LSS of 4SITE

NCT01596595

Principal Investigator: Dr. Asim Yunus, MD (Covenant)

Condition: Primary Prevention of Sudden Cardiac Arrest, Secondary Prevention of Sudden Cardiac Arrest

Device: 4-SITE Lead/Header System (Boston Scientific ENDOTAK RELIANCE® 4-SITE™ Lead and the pulse generator 4-SITE Header.)

Official Title: Longitudinal Surveillance Study of the 4-SITE Lead/Header System (LSS of 4-SITE)

Sponsor: Boston Scientific Corporation

Purpose: Post-approval studies of implanted leads provide an opportunity to observe and assess patient outcomes and technology performance in a real-world setting. The goal of the study is to evaluate, document and report on the appropriate clinical performance, long-term reliability and the functional integrity of the Boston Scientific ENDOTAK RELIANCE® 4-SITE™ Lead and the pulse generator 4-SITE Header.

Inclusion Criteria:

- medically indicated for ICD/CRT-D
- received/plan to receive study lead
- willing for long-term follow-up

Exclusion Criteria:

- unwilling to comply with protocol

Source: https://clinicaltrials.gov/ct2/show/NCT01596595
Retrieved on: 7/7/2017