**Improving Sleep for Patients with Central Sleep Apnea**

<INSERT FACILITY NAME> is among the first hospitals in <INSERT STATE, REGION OR CITY NAME> to offer patients the **rem**edē**®** System, a breakthrough treatment that has been shown to improve sleep, breathing and quality of life in adult patients with moderate to severe central sleep apnea (CSA). People with moderate to severe CSA often suffer from chronic fatigue, daytime sleepiness, and memory or concentration problems.1

<Insert a quote attributed to the implanting physician. Potential quote is below or insert your own quote. >

“The **rem**edē**®**System provides physicians with an innovative therapy for patients with moderate to severe central sleep apnea,” said <PHYSICIAN>, M.D., at <HOSPITAL>. “This therapy has been proven to reduce the number of sleep apnea events which will improve daytime sleepiness and quality of life.”

Central sleep apnea is a serious type of sleep-disordered breathing that occurs when the brain does not send the correct signals to the breathing muscles (the diaphragm). The result is an inconsistent breathing rhythm and pattern, leading to repeated arousals from sleep, drops in oxygen levels in the blood, and increased cardiac stress response. For the approximately 75% of CSA patients that have heart failure and/or atrial fibrillation, these central apnea events substantially compound the negative impact of their cardiovascular disease, contributing to the downward cycle of heart failure and leading to higher mortality and hospitalizations.2,3

The FDA-approved **rem**edē**®**System is an implantable therapy that monitors and stabilizes the breathing pattern to restore sleep throughout the night. The **rem**edē**®**System is placed by a cardiologist during a minimally invasive outpatient procedure. When the patient is asleep, the **rem**edē**®**System stimulates a nerve in the chest (phrenic nerve) to send signals to the large muscle that controls breathing (the diaphragm). These signals stimulate breathing in the same way that the brain signals breathing.

**CLINICAL STUDY RESULTS**

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

* 89% of patients had a reduction in the number of sleep apnea events4
* 78% of patients had an improvement in quality of life4
* 95% of patients reported they would “elect to have the medical procedure again”4
* Patients treated with **rem**edē**®**System demonstrated clinically significant reduction in daytime sleepiness4,5

**DIAGNOSING CENTRAL SLEEP APNEA**

CSA symptoms can be subtle and often overlap with co-existing symptoms that occur from other causes such as chronic heart failure, atrial fibrillation, and stroke. To diagnose CSA, a physician will prescribe a home or in-lab sleep study to determine whether the sleep disturbance results from inappropriate signals from the brain (CSA) or an airway blockage (obstructive sleep apnea, or OSA).

*The****rem****edē System received U.S. Food and Drug Administration (FDA) approval in 2017.*

CONTACT US

<INSERT IMPLANTING PHYSICIAN(S)

NAME(S), CONTACT INFORMATION &

PHOTOGRAPH(S)>

**REFERENCES**

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2. Khayat et al. 2015;36:1463-9 *Eur Heart J*
3. Khayat et al. *J Card Fail* 2012;1 8:534-540
4. Costanzo, M. R., Ponikowski, P., Javaheri, S., et al. Sustained Twelve Month Benefit of Phrenic Nerve Stimulation for Central Sleep Apnea. *The American Journal of Cardiology*. 2018; DOI:10.1016/j.amjcard.2018.02.022.
5. Costanzo M, et al. Transvenous neurostimulation for central sleep apnea: a randomized controlled trial. The Lancet. 2016; 388: 974-82.

**The remedē® System**

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 visit remede.zoll.com, call +1-952-540-4470 or email info@remede.zoll.com.

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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MKT1624, Rev B