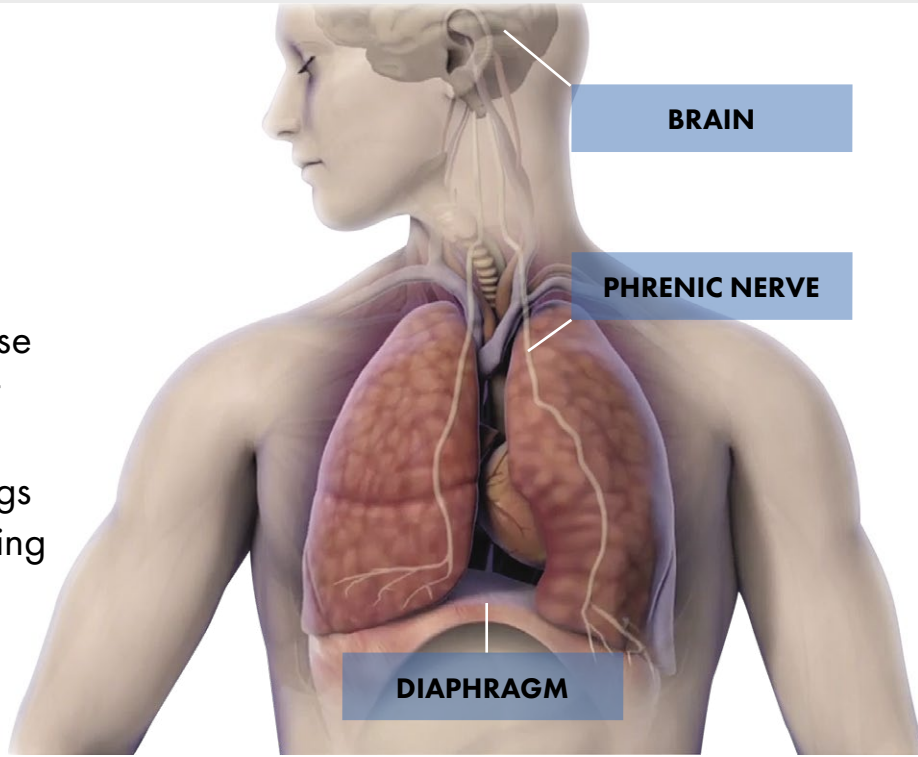
Understanding the **rem**edē® system

FOR CENTRAL SLEEP APNEA

What is Central Sleep Apnea (CSA)?

In **normal breathing,** the brain controls the respiration by sending signals down the phrenic nerve to the breathing muscles (mainly the diaphragm).

Central sleep apnea is a nighttime disease in which the brain does not send the correct signals to the breathing muscles. When the diaphragm does not move properly, the lungs do not have a consistent rhythm and breathing becomes irregular.



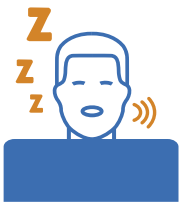
How sleep apnea affects your health

On a daily basis, people with sleep apnea may experience:

Lacking stamina or feeling fatigued

Feeling sleepy or drowsy during the day

Experiencing "brain fog" or the sensation of becoming less mentally sharp

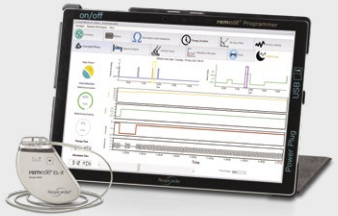


Have trouble sleeping restfully

Long term, sleep apnea can contribute to other health problems:

Complications of sleep apnea	
Arrhythmia	Diabetes
Drowsiness	Fatigue
Headache	Heart Attack
Hypertension	Impotence
Lung Hypertension	Memory Loss
Obesity	Stroke

remedē® System



The **rem**edē® System is a proven, implantable sleep therapy specifically designed for treating moderate to severe central sleep apnea (CSA). It is unique because it:

RESTORES a natural breathing pattern by using the body's own breathing system

RELIEVES patient compliance concerns by automatically delivering therapy each night

TAILORS therapy to each patient through customized programming to closely resemble natural breathing while asleep

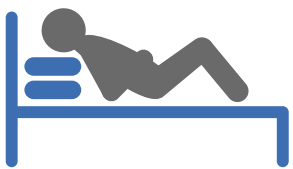
NO MASK or external equipment

remedē therapy activates automatically each night

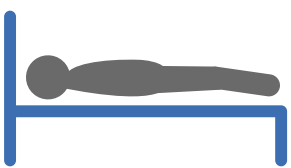
Therapy is delivered when:

