remedē®

PATIENT AMBASSADOR PROFILE

Patient Story

Patient Name: Lawrence R. Pigeon, Former Naval Aviator

Spouse/Caregiver: Stephanie D. Pigeon

Date of remedē implant: July 17, 2020

Patient Story: In May, 2017, during a scheduled bronchoscopy, it was discovered that I was in AFib, so instead, I was ushered off to the ER for the treatment of my runaway heart rate. My subsequent sleep study provided a diagnosis of predominantly Central Sleep Apnea (CSA). At this time, I was fitted for a CPAP and remember a feeling of amazement at the value of improved sleep through the CPAP device and the excitement of being cleared to travel to Bali to see my daughter get married.

In late November, 2018, I suffered a setback with a fairly serious episode of congestive heart failure and spent five days in the hospital. By now, I had grown weary and intolerant of the CPAP mask and became fascinated by ads I had seen on implantable sleep apnea device alternatives. My numerous internet searches produced bits and pieces of data on **rem**edē®, all of which proved encouraging. I took my research to a VA physician, who agreed that the data were encouraging, but advised that the local VA was not yet an implanting center. So, advocating on my own behalf, I contacted Respicardia directly. The staff there generously provided me numerous options in my geography which eventually led to my **rem**edē implant on July 17, 2020, and thus, my return to a far better quality of life.

Patient Activity Level/Hobbies/Pastimes: Now that I am a very active, satisfied **rem**edē patient, and enjoy the benefits of its therapy, I'm even more convinced of its needed application in the VA community. I have now begun the process to dedicating some of my resources to advocating for the **rem**edē System for other Veterans in need. I'm also now better able to enjoy my family, my commercial real estate endeavors and my work at a local winery.

Medical Summary

Patient Age: 73
Date of CSA Diagnosis: May 26, 2017
Other therapies tried before remedē: CPAP, ASV

Medical Team

Referring Center: Comprehensive Sleep Care Center of Virginia (CSCC)

Sleep Center: Comprehensive Sleep Care Center of Virginia (CSCC)
Implanting Center: Allina Health United Hospital

Pre- and Post- remedē Sleep Metrics*

Before remedē Therapy

Apnea Hypopnea Index (AHI): 42.7/hr
Central Apnea Index (CAI): 20.7/hr

After 5 Years of remedē Therapy

Apnea Hypopnea Index (AHI): 14.1/hr
Central Apnea Index (CAI): 0.3/hr

**Sleep data obtained from patient sleep studies prior to and most recent post-remedē System therapy activation.*

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The account given is genuine and documented.

Each story represents a unique individual experience and does not provide any indication, guide, warranty or guarantee as to the response other people may have to the therapy.

The table below provides median change in AHI and CAI from the **rem**edē Pivotal Trial. Individual patient results may vary.

	BASELINE (N=131)	1 YEAR (N=115)	2 YEARS (N=101)	5 YEARS (N=42)
Apnea Hypopnea Index (AHI)	**46** [34, 60]	**18** [9, 34]	**16** [7, 32]	**17** [9, 34]
Central Apnea Index (CAI)	**23** [13, 39]	**1** [0, 4]	**1** [0, 3]	**1** [0, 5]

Reported as median [interquartile range].

Please speak with your doctor to determine if this therapy is right for you.
Full Important Safety Information can be found at remede.zoll.com.

Important Safety Information
The **rem**edē® 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 **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. For further information, please visit remede.zoll.com, call 952-540-4470 or email info@remede.zoll.com. **Indication for use:** The **rem**edē System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe Central Sleep Apnea (CSA) in adult patients. **Contraindications:** The **rem**edē 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 **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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For subsidiary addresses and fax numbers, as well as other global locations, please go to www.zoll.com/contacts.

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