CELESTIAL

NCT00810264

Principal Investigator: Dr. Asim Yunus, MD (S. Washington Office)

Condition: Congestive Heart Failure

Device: CRT Therapy - LV Lead Registry

Official Title: Post Approval Registry of Corox OTW, Endocardial, Left Ventricular Steroid Lead, Bipolar (CELESTIAL)

Sponsor: Biotronik, Inc.

Purpose: The objective of this study is to confirm the long-term safety and reliability of the Corox OTW BP left ventricular (LV) pacing lead. As a condition of approval, the FDA required that a registry documenting the post approval clinical experience of these leads be designed and implemented.

Inclusion Criteria:

- Successfully implanted BIOTRONIK CRT system, including a Corox 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
- Inability to provide date of implant, devices implanted, age, gender, and whether the patient experienced any protocol-defined adverse events since implant

Source: https://clinicaltrials.gov/ct2/show/NCT00810264
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