator implantation. *Europace*. May 2011;13(5):683-688.
[17] Leong-Sit P, Gula LJ, Diamantouros P, et al. Effect of defibrillation testing on management during implantable cardioverter-defibrillator implantation. *Am Heart J*. December 2006;152(6):1104-1108.
[18] Pires LA, Johnson KM. Intraoperative testing of the implantable cardioverter-defibrillator: how much is enough? *J Cardiovasc Electrophysiol*. February 2006;17(2):140-145.
[19] Healey JS, Hohnloser SH, Glikson M, et al. Cardioverter defibrillator implantation without induction of ventricular fibrillation: a single-blind, non-inferiority, randomized controlled trial. *Lancet*. February 28, 2015;385(9970):785-791.
[20] Mathiesen D, Bhatia V, Formosa E, et al. Prediction of Patient Comfort for Extravascular and Subcutaneous Implantable Cardioverter-Defibrillation Devices Using Modeling. AHA Abstract 13385. *Circulation*. November 8, 2021;144:A13385.
[21] Arenal A, Proclemer A, Kloppe A, et al. Different impact of long-detection interval and anti-tachycardia pacing in reducing unnecessary shocks: data from the ADVANCE III trial. *Europace*. November 2016;18(11):1719-1725.
[22] Schuger C, Daubert JP, Zareba W, et al. Reassessing the role of antitachycardia pacing in fast venrtricular arrhythmias in primary prevention implantable cardioverter-defibrillator recipients: Results from MADIT-RIT. *Heart Rhythm*. March 2021;18(3):399-403.
[23] Lee S, Stern R, Wathen M, et al. Anti-Tachycardia Pacing Therapy Effectively Terminates Fast Ventricular Tachycardia after Longer Detection Duration in Primary Prevention Patients: Results from the PREPARE Trial. *Heart Rhythm*. 2008;5(5):S334-S356.
[24] Sterns LD, Auricchio A, Schloss EJ, et al. Anti-tachycardia pacing success in implantable cardioverter defibrillators by patient, device, and programming characteristics. *Heart Rhythm*. February 2023;20(2):190-197.
[25] Thompson AE, Marshall M, Lentz L, Mazzetti H. Three-Year Extraction Experience of a Novel Substernal Extravascular Defibrillation Lead in Sheep. *Pacing Clin Electrophysiol*. March 2022;45(3):314-322.
[26] Data on file.

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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