IN SEARCH OF BETTER SLEEP?

Discover remedē®

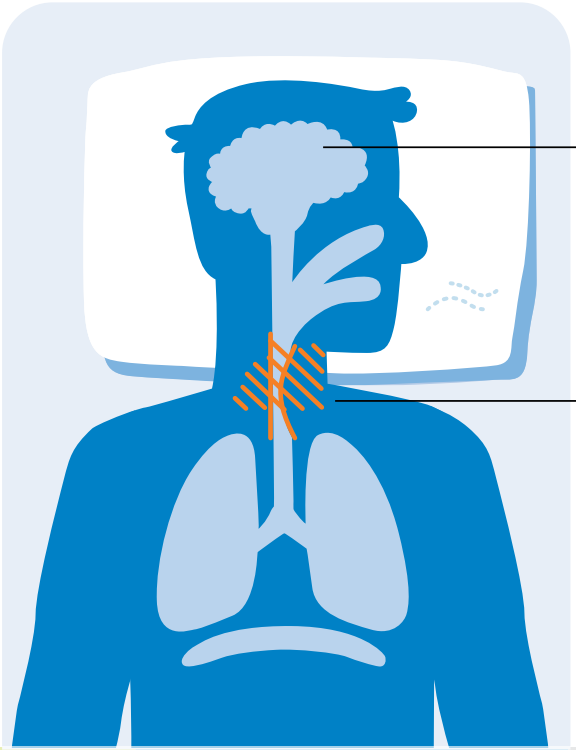
NON-MASK THERAPY FOR CENTRAL SLEEP APNEA (CSA)

CENTRAL SLEEP APNEA	remedē® SYSTEM	IMPLANT PROCEDURE	IMPLANT PROCEDURE

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.

How sleep apnea affects your health

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

Chronic fatigue

Excessive daytime sleepiness

Brain fog or cognitive impairment

Difficulty falling asleep or getting restful sleep

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

Discover the **rem**edē® System

If restless nights are disrupting your days, it may be time to consider the **rem**edē System–the first FDA-approved maskless therapy designed to treat moderate to severe CSA in adults. 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 are required

remedē therapy activates automatically each night

Therapy is delivered when:

It is within your pre-programmed sleeping hours

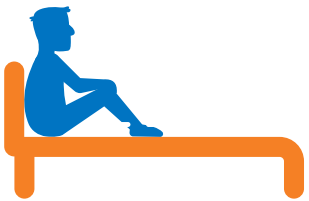
AND you are laying lower than your programmed sleeping angle

AND you are still

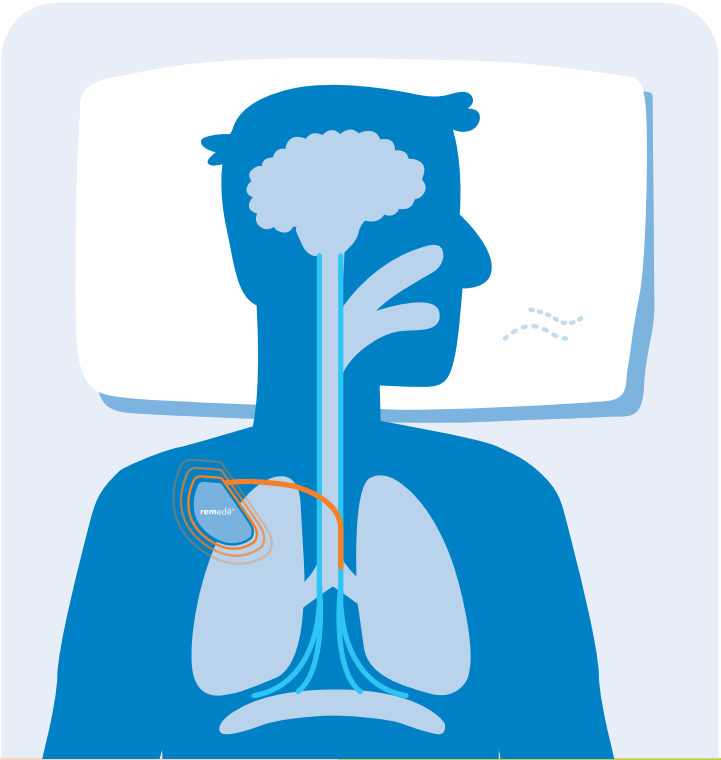
Therapy is paused when:

You roll over

OR when you sit up



How **rem**edē restores your nighttime breathing

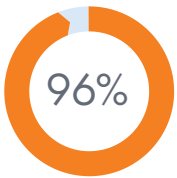


During sleep, the **rem**edē System activates, signaling the phrenic nerve to stimulate breathing. This results in return of a more normal breathing pattern to reduce the episodes of apnea.

