Synopis of Clinical Investigation Plan (CIP)

Subcostal Temporary Extracardiac Pacing (STEP) Study

Clinical Study of the AtaCor Extracardiac Pacing System

Excerpt from DOC-10052, Revision A

23 July, 2019

NCT 04096365

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Synopsis of the Clinical Investigation

Study Name	Subcostal Temporary Extracardiac Pacing (STEP) Study
Study Objectives	To evaluate initial safety and performance of the AtaCor Temporary Pacing System. Safety will be evaluated through analysis of all Adverse Events. Performance will be evaluated through (1) the incidence of successful StealthTrac Lead placement using the MACH I Delivery Tool, (2) measurements of capture thresholds, sensed R-wave amplitudes, pacing impedance and concomitant skeletal muscle stimulation at rest, in multiple postures and during in-hospital ambulation, and (3) differences in cardiac conduction (12 lead ECG) and function (Echocardiography) while pacing with temporary transvenous lead, the AtaCor StealthTrac Lead and during intrinsic conduction.
Study Size	Up to 15 Subjects inserted with the StealthTrac Lead from a maximum of three (3) investigation sites. This study is not statistically-powered. Results may be used to generate hypotheses for subsequent clinical investigations.
Study Duration	The total expected duration of the investigation is four (4) to six (6) months, comprising two (2) to four (4) months for enrollment and follow-up, plus an additional two (2) months to analyze study data and prepare a final report. Subject participation consists of an in-hospital device evaluation up to seven (7) days and a 30-day post-removal follow-up visit to detect any latent adverse events after hospital discharge.
Study Design	Prospective, subacute (in-hospital), single-arm, multicenter
Study Population	To participate in this clinical investigation, Subjects must meet all the following criteria: 1. Indicated for closed-chest cardiac invasive procedure with the potential for intra-procedural or post-procedural bradycardia and willing to be hospitalized for a minimum of 2 days post procedure. Examples of such procedures include: transfemoral transcatheter aortic valve replacement (TAVR), balloon valvuloplasty, permanent pacemaker implantation and pacing lead extractions/revisions. 2. Physically and mentally capable of providing informed consent. 3. At least 18 years of age or of legal age to provide consent as required by local and national requirements. To participate in this study, Subjects must not meet any the following criteria: 1. Contraindicated or clinically unsuitable for transvenous lead placement; 2. Implanted with an implantable cardioverter defibrillator (ICD) or transvenous defibrillation lead at the time of enrollment; 3. History of a prior sternotomy (median or partial); 4. History of prior surgery with disruption of the lung, pericardium or connective tissue between the sternum and pericardium; 5. History of significant anatomic derangement of the thorax (e.g., pectus excavatum), prior chest radiation therapy or other reasons which may cause pericardial adhesions or complicate the AtaCor Temporary Pacing System insertion procedure; 6. History of pericardial disease, pericarditis or mediastinitis; 7. History of chronic obstructive pulmonary disease (COPD); 8. NYHA functional classification IV at the time of enrollment; 9. History of congenital heart disease; 10. Patients with circumstances that prevent data collection or follow-up, including conditions that prevent ambulation and testing in multiple postures; 11. BMI $\geq$ 35 kg/m^2; 12. History of allergies to any study device components; 13. Pregnant or lactating (current or anticipated during study follow up); and 14. Participation in any concurrent study without prior, written approval from the Sponsor.

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Figure 1 provides an overview of study activities. Enrolled Subjects will have a market-released transvenous pacing lead and investigational StealthTrac Lead placed. Both leads will be evaluated to confirm ventricular sensing and capture. Diagnostic echocardiograms will be performed to detect any pericardial effusions caused by inserting the StealthTrac Lead. The index procedure will be performed according to standard of care methods, after which the StealthTrac Lead will be used to deliver high rate pacing (160 to 220 BPM) in clinically appropriate Subjects. The electrical performance of both leads will be reconfirmed, and lead positions will be documented using x-ray before the Subject leaves the procedure room. The day after the procedure, Subjects will undergo a 12 lead ECG while pacing with each lead.

