CathVision

A Prospective, Single Center, Pilot Study Using the CathVision ECGenius® system to Collect Electrogram Data to Test an Ablation Impact Algorithm

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PROTOCOL SYNOPSIS

Title	A Prospective, Single Center, Pilot Study Using the CathVision ECGenius® system to Collect Electrogram Data to Test an Ablation Impact Algorithm
Investigational Device	CathVision ECGenius® System
Intended Use	To acquire, amplify, digitize, and record atrial intracardiac electrophysiology signals during cardiac electrophysiology studies for the treatment of persistent atrial fibrillation and to use the recorded data to test the performance of an ablation impact algorithm.
Objectives	Collect electrophysiological data during atrial fibrillation (AF) ablation procedures to test an algorithm for AF responses.
Study Design	A prospective, single-center, pilot study using the CathVision ECGenius® system and the Ablation Impact Analyzer software in radiofrequency (RF) ablation procedures. Subjects with persistent atrial fibrillation who are indicated to undergo an RF ablation to treat persistent AF may be enrolled in the Study. Intracardiac signals will be passively recorded using the investigational ECGenius® System in parallel with the commercial (FDA Approved) EP Workmate, Abbott Inc. EP recording system. The investigational device will not be used for direct clinical care decisions or therapy. The validation of the automated algorithm will be performed offline.
Sample Size	Up to 30 patients may be enrolled in this pilot study.
Investigational Site	NYU Heart Rhythm Centre, New York, USA
Study Duration / Follow-up Period	Study enrollment is planned for one to three months.
Primary Objective	The Primary endpoint of the study will be evaluated as the safety and technical success of CathVision ECGenius® System to collect and record intracardiac signals during EP procedures. With focus on: The assessment of the performance of an ablation impact algorithm for analyzing AF responses.

Secondary Objective	The secondary objectives are: • Assessment of the performance of an AF cycle length algorithm
Safety Endpoint	Evaluation of adverse events and/or device malfunctions reported with the use of the CathVision ECGenius® System during the procedure until discharge.
Enrollment Criteria	Inclusion Criteria Eligible patients will meet all of the following inclusion criteria: 1. Patients scheduled for RF ablation indicated by the investigator for the treatment of persistent atrial fibrillation. 2. Male or female ≥ 21 years of age. 3. Able and willing to provide written informed consent prior to any clinical investigation related procedure. Exclusion Criteria Eligible patients will not meet any of the following exclusion criteria: 1. Current participation in another investigational drug or device study that interferes with this study. 2. Patients who, in the opinion of the investigator, are not candidates for this study. 3. Presence of other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's opinion, could limit the patient's ability to participate in the clinical investigation or to comply with follow-up requirements, or impact the scientific soundness of the clinical investigation results. 4. Life expectancy less than 12 month, in the opinion of the Investigator. 5. Patients who are considered part of any vulnerable population. 6. Patient is a prisoner.