remedē® System

In search of better sleep?

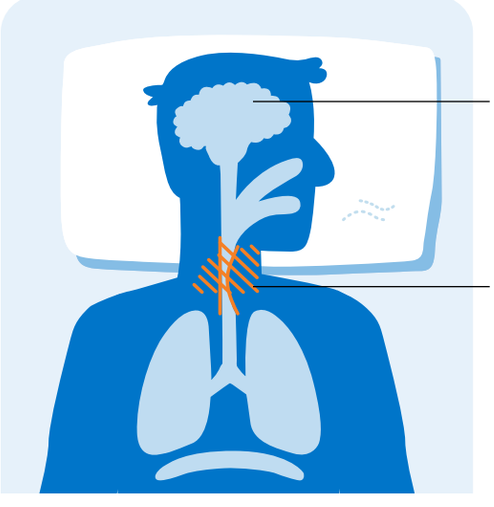
Discover the remedē® System

NON-MASK THERAPY FOR CENTRAL SLEEP APNEA (CSA)

WHAT IS CENTRAL SLEEP APNEA (CSA)?

Most people associate "sleep apnea" with a specific sleep disorder called Obstructive Sleep Apnea (OSA).

People with OSA often snore and have difficulty breathing well during the night because the upper airway is partially or completely blocked. People with CSA have irregular breathing during the night because the brain fails to communicate properly with the diaphragm.

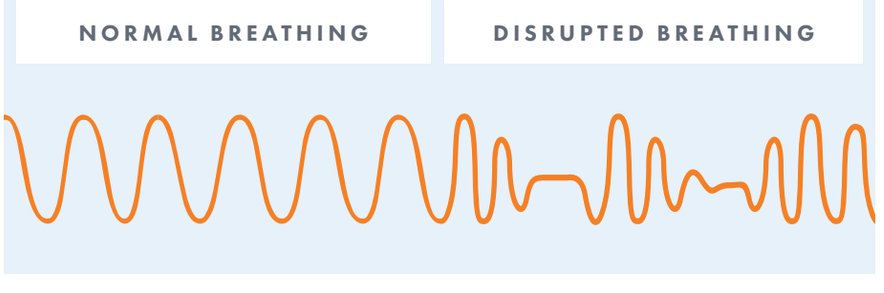


Central Sleep Apnea (CSA) occurs when the part of the brain that controls your breathing does not function correctly during sleep.

Obstructive Sleep Apnea (OSA) is caused by blockages in the upper airway that restrict oxygen to the body.

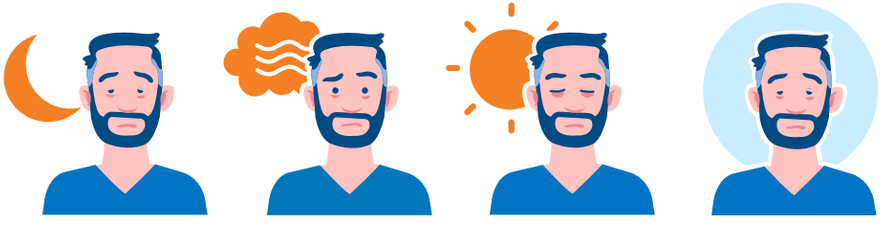
WHAT DOES CSA LOOK LIKE?

Untreated CSA causes a disrupted breathing pattern:



WHAT DOES CSA FEEL LIKE?

Untreated CSA can lead to a number of symptoms that can disrupt your nights and your days:[1,2]



Difficulty falling asleep or getting restful sleep

Brain fog or cognitive impairment

Excessive daytime sleepiness

Chronic fatigue

WHY TREAT CSA?

Because CSA causes symptoms similar to those of obstructive sleep apnea, heart failure, atrial fibrillation, and other medical conditions, it can be difficult for people to know whether their feelings of poor health are due to CSA or other serious conditions.

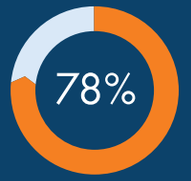
Additionally, CSA is common among people with heart disease, especially heart failure and atrial fibrillation.[3,4]

Over the long-term, untreated CSA results in low oxygen levels, which are linked to high blood pressure, abnormal heart rhythm, heart attack, and even death.[4]

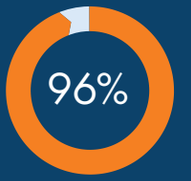
HOW IT WORKS

The **rem**edē System automatically turns on and stimulates the diaphragm to restore breathing in the same way the brain does.

