

# COSMO

**Principal Investigator:**

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**Sponsor:**

Biotronik

**Study Purpose:**

Clinical Protocol for the COSMO Post Approval Registry (Corox OTW Steroid LV Lead Monitoring)

**Objective:**

The purpose of this study is to confirm the long term safety and effectiveness of the Corox OTW Steroid LV Lead, a non-investigational lead. The study involves the collection and analysis (testing) of data at regular follow-up visits with your doctor. These follow up visits with your doctor are no different than would otherwise occur were you not to enroll in the study.

**Inclusion**

- ♥ Has the patient received a successfully implanted Kronos LV-T CRT-D ICD system (or other Biotronik CRT-D ICD), including a Corex OTW Steroid LV lead, within the last 30days?
- ♥ Is the patient able to understand the nature of the study and give informed consent?
- ♥ Is the patient available for follow-up visits on a regular basis at the investigational site?
- ♥ Is the patient's age  $\geq$  18 years?

**Exclusion**

- ♥ Is the patient enrolled in another cardiovascular or pharmacological clinical investigation?
- ♥ Does the patient have planned cardiac surgical or interventional measures in the next 6 months?
- ♥ Is the patient expected to receive a heart transplant within the next 6 months?
- ♥ Is the patient's life expectancy  $<$  6 months?
- ♥ Does the patient have another life-threatening, underlying illness separate from their cardiac disorder?
- ♥ Is the patient pregnant?
- ♥ Is the patient eligible for enrollment?

**Status:**

Follow-up ONLY!

## **COSMO**

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.