remedē® System

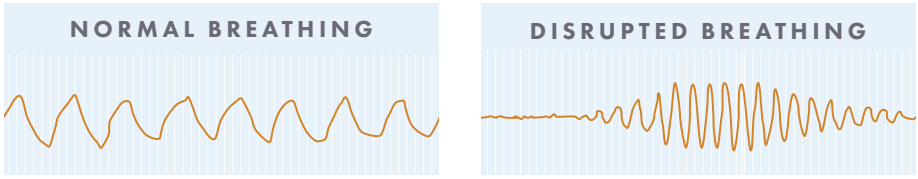
MANAGING CENTRAL **SLEEP APNEA**

WHAT IS CENTRAL SLEEP APNEA?

When most people hear "sleep apnea", they think of obstructive sleep apnea. People with obstructive sleep apnea often snore and have difficulty breathing well during the night because the upper airway is partially or completely blocked.

People with central sleep apnea (CSA) suffer from a different disease. Unlike obstructive sleep apnea, central sleep apnea is a neurological condition that occurs when the brain does not send the correct signals to the breathing muscle (the diaphragm). When the diaphragm does not move properly, the lungs do not have a consistent rhythm and breathing becomes irregular.

CSA occurs more frequently among people who have other diseases such as chronic heart failure and atrial fibrillation.[1]



WHY TREAT CENTRAL SLEEP APNEA

Central sleep apnea is associated with many symptoms that may be impacting your quality of life, including:[2]

- Breathing that temporarily stops while asleep
- Shortness of breath at night
- Difficulty concentrating
- Nighttime urination
- Daytime fatigue
- Decreased stamina

Some symptoms of CSA are similar to those of heart failure and atrial fibrillation, which may make it difficult for patients to know whether CSA may be contributing to their feelings of poor health.

Long term, untreated CSA results in low oxygen levels, which are linked to high blood pressure, abnormal heart rhythm, heart attack, and even death.[1]

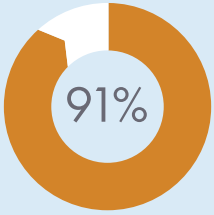
IMPROVE YOUR QUALITY OF LIFE

The **rem**edē® System is a revolutionary Central Sleep Apnea (CSA) treatment that improves sleep, enhances well-being, and reduces daytime sleepiness, enabling better overall health.

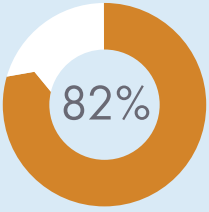
The **rem**edē System is a breakthrough implantable system that safely and effectively treats moderate to severe CSA in adult patients. The system includes a battery powered device implanted under the skin during an outpatient procedure.[3]

CLINICALLY PROVEN CSA TREATMENT OF CHOICE

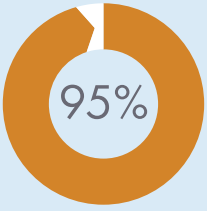
In a clinical study, the **rem**edē System has been shown to reduce the effects of CSA.[4]



91% of patients had a reduction in the number of sleep apnea events per hour at 12 months*



82% of patients experienced an improvement in their quality of life at 12 months**



95% of implanted patients would elect to have the procedure again

*At 6 months, 48% of the control group had a positive change in apnea events per hour.
**At 6 months, 13% of the control group had an improvement in quality of life.

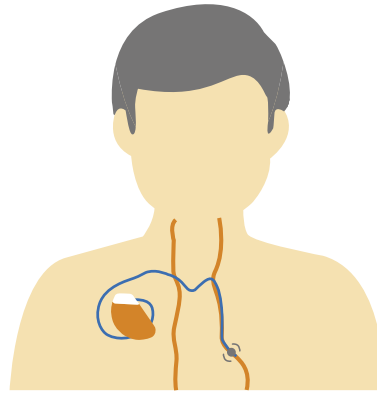
"When it got turned on for the first time, I felt like it was the first time I had slept in over ten years."

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

HOW IT WORKS[3]

When breathing has become disrupted during sleep, the **rem**edē System signals one of the main nerves (the phrenic nerve) inside the chest to stimulate breathing in the same way that the brain signals breathing.

The system turns on automatically at night when you are falling asleep. It helps you breathe throughout the night and does not require you to wear anything on your face.



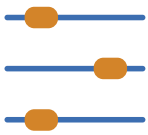
GETTING THE **rem**edē SYSTEM

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

A sleep study will help your doctor determine whether you have central sleep apnea and are a good candidate for therapy.

2. On the day of the procedure

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



3. Over the first three months of therapy

You will work with your doctor to ensure that the therapy is customized for your individual needs.

FREQUENTLY ASKED QUESTIONS[5]

How do I know if the remedē System therapy is right for me?
The **rem**edē System is designed for adult patients with moderate to severe central sleep apnea. Talk to your doctor to determine your type and severity of sleep apnea.

What is the cost? Is it 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 together with you, the hospital, and the 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?
Most pacemakers and cardiac devices are implanted in the left side of the chest. The **rem**edē System can be implanted in either side of the chest, leaving room for a cardiac device.

Who is not a candidate for the remedē System? The **rem**edē System is approved by the Food and Drug Administration (FDA) to treat moderate to severe central sleep apnea in adult patients. The **rem**edē System should not be placed if an active infection is present. The **rem**edē System cannot be used with magnetic resonance imaging (MRI). Talk to your doctor about whether the **rem**edē System is right for you.

TALK TO YOUR DOCTOR

to find out if the **rem**edē System is right for you.

Visit **remede.zoll.com/remede-system** to learn more.

Our **rem**edē Patient Liaison Team is here to help!

SCAN THE QR CODE TO GET PERSONALIZED HELP:

- **Finding** a doctor near you
- **Registering** for an upcoming webinar about **rem**edē
- **Answering** your questions via phone call or email with a **rem**edē Patient Liaison
- **Connecting** with a **rem**edē patient

[1] Oldenburg O, et al. *Eur J Heart Fail* 2007; 9:251-257.
[2] Befanki T, Abraham WT. *Europace* 2016: 18:1123-1134.
[3] **rem**edē® System: System Implant and Clinician Use Manual, https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160039c.pdf.
[4] Costanzo MR, et al. *Am J Cardiol* 2018; 121:1400-1408.
[5] **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 (CSA) in adult patients. Your doctor will need to evaluate your condition to determine if the **rem**edē System is right for you. You will not be able to have an MRI or diathermy (special heat therapies) if you have the **rem**edē System implanted. 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. For further information, please visit remede.zoll.com, call 952-540-4470 or email info@remede.zoll.com. **Indication for use:** The **rem**edē System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe Central Sleep Apnea (CSA) in adult patients. **Contraindications:** The **rem**edē System is contraindicated for use in patients with an active infection or patients known to require magnetic resonance imaging (MRI). See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events. **Rx Only.**
The **rem**edē® System, **rem**edē® EL System, and **rem**edē® EL-X System have received FDA approval.
The **rem**edē® System model 1001 has received CE Mark approval.

ZOLL MEDICAL CORPORATION

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

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

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