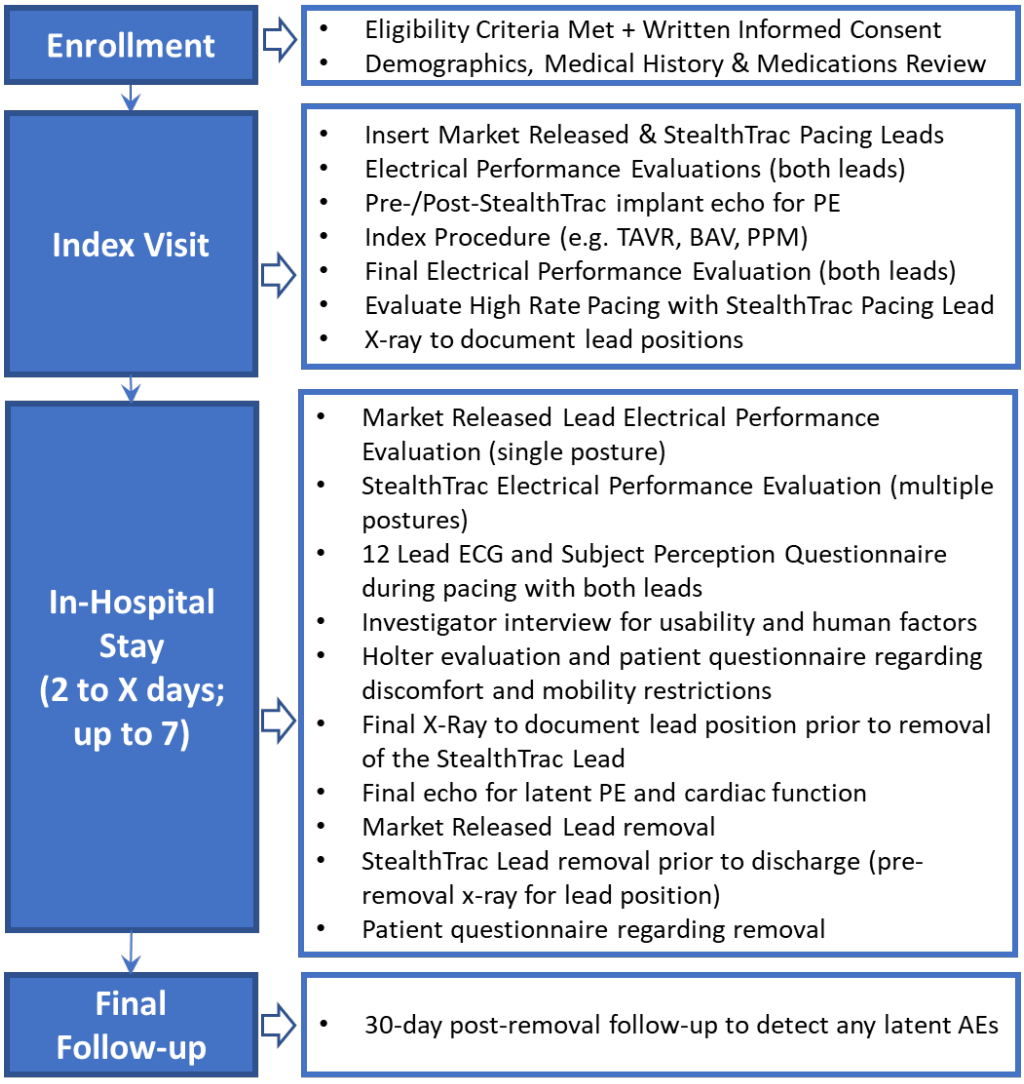

Figure 1. Study Flow Chart

Both leads will undergo daily Electrical Performance Evaluations and in multiple postures when clinically appropriate. Post-operative evaluations will be performed during periods of rest and during activity. Appropriate pacing performance during activity will be evaluated using ECG Holter monitor recordings. Subjects will also be asked patient-centric questions about their experience with the StealthTrac Lead throughout the study period.

Evaluations will continue until the Subject is discharged from the hospital, with a minimum of two (2) and a maximum of seven (7) evaluation days after the index procedure. Prior to StealthTrac Lead removal, an X-Ray will be taken to document the final lead position and diagnostic echocardiography will be performed to (1) detect any latent pericardial effusions and (2) assess differences in cardiac function with intrinsic conduction and while pacing with the StealthTrac Lead and market released lead. A final follow-up will be performed 25-30 days after removal to identify any latent adverse events before the Subject exits the study.

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