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The Extravascular Implantable Cardioverter-Defibrillator: The Pivotal Study Plan

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Abstract

Background: Transvenous implantable cardiac defibrillators (TV ICD) provide life-saving therapy for millions of patients worldwide. However, they are susceptible to several potential short- and long- term complications including cardiac perforation and pneumothorax, lead dislodgement, venous obstruction, and infection. The extravascular ICD (EV ICD) system's novel design and substernal implant approach avoids the risks associated with TV ICDs while still providing pacing features and similar generator size to TV ICDs. Study Design: The EV ICD pivotal study is a prospective, multi-center, single-arm, non-randomized, pre-market clinical study designed to examine the safety and acute efficacy of the system. This study will enroll up to 400 patients with a Class I or IIa indication for implantation of an ICD. Implanted subjects will be followed up to approximately 3.5 years, depending on when the patient is enrolled. Objective: The clinical trial is designed to demonstrate safety and effectiveness of the EV ICD system in human use. The safety endpoint is freedom from major complications, while the efficacy endpoint is defibrillation success. Both endpoints will be assessed against prespecified criteria. Additionally, this study will evaluate antitachycardia pacing (ATP) performance, electrical performance, extracardiac pacing sensation, asystole pacing, appropriate and inappropriate shocks, as well as a summary of adverse events. Conclusion: The EV ICD pivotal study is designed to provide clear evidence addressing the safety and efficacy performance of the EV ICD System.

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