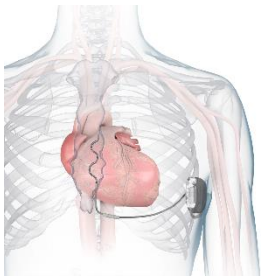
Medtronic

Engineering the extraordinary

Aurora EV-ICD™ MRI SureScan™ (Extravascular Implantable Cardioverter-Defibrillator) System

Sudden Cardiac Arrest	Sudden cardiac arrest (SCA) is a sudden, abrupt loss of heart function. Most sudden cardiac arrest episodes are caused by the rapid and/or chaotic activity of the heart known as ventricular tachycardia (VT) or ventricular fibrillation (VF). These are abnormalities of the heart's electrical conduction system.
Technology Overview	Transvenous implantable cardioverter-defibrillators (ICDs) have been saving lives for more than 30 years by delivering a lifesaving shock or painless pacing to stop life-threatening fast or irregular heartbeats. The Medtronic Aurora EV-ICD is intended to provide the benefits of traditional, transvenous ICDs in a single system and implant procedure, but without placing leads in the heart or vasculature. Those common benefits include: ▪ Lifesaving defibrillation therapy to interrupt dangerously fast heart rhythms that can lead to sudden cardiac arrest ▪ Anti-tachycardia pacing to terminate arrhythmias, potentially avoiding a defibrillation shock ▪ Pause prevention pacing, which provides back-up pacing for brief, intermittent heartbeat pauses.  In addition, the device is the same size (33 cc) and shape as traditional ICDs, with up to 11.7 years of projected longevity. The Aurora EV-ICD is implanted below the left armpit (in the left mid-axillary region), and the Epsila EV™ MRI SureScan™ defibrillation lead is placed under the breastbone (sternum) using a minimally invasive approach. Placing the leads outside the heart and veins is designed to help avoid long-term complications that may be associated with transvenous leads, such as vessel occlusion (narrowing, blockage or compression of a vein) and risks for blood infections. 
Extravascular ICD Pivotal Study	The EV ICD system was evaluated in a worldwide pivotal study. The prospective, multicenter, single-arm, non-randomized, pre-market clinical study assessed the safety and effectiveness of the Medtronic EV ICD system for patients at risk of sudden cardiac death. The EV ICD Pivotal study enrolled 356 patients at 46 sites in 17 countries in North America, Europe, the Middle East, Asia, Australia and New Zealand. Study results were presented as a late breaking clinical trial at ESC Congress 2022 and simultaneously published in *The New England Journal of Medicine.*[1]

	In the pivotal study, EV ICD System achieved a defibrillation success rate of 98.7% and met its safety endpoints of freedom from major system and/or procedural complications at six months after implant.[1] Safety and effectiveness results were sustained out to 18 months.[2]
Regulatory Status	In 2023, Medtronic received FDA approval and CE (*Conformité Européenne*) Mark for the Aurora EV-ICD ™ MRI SureScan™ (Extravascular Implantable Cardioverter-Defibrillator) and Epsila EV™ MRI SureScan™ defibrillation lead to treat dangerously fast heart rhythms that can lead to sudden cardiac arrest (SCA). Medtronic also has secured regulatory approval for proprietary tools to support implant procedures of the EV ICD system.

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[1] Friedman P, Murgatroyd F, Boersma LVA, et al. Efficacy and Safety of an Extravascular Implantable Cardioverter-Defibrillator. N Engl J Med 2022; 387:1292-1302.
[2] Friedman P, Murgatroyd F, Boersma LVA, et al. Chronic Safety and Performance of the Extravascular ICD: Results from the Global EV ICD Pivotal Study. Heart Rhythm Society late breaking clinical trials, May 20, 2023.