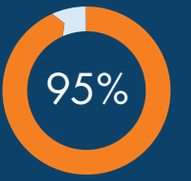
CLINICALLY PROVEN TO IMPROVE SLEEP, BREATHING AND QUALITY OF LIFE



78% of patients reported improved quality of life using the Patient Global Assessment[5]



96% reduction in Central Apnea Index at 1 year[6]



95% of patients said they would elect to have the medical procedure again[5]

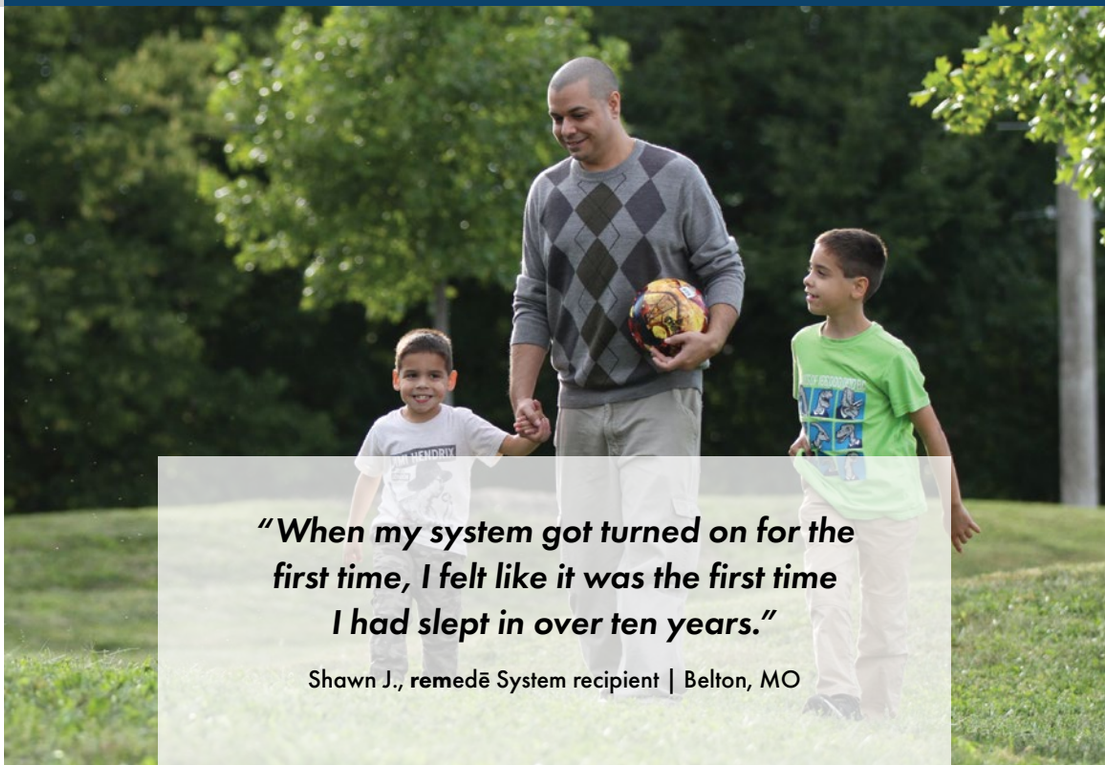
Improvements in sleep disordered breathing and quality sustained out to 5 years[6]

DISCOVER THE **rem**edē® SYSTEM

If restless nights are disrupting your days, it may be time to consider the **rem**edē System—the first and only FDA-approved non-mask therapy designed to treat moderate to severe central sleep apnea in adults.

BREATHE EASIER, SLEEP EASIER—TREAT CSA WITHOUT MASKS OR MEDICATIONS

remedē is a small, implantable device that activates automatically and restores a more normal breathing pattern—enabling you to treat your CSA without a mask or medications. **rem**edē is designed to help you rest easy, sleep peacefully— and have more energy for what you love.



"When my system got turned on for the first time, I felt like it was the first time I had slept in over ten years."

Shawn J., **rem**edē System recipient | Belton, MO

GETTING THE **rem**edē SYSTEM

1. Before getting your **rem**edē **System**

Your doctor may order a sleep study to help determine whether you have central sleep apnea and if you're a good candidate for the **rem**edē System.

2. On the day of your procedure

Your doctor will place your system under the skin in your upper chest area. Most people who receive the **rem**edē System stay overnight in the hospital and go home the next day. You will be able to get back to most of your daily routine within a week.

3. Over the first three months of therapy

You will work with your doctor to customize the therapy for your individual needs to ensure that you receive optimal treatment for your central sleep apnea.

Access post-implant precautions and safety information on our website by scanning the QR code

FREQUENTLY ASKED QUESTIONS[7]

