

# RELIANCE Quadripolar Defibrillation leads (4-site) Field Following

Published: 27-04-2009

Last updated: 04-05-2024

The purpose of this study is to evaluate and document appropriate clinical performance of the new RELIANCE Quadripolar (4-SITE) defibrillation lead and the 4-SITE Header / Lead interface when connected to the TELIGEN 100 HE 4-SITE (VR or DR)...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Cardiac arrhythmias
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON33403

### Source

ToetsingOnline

### Brief title

The 4-SITE Field Following Study (4-SITE FF)

### Condition

- Cardiac arrhythmias

### Synonym

Ventricular Tachyarrhythmia's - cardiac rythm disorder

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Boston Scientific

**Source(s) of monetary or material Support:** Boston Scientific

## Intervention

**Keyword:** 4-SITE Header/Lead interface, Quadripolar Defibrillation lead, single connector Defibrillation lead

## Outcome measures

### Primary outcome

The primary objective of this study is to evaluate appropriate performance of the RELIANCE 4-SITE defibrillation lead and of the new 4-SITE Header / Lead interface by demonstrating - appropriate detection and shock conversion of induced Ventricular tachyarrhythmia\*s (VT/VF) -appropriate pacing thresholds, shock and pacing lead Impedances at follow-up as a measure of lead integrity over 12 month time, and - Appropriate sensing and absence of artefacts / non-sustained / sustained episodes resulting from transient potentials (artefacts) originating from incomplete lead / header contact.

### Secondary outcome

The secondary objectives are to document Implant Experience by collecting and analyzing information regarding 4-Site system handling, and to answer clinical questions by performing different types of retrospective analysis of study data.

## Study description

### Background summary

The purpose of the study is to test a new lead: de RELIANCE quadripolar (4-SITE) defibrillation lead implanted together with an implantable 4-SITE cardioverter defibrillator (\*4-SITE ICD\*) from Boston Scientific: the TELIGEN

100 HE 4-SITE ICD (VR or DR) of the COGNIS 100 HE 4-SITE CRT-D.  
The 4-SITE lead is special because it only has one pin to attach it to the device rather than the 3 pins used with previous style leads. This one pin contains all the functions from the previous lead type.

## **Study objective**

The purpose of this study is to evaluate and document appropriate clinical performance of the new RELIANCE Quadripolar (4-SITE) defibrillation lead and the 4-SITE Header / Lead interface when connected to the TELIGEN 100 HE 4-SITE (VR or DR) implantable cardioverter defibrillator ICD, or the COGNIS 100 HE 4-SITE cardiac resynchronization therapy CRT-D.

## **Study design**

This is a Prospective, multi-centre, field following study with data collected from a maximum of 450 patients at up to 50 study centres worldwide. Patients enrolled for the study will be followed for a period of 12 month after implant: at implant, pre-discharge (optional), 1, 3, 6, 9 and 12-months. It is estimated that the patient enrollment will be completed in approximately 9 months. The study is expected to start enrollment in Q2 of 2009. The total duration of the study is expected to be approximately 21 month.

## **Study burden and risks**

Burden : patients require an additional visit at month 1, 3 and 9 months.

Risk : the risks related to study participation are the same as when the patient would not participate to the study.

## **Contacts**

### **Public**

Boston Scientific

Lambroekstraat 5D

1831 Diegem

BE

### **Scientific**

Boston Scientific

Lambroekstraat 5D

1831 Diegem

BE

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

#### Study Specific

- ICD / CRT-D Indication according to normal clinical practice
- Patients receiving:
  - a single or dual chamber 4-SITE compatible ICD
  - or a 4-SITE compatible CRT-D
  - one of the RELIANCE 4-SITE defibrillation leads
- Patients currently implanted with a pacemaker
  - upgraded to a 4-SITE compatible ICD or CRT-D (4-SITE header)
  - one of the RELIANCE 4-SITE defibrillation leads

#### General

- Willing and capable of providing informed consent for
- undergoing a 4-SITE system implant,
- participating in all testing associated with this clinical investigation at an approved clinical investigational centre and at the intervals defined by this protocol
- Geographically stable patients who are available for follow-up at a study centre
- Age 18 or above, or of legal age to give informed consent specific to national law

### **Exclusion criteria**

#### Study Specific

- ICD and CRT-D Patients scheduled for a device replacement
- CRM Patients who have or who would need an lead adaptor
- All patients who have an active or non-active defibrillation lead other than 4-SITE

#### General

- Not willing and not capable of providing informed consent, undergoing a device implant, participating in all testing associated with this clinical investigation (including VT/VF shock conversion) at an approved clinical investigational centre and at the intervals defined by this

protocol

- Patients who were in NYHA Class IV during the last 3 month
- Patients with pre-existing diseases, which may confound study results
- Patients currently requiring dialysis,
- Cancer patients
- Patients with drug and/or alcohol abuse history
- Life expectancy < 12 months (or expected heart transplant within 12 months)
- Patients on a Heart Transplant List
- Women who are pregnant or plan to become pregnant. Method of assessment per physician discretion.
- Enrolled in any other concurrent study

## Study design

### Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-05-2009
Enrollment:	60
Type:	Actual

## Ethics review

Approved WMO	
Date:	27-04-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL27592.058.09