remedē® System

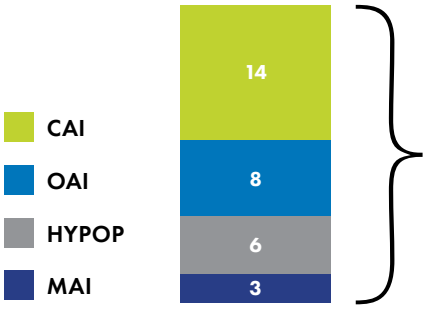
Patient Selection for Phrenic Nerve Stimulation with remedē®

The remedē System is FDA approved for the treatment of moderate-to-severe CSA in adult patients[1] with:

- No requirement to have tried and failed other therapies for CSA
- No upper limit of Apnea Hypopnea Index (AHI)
- No upper limit of patient Body Mass Index (BMI)

The remedē System is contraindicated for patients with an active infection.

Appropriate candidates for the remedē System may have events other than central apneas noted during the sleep study



Sample AHI Breakdown (Total AHI = 31)

- Patients for **rem**edē therapy should have moderate-to-severe sleep apnea with AHI ≥ 15
- In the **rem**edē Pivotal Trial, patients had more central apneas than obstructive apneas[2]

Hypopneas may be central or obstructive in nature and do not exclude patients for remedē therapy

Does your practice differentiate hypopneas as central vs obstructive?

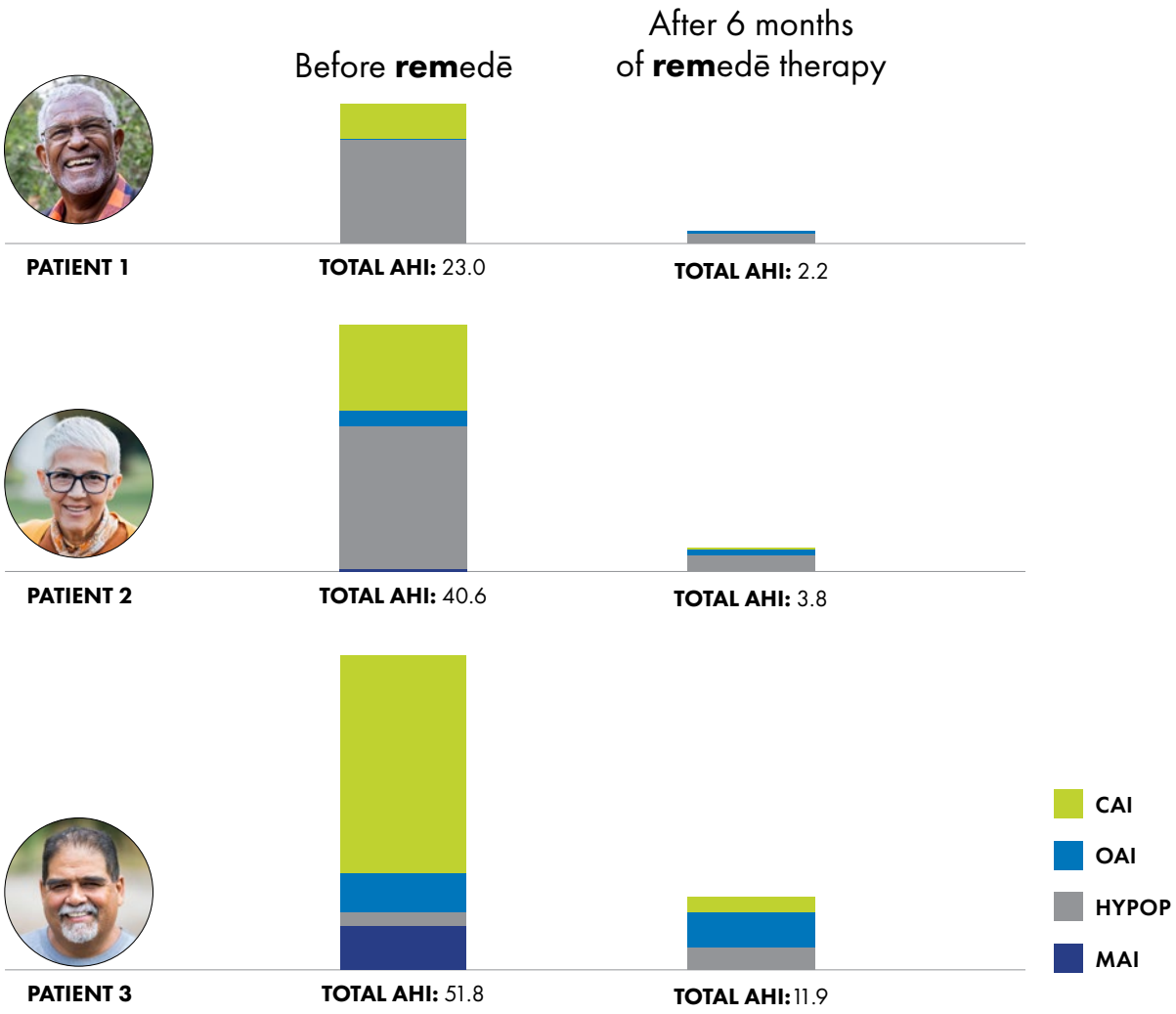
Consider **rem**edē if...

- Yes, for all sleep studies → **CAHI ≥ 15**
- Yes, but only if needed → Differentiate hypopneas if CAI ≥ 5 → **CAHI ≥ 15**
- No → **AHI ≥ 15 and CAI > OAI**

CAHI = Central Apnea Hypopnea Index

ZOLL®

See how the **rem**edē System has made significant improvements on these patients despite the wide range of sleep apnea events they presented.



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.

Candidates for the remedē System can present a broad range of events other than central apneas.

To learn more, contact us or visit remede.zoll.com

[1] **rem**edē® System Instructions for Use.
[2] Costanzo, et al. *Lancet* 2016; 388: 974–82.

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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