Heart failure (HF) involves costly hospitalizations with 25% of HF patients requiring readmission within 30 days after initial hospitalization. The MultiSENSE study validated the performance of the HeartLogic™ Heart Failure Diagnostic to proactively predict worsening heart failure using a proprietary algorithm. The algorithm combines data from sensors in an implantable device evaluating heart sounds, thoracic impedance, respiration rate and volume, heart rate and activity over time.

The HeartLogic Heart Failure Diagnostic and sleep incline trend have CE Mark and U.S. Food and Drug Administration approval within the Resonate™ family of ICD and CRT-D systems.

The following were observed in the MultiSENSE Study:

**THE HEARTLOGIC DIAGNOSTIC PERFORMANCE**

- Observed sensitivity to detect a hospitalization or unplanned intravenous therapy primarily for heart failure of 70%
- Low burden of less than two total alerts per patient per year
- Success in alerting clinicians of an associated HF event with weeks of advance notice
- 34-day median alert window
- 89% of events had alert occur at least 2 weeks before event

**HF EVENT RATE DURING AN ALERT**

- 10 times higher HF event rate when in vs. out of alert (0.80 vs. 0.08 events per patient per year)
- 5.9 times higher HF event rate when in vs. out of alert after adjusted for baseline characteristics: N-terminal pro B-type natriuretic peptide (NT-proBNP), history of atrial fibrillation, renal disease, New York Heart Association (NYHA) functional classification, diabetes, left ventricular ejection fraction, plasma total protein and sodium
- 83% of patient-days out of alert

**SLEEP INCLINE TREND**

- Available only in the Boston Scientific Resonate™ family of implantable cardioverter defibrillator (ICD) and CRT-D devices in addition to the HeartLogic Diagnostic
- Elevated sleep incline angle was indicative of Orthopnea or Paroxysmal nocturnal dyspnea

The study assessed more than 900 patients who had enhanced sensor data collection enabled in their cardiac resynchronization therapy defibrillator (CRT-D) systems. The data validated the alert to have:

- an observed sensitivity of **70%**
- The ability to provide weeks of advance notice – a median of **34-days** ahead of an impending HF event – and low burden for detecting indications of worsening HF.4
INDICATIONS AND USAGE

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any of the following classifications: Moderate to severe heart failure (NYHA Class III/IV) with EF < 35% and QRS duration > 130 ms, EF < 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

CONTRAINDICATIONS

There are no contraindications for this device.

WARNINGS

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillator equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require emergency resuscitation. Do not use this pulse generator with another pulse generator. Program the pulse generator Tach Mode(s) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braze the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4-LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implant a system that uses both a DF4-LLHH or DF4-LLHO and IS4-LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a magnet. For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home. For specific information on precautions, contraindications, warnings/precautions and adverse events. Rx only. (Rev. D) 04677 4 AH

REFERENCE

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. D) 04677 4 AH

ICD Systems – RESONATE™, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL

INDICATIONS AND USAGE

Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS

Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis, or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning, or patients with a unipolar pacemaker.

WARNINGS

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillator equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require emergency resuscitation. Do not use this pulse generator with another pulse generator. Program the pulse generator Tach Mode(s) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braze the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a magnet. For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet, and an EGM has been stored, or after 60 days have elapsed from the day that EGM was enabled, the patient should not apply the magnet.