How do I know if the **rem**edē **System is right for me?**

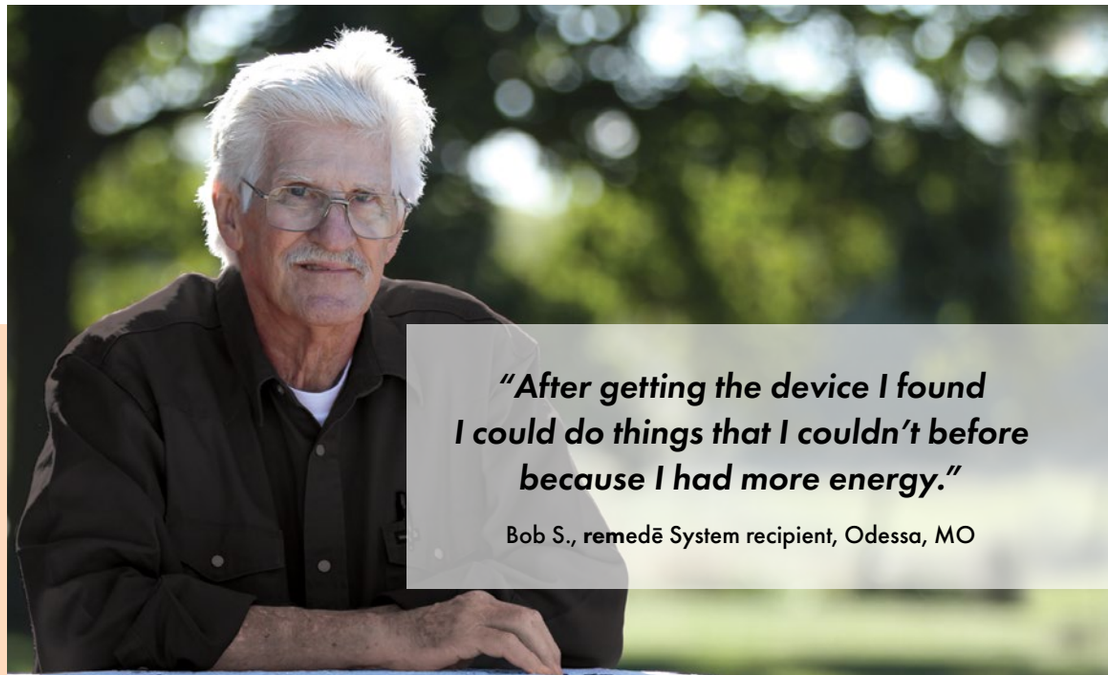
The **rem**edē System is approved by the Food and Drug Administration (FDA) to treat moderate to severe central sleep apnea (CSA) in adults. To determine the type and severity of sleep apnea you have, and whether **rem**edē is right for you, talk to your doctor. Please note that the **rem**edē System should not be placed if an active infection is present.

Is the remedē System covered by insurance?

The **rem**edē System is being covered by an increasing number of insurance plans, but every insurance plan is different. Your medical team will work with you, your hospital, and your insurance company to assess whether the **rem**edē System will be covered by insurance.

What if I already have a pacemaker or other cardiac device?

Because most pacemakers and cardiac devices are usually implanted on the left side of the chest, it may still be possible to receive the **rem**edē System, which can be implanted on either side of the chest.



Ask your doctor if **rem**edē is right for you

Because better days start with better nights.

Visit **remede.zoll.com** to learn more, or scan the QR code to get personalized help from our Patient Education Team

- **Find** an implanting doctor near you
- **Register** for an upcoming webinar about **rem**edē
- **Answer** questions via phone or email
- **Connect** with a real **rem**edē patient

[1] Costanzo M.R., Khayat R., Ponikowski P., et al. Mechanisms and clinical consequences of untreated central sleep apnea in heart failure. *J Am Coll Cardiol.* 2015; 65:72–84.
[2] Dempsey JA. Crossing the apnoeic threshold: causes and consequences. *Exp Physiol* 90: 13–24, 2005.
[3] Bekfani T, Abraham WT. Europace. 2016 Aug;18(8):1123-34. doi: 10.1093/europace/euv435. Epub 2016 May 26.
[4] Oldenburg O, et al. *Eur J Heart Fail* 2007; 9:251-257.
[5] Costanzo MR, Ponikowski P, Javaheri S, et al. Sustained Twelve Month Benefit of Phrenic Nerve Stimulation for Central Sleep Apnea. *Am J Cardiol.* 2018. pii: S0002-9149(18)30258-3. doi: 10.1016/j.amjcard.2018.02.022.
[6] Costanzo MR, Javaheri S, Ponikowski P, et al. Transvenous Phrenic Nerve Stimulation for Treatment of Central Sleep Apnea: Five-Year Safety and Efficacy Outcomes. *Nat Sci Sleep.* 2021;13:515-526
[7] **rem**edē® System: Patient Manual, https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160039d.pdf.

Important Safety Information
The **rem**edē® System is indicated for moderate to severe Central Sleep Apnea in adult patients. Your doctor will need to evaluate your condition to determine if the **rem**edē System is right for you. The **rem**edē System is MR Conditional but conditions apply. Please make sure that your physician knows about the conditions and precautions to ensure safety, which can be found in the **rem**edē System MRI guidelines manual. You should not have the **rem**edē System implanted if you have an infection and you will not be able to have diathermy (special heat therapies) after implantation. The **rem**edē System may be used if you have 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 **rem**edē System may not work for everyone. There are additional risks associated with removing your system. If you and your doctor decide to remove the system, another surgery will be required.

Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of the **rem**edē System.

Rx only. For further information, please visit remede.zoll.com, call +1-952-540-4470 or email info@remede.zoll.com.

ZOLL MEDICAL CORPORATION

12400 Whitewater Dr., Suite 150 | Minnetonka, MN 55343 | 952-540-4470 | info@remede.zoll.com | remede.zoll.com

Printed in the U.S.A.
MKT 1346, Rev D

For subsidiary addresses and fax numbers, as well as other global locations, please go to www.zoll.com/contacts.

ZOLL®