IMPROVING SLEEP FOR PEOPLE WITH CENTRAL SLEEP APNEA

remedē® System

DO YOU SEE PATIENTS WITH CENTRAL SLEEP APNEA WHO REMAIN SYMPTOMATIC OR STRUGGLE WITH CURRENT TREATMENT OPTIONS?

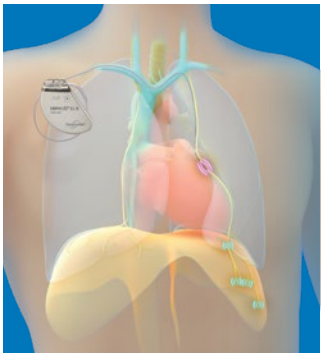
Central Sleep Apnea (CSA) is a serious breathing disorder leading to poor cardiovascular outcomes and negatively affecting quality of life. For the estimated 70-80% of CSA patients that have heart failure, untreated CSA contributes to the downward cycle of heart failure and leads to higher mortality and hospitalizations.[1-3] However, treatment options for CSA patients are limited, especially within the heart failure population with reduced ejection fraction.[4]

PROVEN CENTRAL SLEEP APNEA TREATMENT

The **rem**edē® System is a breakthrough treatment that has been shown to improve sleep, breathing and quality of life in adult patients with moderate to severe CSA.[5]

The **rem**edē System is FDA-approved for adult patients with moderate to severe CSA.[6] It is a fully-implantable therapy that activates automatically each night. It uses electrical signals to stimulate the phrenic nerve and activate the diaphragm, maintaining respiratory drive at a natural breathing rate while the patient is sleeping. It is approved for all etiologies of CSA, including CSA with concomitant heart failure, where other treatment options may cause harm or be ineffective.[4] Notably, the **rem**edē System was granted a Transitional Pass-through Payment by CMS[7,8] – a payment reserved for technologies that CMS deems "substantially improves the diagnosis or treatment of an illness."

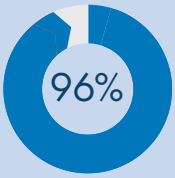
IMPLANT PROCEDURE



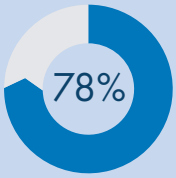
The **rem**edē System is placed during a minimally invasive outpatient procedure by a cardiologist. The **rem**edē System includes a battery powered device placed under the skin in the upper chest area, a thin wire (lead) to deliver the therapy (stimulation lead), and a second, optional lead to sense breathing (sensing lead). The procedure takes an average of two to three hours and is performed under light sedation. Most patients are able to go home after a one-night stay in the hospital and can return to most of their normal routine within a week.

The **rem**edē System received U.S. Food and Drug Administration (FDA) approval in October 2017. If you see patients with CSA and would like to offer the **rem**edē System through your practice or via referral to an active center, please contact **info@remede.zoll.com** or visit **remede.zoll.com**.

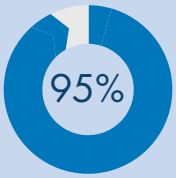
In a clinical study, the **rem**edē System has been shown to reduce the effects of CSA.



96% reduction in the median Central Apnea Index at 1 year[9]



78% of patients had an improvement in quality of life at 1 year[10]



95% of patients reported they would "elect to have the medical procedure again"[10]

5-year data

Safety and efficacy sustained through 5 years[9]

[1] Dymedex data on file, 2014.
[2] Khayat R, et al. Sleep disordered breathing and post-discharge mortality in patients with acute heart failure. *Eur Heart J*. 2015 Jun 14;36(23):1463-9.
[3] Khayat R, et al. Central sleep apnea is a predictor of cardiac readmission in hospitalized patients with systolic heart failure. *J Card Fail*. 2012 Jul;18(7):534-40.
[4] Aurora RN, et al. Updated Adaptive Servo-Ventilation Recommendations for the 2012 AASM Guideline: "The Treatment of Central Sleep Apnea Syndromes in Adults: Practice Parameters with an Evidence-Based Literature Review and Meta-Analyses". *J Clin Sleep Med*. 2016 May 15;12(5):757-61.
[5] Costanzo MR, et al. Transvenous neurostimulation for central sleep apnea: a randomized controlled trial. *The Lancet*. 2016; 388: 974-82.
[6] The **rem**edē System Implant and Clinician Use Manual, submitted as part of FDA PMA: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160039C.pdf
[7] CMS List of Device Category Codes for Present or Previous Pass-Through Payment and Related Definitions Related January 2018.
[8] CMS-1695-FC. CY2019 OPPS Final Rule. Vol. 83, No. 225 Pg. 58939.
[9] Costanzo MR, 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.
[10] Costanzo MR, et al. Sustained Twelve Month Benefit of Phrenic Nerve Stimulation for Central Sleep Apnea. *Am J Cardiol* 2018;121:1400-8.

Important Safety Information
The **rem**edē® System is indicated for moderate to severe Central Sleep Apnea (CSA) in adult patients. A doctor will need to evaluate the patient's condition to determine if the **rem**edē System is appropriate. The **rem**edē® System should not be implanted during an active infection and patients will not be able to have diathermy (special heat therapies). The device is MR Conditional. The conditions and precautions can be found in the **rem**edē System MRI guidelines manual. The **rem**edē System may be used with 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 the system. If it is decided to remove the system, another surgery will be required. Be sure to understand all 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. **Contraindications:** The **rem**edē System is contraindicated for use in patients with an active infection. 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.

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