

SLS

Principal Investigator:

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Sub-Investigators:

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Sponsor:

Medtronic

Study Purpose:

System Longevity Study (SLS) – 4195 Chronic Performance Sub-Study
Clinical Investigation Plan (CIP)

Objective:

The purpose of SLS is to evaluate and publish the long-term reliability and performance of Medtronic market-released cardiac therapy products by analyzing product survival probabilities. The data gathered in this study may also be used to support the design and development of investigational plans for new cardiac therapy products.

Inclusion Criteria:

- Subject has a new, active Medtronic market-released lead whose enrollment limit has not been achieved and either a pacemaker, defibrillator, or cardiac resynchronization therapy device
- Subject received the new lead within a predetermined length of time, typically 6 months
- Subject plans to receive follow-up care at a study center
- Subject has a Medtronic CapSure Epi Lead (models 4965 and 4968) and plans to receive follow-up at an eligible site. Subject can be enrolled retrospectively.

Exclusion Criteria:

- Subject received an implant at a non-participating center and the implant data and current status cannot be confirmed within 30 days after implant.
- Subject who is, or will be inaccessible for follow-up at an SLS center.
- Subjects implanted with a Medtronic cardiac therapy device whose enrollment limit for that specific product has been exceeded.
- Subjects with exclusion criteria required by local law.

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4195 Chronic Performance Sub-Study Clinical Investigation Plan (CIP)

Inclusion Criteria:

- Subject or appropriate legal guardian provides written informed consent and authorization for access to and use of health information (if applicable)
- Complete implant and follow-up data, including Model 4195 lead-related events are available

AND one of the following must apply:

- Subject is within six months post-implant of a 4195 Model lead connected to a market released Cardiac Resynchronization Therapy (Cardiac Resynchronization Therapy-Pacemaker or Cardiac Resynchronization Therapy-Defibrillator) device. The Medtronic lead must be used for a pacing or sensing application.
- Subject who participated in the Medtronic Attain StarFix Model 4195 Left Ventricular Lead Pre-Market Study.

Exclusion Criteria:

- Subject implanted at a non-participating site, and implant, follow-up data, including Model 4195 lead-related events are not available within 30 days from implant
- Subject who is, or will be inaccessible for follow-up at a study site
- Subject with exclusion criteria required by local law (Europe, Middle East or Africa only)

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.