

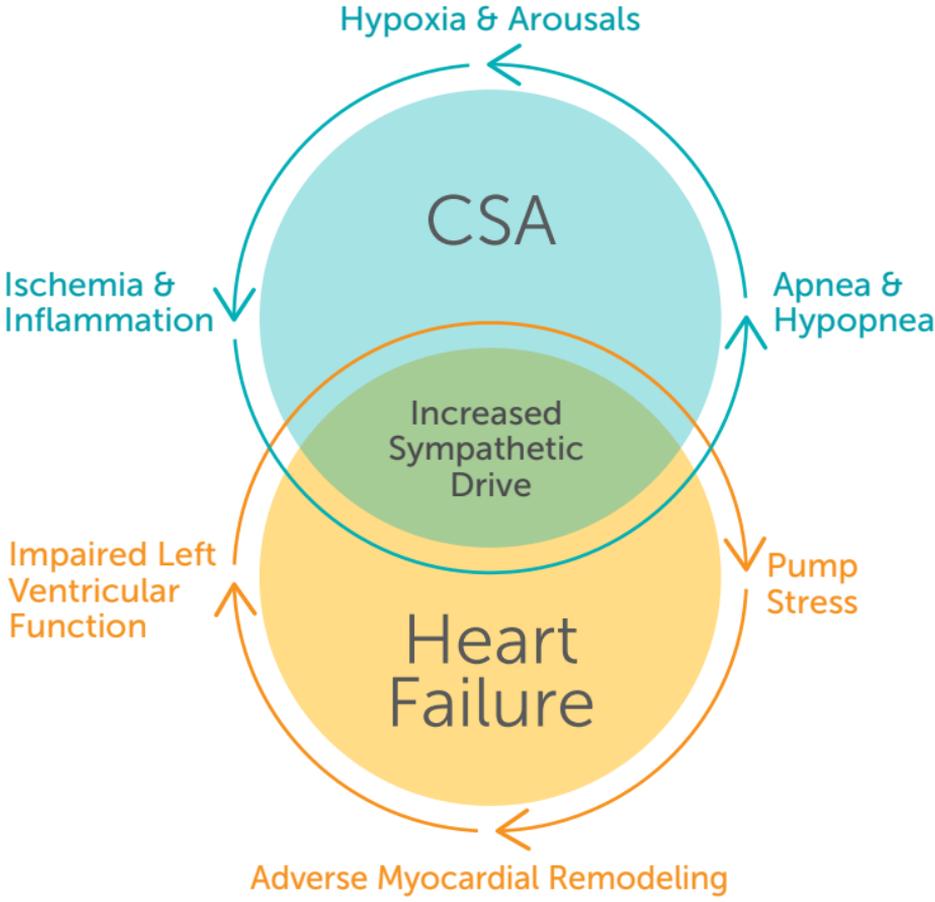
IMPROVING SLEEP

FOR ADULT PATIENTS WITH MODERATE
TO SEVERE CENTRAL SLEEP APNEA

remedē[®]
System

Effects of Central Sleep Apnea and Heart Failure are Intertwined^{1,2}

Central sleep apnea is a serious breathing disorder caused by the brain's failure to send the proper signals to the muscles that control breathing. CSA disturbs the breathing pattern during sleep, negatively affects quality of life and contributes to poor cardiovascular outcomes such as worsening heart failure (HF). CSA affects up to 40% of patients with HF.³



IMPACT OF UNTREATED CSA



Diminished quality of life, including fatigue, cognitive impairment, depression, and memory deficits⁴⁻⁷



2x the Risk

HF combined with CSA doubles the risk of death⁸



50%

50% of HF patients with CSA were readmitted to the hospital at 6 months⁸

The **remedē**® System is a proven, implantable sleep therapy specifically designed for treating central sleep apnea (CSA) in a way that closely resembles the body's natural physiology. It has demonstrated consistent and sustained long-term safety and effectiveness benefits that have shown to reduce the severity of CSA, improve sleep, breathing and quality of life.⁹

- **RESTORES** a normal breathing pattern by using the body's own breathing system

- **TAILORS** therapy to each patient through customized programming that mimics natural breathing while asleep

- **RELIEVES** patient compliance concerns by automatically delivering therapy each night

- **ELIMINATES** external equipment using a mask-free, implantable device that is placed under the skin in the upper chest area during a minimally invasive, outpatient procedure



remedē®
System

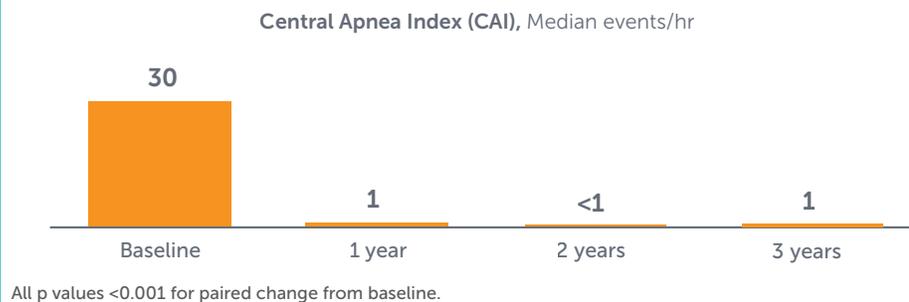
CLINICALLY PROVEN

The **remedē** System Pivotal Trial was a prospective, multi-center, randomized trial to evaluate therapy safety and effectiveness. Six months of data was collected on the treatment group (therapy active) and the control group (therapy withheld). At six months, the former control group began receiving therapy and results versus baseline have been reported for both groups out to three years.^{9,10}

