



AM I ELIGIBLE?

I'd like to talk about a treatment for central sleep apnea

The **remedē**® System is a breakthrough treatment for adult patients with moderate to severe central sleep apnea (CSA).

The **remedē** System has been shown to reduce the severity of CSA and improve sleep, breathing, and quality of life.¹

I'd like to understand if I meet the qualifications for the **remedē** System:

Are you an adult diagnosed with moderate to severe central sleep apnea?

I HAVE BEEN DIAGNOSED WITH CSA

If so, the FDA has approved the **remedē** System for adults with moderate to severe central sleep apnea. Some reasons that people choose **remedē**:

- FDA approved to safely and effectively treat CSA²
- Clinically proven to improve sleep, enhance well-being, and reduces daytime sleepiness¹
- Does not depend on wearing a mask while you sleep
- ASV (adaptive servo-ventilation) therapy has been shown to increase mortality risk in some heart failure patients³

Talk to your doctor about whether the **remedē** System is right for you.

I SUSPECT I MAY HAVE CSA

If you have symptoms of CSA but have not been diagnosed, the first step is to tell your doctor about your symptoms to determine if you need a sleep study.

- Easily fatigued or lack stamina
- Often feel sleepy during the day
- Waking up two or more times per night to use the bathroom
- Diagnosed with heart failure, atrial fibrillation, or stroke
- Experiencing shortness of breath at night
- Breathing that temporarily stops while asleep
- Difficulty concentrating

Talk to your doctor about whether your symptoms should be evaluated with a sleep study.

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Other questions to ask your doctor about the **remedē**® System:

- Am I a candidate for the **remedē** System?
- How does the **remedē** System work?
- How does the **remedē** System differ from other CSA treatment options?
- Is the **remedē** System safe?
- What if I already have a pacemaker or other cardiac device?
- Are there reasons that would prevent me from getting the **remedē** System?
- What is involved with the procedure?
- How long will I have to stay in the hospital?
- How long does it take to recover?
- Will I have any long-term limitations?
- Does the therapy work immediately?

Cost and Coverage

The **remedē** 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 **remedē** System will be covered by insurance.

Talk to Your Doctor

to find out if the **remedē** System is right for you or visit us at remede.zoll.com/find-a-doctor to find a center near you.

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

² PMA FDA Summary of Safety and Effectiveness Data, PMA P160039, October 6, 2017.

³ Cowie MR, Hoehle H, Wegscheider K, et al. Adaptive servo-ventilation for central sleep apnea in systolic heart failure. *New Engl J Med* 2015; 373:1095-1105.

Important Safety Information

The **remedē**® 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 **remedē** System is right for you. You will not be able to have an MRI or diathermy (special heat therapies) if you have the **remedē** System implanted. The **remedē** 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 **remedē** 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 **remedē** System. For further information, please visit remede.zoll.com, call 952-540-4470 or email info@remede.zoll.com.

Indication for use: The **remedē** System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe Central Sleep Apnea (CSA) in adult patients. **Contraindications:** The **remedē** 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 **remedē**® System, **remedē**® EL System, and **remedē**® EL-X System have received FDA approval. The **remedē**® System model 1001 has received CE Mark approval.

ZOLL MEDICAL CORPORATION

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