

CELESTIAL

Principal Investigator:

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Sponsor:

Biotronik, Inc.

Study Purpose:

Post Approval Registry

(Corox OTW, Endocardial, Left VENTricular STeroId LeAd, BipoLar Post Approval Registry)

Objective:

The purpose of this post-approval registry is to confirm long-term safety and successful biventricular pacing for BIOTRONIK's Corox OTW(-S) B Pleft ventricular (LV) pacing leads as used in conjunction with any BIOTRONIK CRT pulse generator (CRT pacemaker (CRT-P) or CRT defibrillator (CRT-D)). The evaluation of safety will be based on the analysis of Corox OTW(-S) BP LV lead related adverse events. The CELESTIAL post-approval registry will provide data to permit characterization of any LV lead failures contributing to patients losing CRT. Additionally, acute and chronic LV lead parameters for pacing thresholds and impedance will be evaluated.

Inclusion Criteria:

- Successfully implanted BIOTRONIK CRT system, including a Corox OTW(-S) BP LV lead, from 7-180 days prior to enrollment
- Able to understand the nature of the registry and give informed consent
- Available for follow-up visits on a regular basis at the investigational site
- Age greater than or equal to 18 years

Exclusion Criteria:

- Enrolled in any IDE clinical study
- Planned cardiac surgical procedures or interventional measures within the next 6 months
- Expected to receive a heart transplant within 1 year
- Life expectancy less than 1 year
- Presence of another life-threatening, underlying illness separate from their cardiac disorder
- Pregnancy

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- Inability to provide date of implant, devices implanted, age, gender, and whether the patient experienced any protocol-defined adverse events since implant

Status:

Active enrollment

If you have any questions, please feel free to contact the coordinators, and they will be happy to answer any questions you have regarding this study.