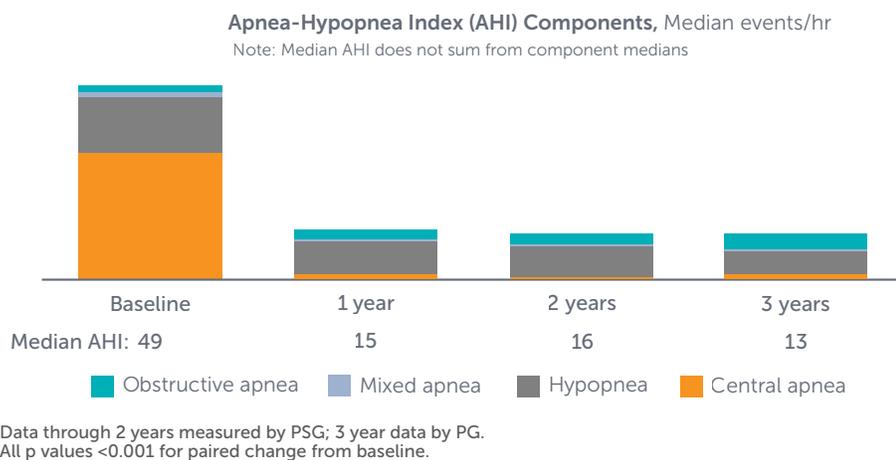
EFFECTIVENESS

Significant Reduction in Sleep Disturbances

99% reduction
in Central Apnea
Index at 2 years⁹

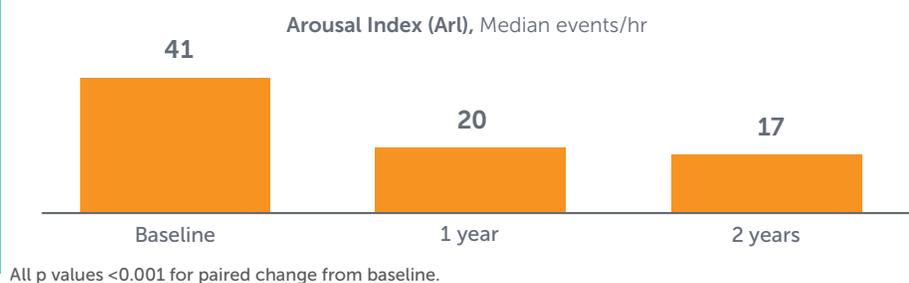


67% reduction
in Apnea-Hypopnea
Index at 2 years⁹



Improvement in Sleep Quality

57% fewer
arousals at 2 years⁹



The results of the study demonstrated that the **remedē System** is:

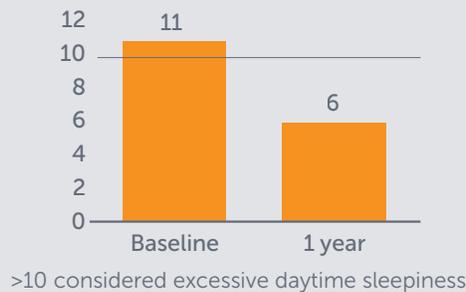
→ **Safe and effective** with all primary and secondary endpoints achieved¹⁰

→ The first therapy to show improvements **in arousals, % REM sleep, and quality of life** in an RCT

QUALITY OF LIFE

82%

of patients reported quality of life improvement using the Patient Global Assessment¹¹

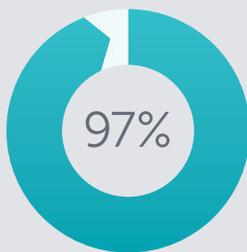


94%

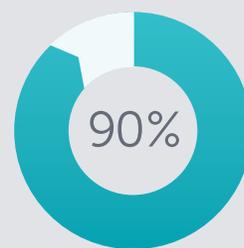
of patients reported they would "elect to have the medical procedure again"¹¹

5.0 point improvement in daytime sleepiness as measured on the Epworth Sleepiness Scale¹¹

SAFETY



97% implant success rate⁹



90% of patients experienced freedom from serious adverse events associated with implant procedure, the **remedē System**, or delivered therapy at 24 months⁹

Serious adverse events: 6% implant related, 3% therapy related, no deaths related to the procedure, system or therapy.

The **remedē System** safely and effectively treats the harmful effects of moderate to severe central sleep apnea in adult patients and has been proven to improve sleep, enhance well-being, and reduce daytime sleepiness, enabling better overall health.

IMPROVE SLEEP.
ONE BREATH AT A TIME.®

IMPROVE LIFE.
ONE DAY AT A TIME.™

Learn more at respicardia.com

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Important Safety Information

The **remedē**® System is indicated for moderate to severe Central Sleep Apnea in adult patients. A doctor will need to evaluate the patient's condition to determine if the **remedē** System is appropriate. Patients will not be able to have an MRI or diathermy (special heat therapies) if the **remedē** system is implanted. The **remedē** System may be used with another stimulation device such as a heart pacemaker or defibrillator; special testing will be needed to ensure the devices are not interacting.

As with any surgically implanted device, there are risks related to the surgical procedure itself which may include, but are not limited to, pain, swelling, and infection.

Once the therapy is turned on, some patients may experience discomfort from stimulation and/or from the presence of the device. The majority of these events are resolved either on their own or by adjusting the therapy settings. The **remedē** System may not work for everyone. There are additional risks associated with removing the system. If it is decided to remove the system, another surgery will be required.

Be sure to understand all of the risks and benefits associated with the implantation of the **remedē** System. For further information, please visit www.respicardia.com, call +1-952-540-4470 or email info@respicardia.com.

Rx Only.

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