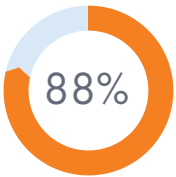
The system turns on automatically at night when you are falling asleep and helps you breathe throughout the night.

Effectiveness of the **rem**edē therapy

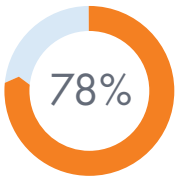
In a clinical research study evaluating patients after 12 months of therapy, **rem**edē has been shown to significantly reduce the effect of CSA:



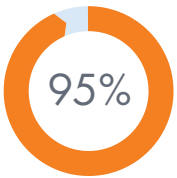
96% reduction in the median Central Apnea Index[1]



88% of patients had a reduction in the number of sleep apnea events per hour[2,3]



78% of patients had an improvement in quality of life[3]



95% of patients would get **rem**edē again[3]

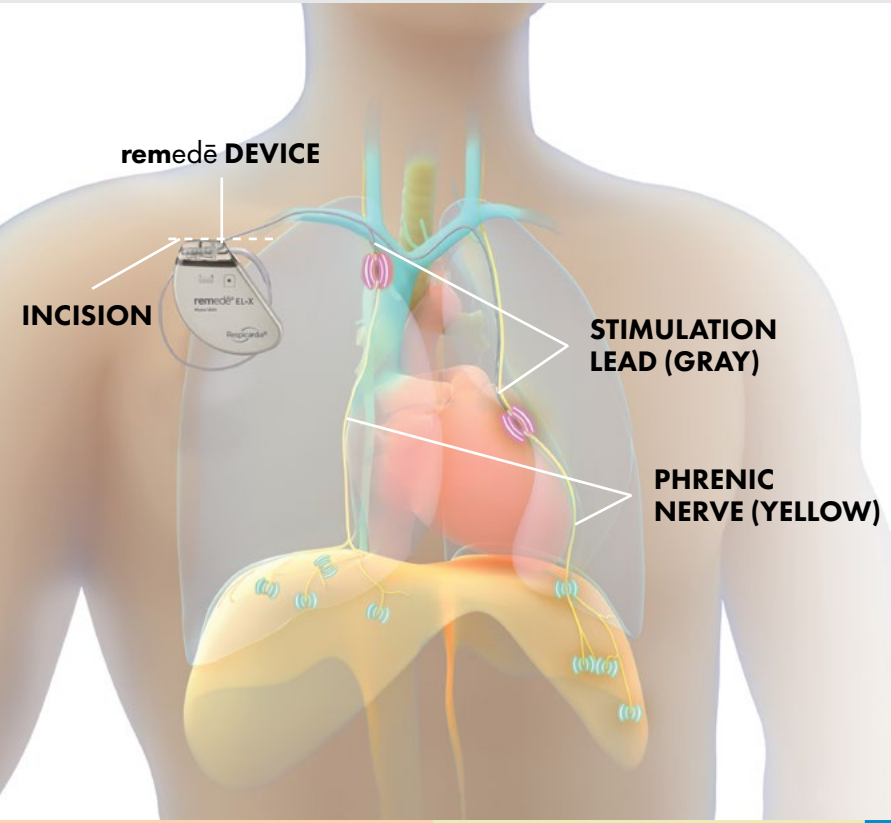
In the **rem**edē Pivotal research trial, 97% of patients had a successful implant and 90% of patients were free from serious adverse events.

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 lead is 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 most of your normal activities 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.
- A lead will be placed in the blood vessels in your upper chest and 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 lead is in the correct position.
- If you have a pacemaker, it will be tested as well to be sure there is no interaction with the **rem**edē System.

2 After your **rem**edē implant procedure

It is typically recommended that you wear a sling to keep your arm in a low position for the first 48 hours.

Avoid raising your arm above your shoulder.

Minimize upper extremities activities and exercise.

Limit friction on the skin over the implanted area.

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

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 6 weeks 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.

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

Because better days start with better nights.

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. 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.

[1] 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.
[2] Costanzo M, et al. Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet*. 2016; 388: 974–82.
[3] 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.

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