It is within your pre-programmed sleeping hours

AND you are reclined past your programmed sleeping angle

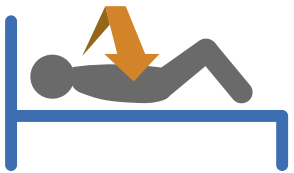


AND you are lying still

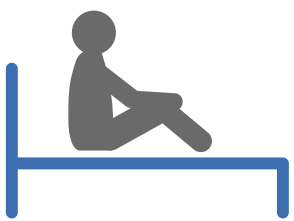


Therapy is paused when:

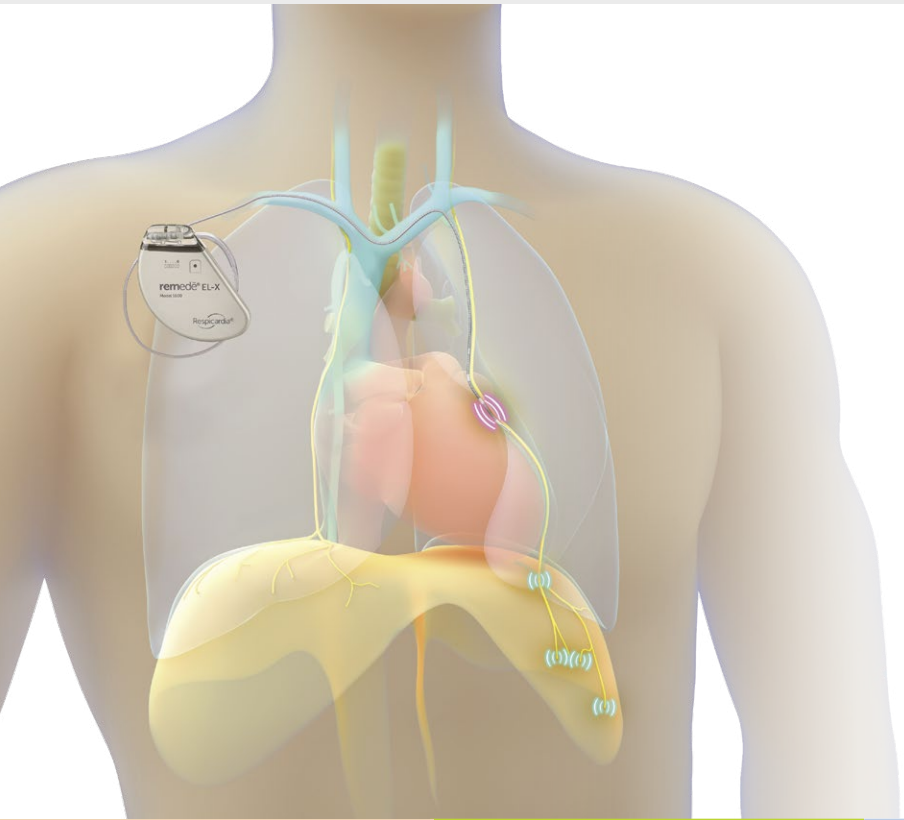
You roll



OR when you sit up



How **rem**edē restores your nighttime breathing

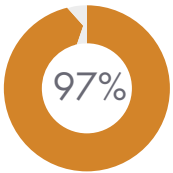


During sleep, the **rem**edē System activates, signaling the phrenic nerve to stimulate breathing. This results in return of a normal breathing pattern to reduce the episodes of apnea.

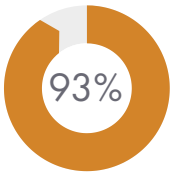
The system turns on automatically at night when you are falling asleep and helps you breathe throughout the night.

Effectiveness of the **rem**edē therapy

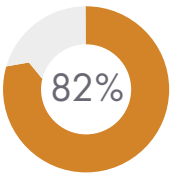
In a clinical research study evaluating patients after 12 months of therapy, **rem**edē has been shown to significantly reduce the effect of CSA:[1]



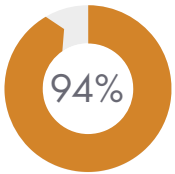
97% reduction in the median Central Apnea Index



93% of patients had a reduction in the number of sleep apnea events per hour



82% of patients had an improvement in quality of life



94% of patients would get **rem**edē again

Note: At 6 months, 48% of the control group had a positive change in apnea events per hour and 13% of the control group had an improvement in quality of life.[2]

