

SHORT TITLE: LSS for 4-SITE

RESEARCH PROTOCOL TITLE: The Longitudinal Surveillance Study of the 4-SITE Lead/Header System

PRINCIPAL INVESTIGATOR: E. Wayne Grogan, Jr., MD

RESEARCH SPONSOR: Boston Scientific Corporation

Clinical Trials.Gov Listing at: <http://clinicaltrials.gov/ct2/show/NCT01596595?term=LSS+4-site&rank=1>

STUDY PURPOSE

This study will evaluate and report on the long-term reliability and performance of Boston Scientific's FDA approved, 4-SITE Lead/Header device system. Device systems consist of a "pulse generator" and up to three (3) leads. The pulse generator contains the power source (battery) and the electronic components. The leads are wires that carry electrical impulses from the pulse generator to the patient's heart (for pacing and/or shocking the heart as needed).

ELIGIBILITY CRITERIA FOR SUBJECTS

Subject has or will receive an implanted Internal Cardiac Defibrillator with the 4-Site Lead/Header system.

SUBJECT PAYMENT

There is no compensation for participating in this study.

RESEARCH LOCATION AND CONTACT PERSON

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