

The Development of the Extravascular Defibrillator with Substernal Lead Placement: A New Frontier for Device-Based Treatment of Sudden Cardiac Arrest

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Abstract

Introduction: The extravascular ICD (EV ICD) system with substernal lead placement is a novel non-transvenous alternative to current commercially available ICD systems. The EV ICD provides defibrillation and pacing therapies without the potential long-term complications of endovascular lead placement. **Methods:** This paper summarizes the development of the EV ICD, including the pre-clinical and clinical evaluations that have contributed to system and procedural refinements to date. **Results:** Extensive pre-clinical research evaluations and 4 human clinical studies with >140 combined acute and chronic implants have enabled the development and refinement of the EV ICD system, currently in worldwide pivotal study. **Conclusion:** The EV ICD may represent a clinically valuable solution in protecting patients from sudden cardiac death while avoiding the long-term consequences of transvenous hardware. The EV ICD offers advantages over transvenous and subcutaneous systems by avoiding placement in the heart and vasculature; relative to subcutaneous systems, EV ICD requires less energy for defibrillation, enabling a smaller device, and provides pacing features such as anti-tachycardia and asystole pacing in a single system.

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