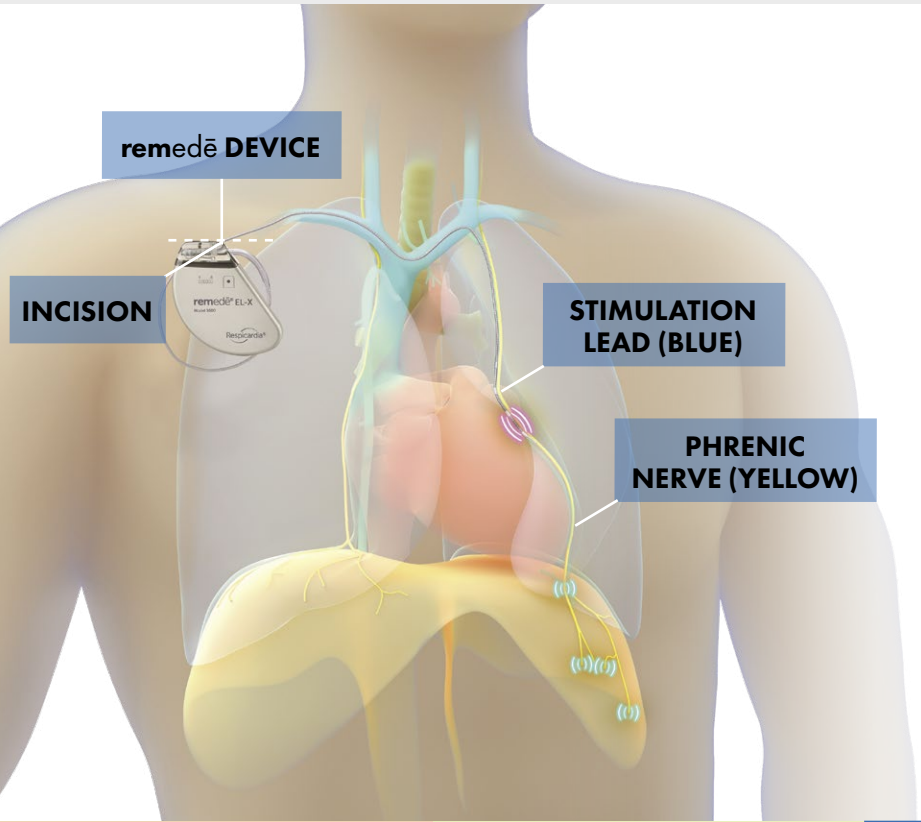
In the **rem**edē Pivotal research trial, 97% of patients had a successful implant and 91% of patients were free from serious adverse events.

The most common events include:

- Movement or dislodgement of the leads of the **rem**edē System
- Infection at the site of the incision
- Pain or discomfort at the site
- Bruising or swelling at the site

No long-term detrimental effects from the implant or therapy were reported.

remedē implant procedure summary



- Your doctor will place the **rem**edē System under the skin in the upper chest area
- Light sedation will be used during the procedure
- After the leads are in place, your doctor secures the device in your upper chest area
- The incision will be closed, and a dressing applied
- You may stay overnight or go home later that same day
- You will be able to return to your normal routine in about a week

1 During your **rem**edē implant procedure

- The procedure typically takes between 2 and 3 hours
- You will receive light sedation. You will be awake but may be drowsy
- One or two leads will be placed in the blood vessels in your upper chest and the leads will be attached to the device. The device is placed under the skin and stitches are used to close the incision
- The doctor will use X-ray and contrast dye to be sure the leads are in the correct position

2 After your **rem**edē implant procedure

- If you have a pacemaker, it will be tested as well to be sure there is no interaction with the **rem**edē System
- **rem**edē will be not be activated at implant, but will be monitoring how you sleep for the first 4-6 weeks
- It is best to limit the mobility of the right arm (or left arm if left-sided device placement), and avoid lifting your arm above shoulder level for several weeks after the implant procedure, as these movements could impair the healing process
- Avoid repetitive upper extremity activities and exercise which can damage the implanted leads

3 Follow up after your **rem**edē implant procedure

- You may go to the cardiology clinic for a check of your incision in 7-14 days
- The device will be activated about one month after implant in the sleep or cardiology clinic. This visit will take about an hour.
- It may take some time to get the device customized to your individual needs
- Over the next few months you will have follow up visits in the clinic to ensure that the device is optimized

Learn More

We encourage you to learn more by visiting remede.zoll.com/learn-more, emailing customercare@remede.zoll.com, or by scanning the QR code to:

- ask questions about **rem**edē
- review the clinical data on **rem**edē
- attend a monthly webinar for patients considering **rem**edē
- set up a personal phone call with a **rem**edē patient

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

[1] Fox, H., Oldenburg, O., Javaheri, S., et al. *SLEEP*, zsz158, https://doi.org/10.1093/sleep/zsz158.
[2] Costanzo M, et al. Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet.* 2016; 388: 974–82.

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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

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