A Randomized Trial Evaluating the Safety and Effectiveness of the remedē® System in Patients with Central Sleep Apnea (CSA)

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**Key Inclusion Criteria**

Central Sleep Apnea is confirmed by core lab analysis of PSG with EEG:

- AHI greater than or equal to 20
- At least 50% of all apneas central, with at least 30 central apnea events
- Obstructive apneas should be less than or equal to 20% of the total AHI

**Key Exclusion Criteria**

Within the 3 months prior to baseline testing, any of the following:

- Uncorrected severe valvular stenosis, valve replacement or repair (percutaneous or surgical), myocardial infarction (MI), coronary artery bypass grafting (CABG) surgery, percutaneous coronary intervention (PCI), cardiac ablation, new cardiac resynchronization device or new pacemaker implant.

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**Why Should Central Sleep Apnea be Treated?**

CSA occurs in up to 40% of patients with heart failure (systolic and diastolic). CSA is linked to mortality, arrhythmias, and hospitalizations in heart failure patients. Data from the Pilot Study show clinically meaningful improvements in oxygen, arousals, apnea hypopnea index (AHI), sleep quality, and quality of life.

**Why Should the remedē® System be Considered?**

The remedē® System is fully implantable, operates without a need for patient activation and designed to provide a high level of compliance. The remedē® System is a fully implantable transvenous device that is designed to restore normal sleep and breathing by stimulating the phrenic nerve. The remedē® System activates automatically when the patient sleeps. This trial will determine the safety and effectiveness of the remedē® System in patients with central sleep apnea.

**How Are Patients with CSA Identified?**

Screening can be done with a home sleep study. Diagnosis of CSA is simple and done with a sleep study (PSG). Severity of CSA is measured by apnea hypopnea index (AHI—events per hour).

**Patients at High risk for CSA:**

- Recent heart failure hospitalization
- Atrial or ventricular arrhythmias
- Nocturia (3 or more times per night)
- Witnessed apneas or daytime fatigue

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**The remedē® System Pivotal Trial Purpose**

This is a prospective, multicenter, randomized trial with blinded assessment of primary endpoints to evaluate the safety and effectiveness of therapy delivered by the remedē® System in subjects with moderate to severe central sleep apnea (CSA) and optimal medical management, compared to outcomes in randomized control subjects receiving optimal medical management and implanted but inactive remedē® Systems.

**The remedē® System Pivotal Trial Endpoints**

**Primary Effectiveness Endpoint**

The primary effectiveness objective of the trial is to demonstrate that the Treatment group achieves an AHI reduction from baseline to 6 months post-therapy initiation that is greater than the Control group, as evaluated by a blinded core lab.

**Primary Safety Endpoint**

The primary safety endpoint will be the freedom from serious adverse events (SAEs) associated with the implant procedure, the remedē® System, or the delivered therapy at 12 months post therapy initiation visit. All adverse events in study subjects (including all requiring hospitalization and/or resulting in death) will be documented and reported, regardless of their relatedness to the remedē® System and time of occurrence.

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**For additional information please visit www.clinicaltrials.gov and www.respicardia.com**