ICD-9-CM Coordination and Maintenance Committee Meeting

September 18, 2013

Introduction

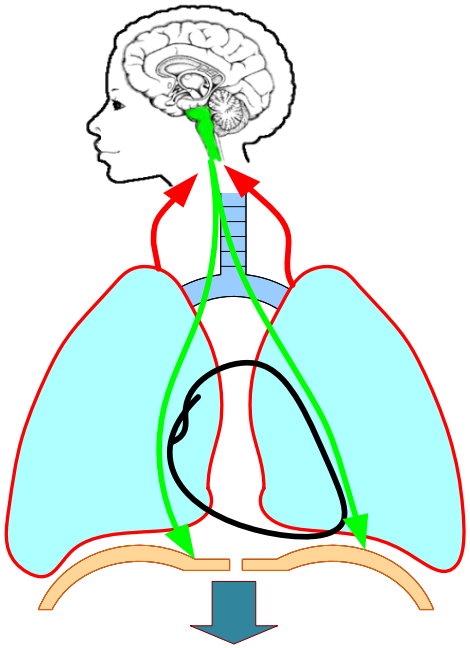
Respicardia has developed a neurostimulation device, **the remedē® System**, to treat Central Sleep Apnea (CSA)

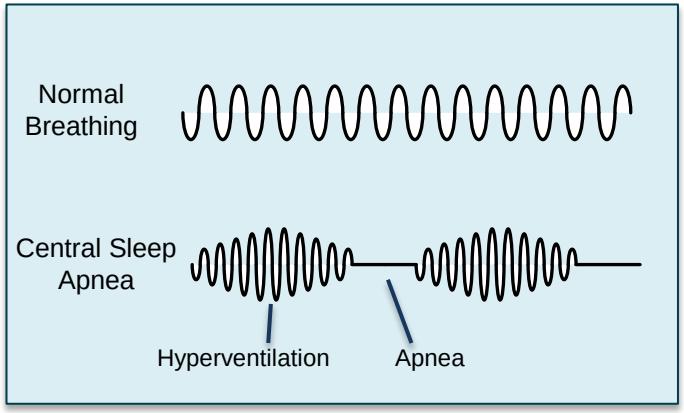
Purpose of this presentation is to request new ICD 10 codes for lead placement

Agenda

- Overview of Central Sleep Apnea (CSA)
- **rem**edē® System therapy as a treatment for CSA
- Description of the **rem**edē® System
- Implant/Explant Procedures of the **rem**edē® System
- Rationale for new ICD-10-CM codes
- Q&A

What is Central Sleep Apnea?



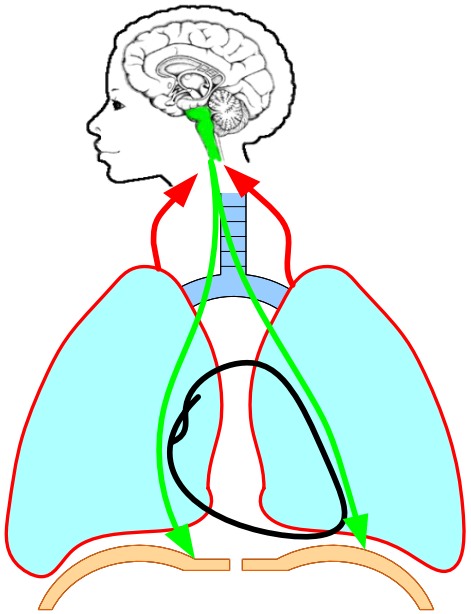


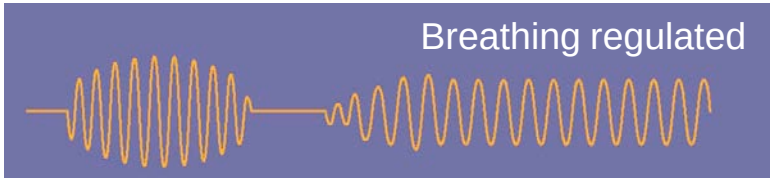
- Pattern of breathing (hyperventilation followed by apnea or hypopnea) caused by a **failure of the brain to respond appropriately to changes in CO_2**
- CSA is a **devastating disease** that increases hypoxia, ventricular and atrial arrhythmias, arousals, sympathetic activation and results in increased stress on the heart, adverse myocardial remodeling and impaired LV function
- Primarily seen in patients with **heart failure and atrial fibrillation**

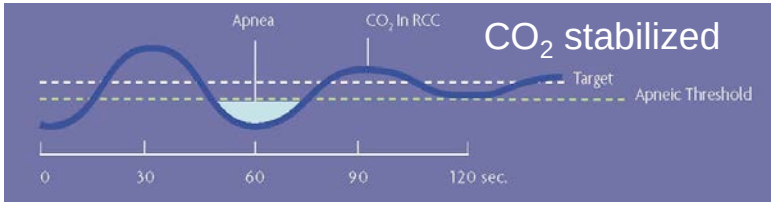
Brenner et al. Trends Cardiovasc Med 2008;18:240-7.
Bitter et al. EJHF 2009; 11:602-8.
Prinz et al. Postgrad Med J 2011;87:485-62.

Respicardia® Respiratory Rhythm Management™

CSA Can Be Treated by **rem**edē® System Therapy



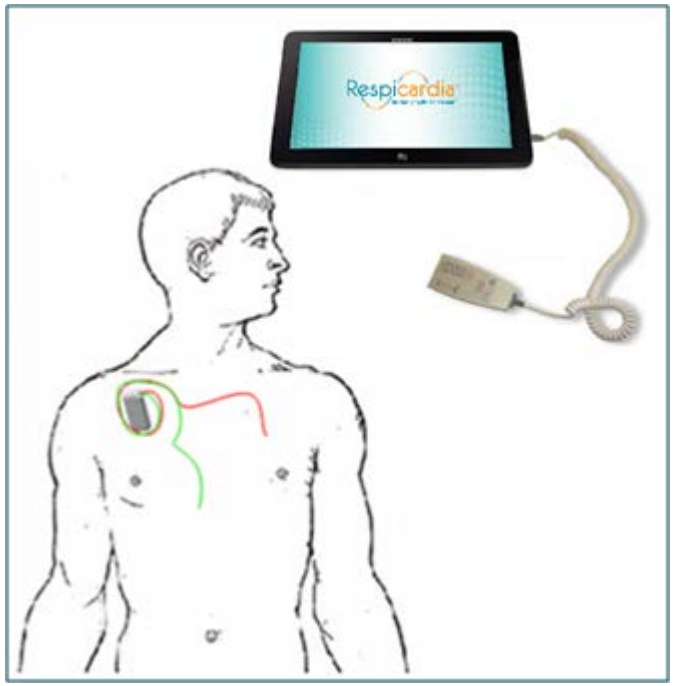




- During sleep, respiration is regulated by the brain's Respiratory Control Center (RCC) whose goal is to maintain a constant blood CO_2 level
- To keep CO_2 regulated, the RCC sends signals to the diaphragm via the phrenic nerves and controls the pattern of breathing
- In patients with increased sympathetic drive and overactive chemoreceptors, the RCC sends inappropriate signals to the diaphragm causing an irregular pattern of breathing
- Intervening in this pathway by managed stimulation of the phrenic nerve via the **rem**edē® System contracts the diaphragm regulating breathing and stabilizing CO_2

remedē® System Overview

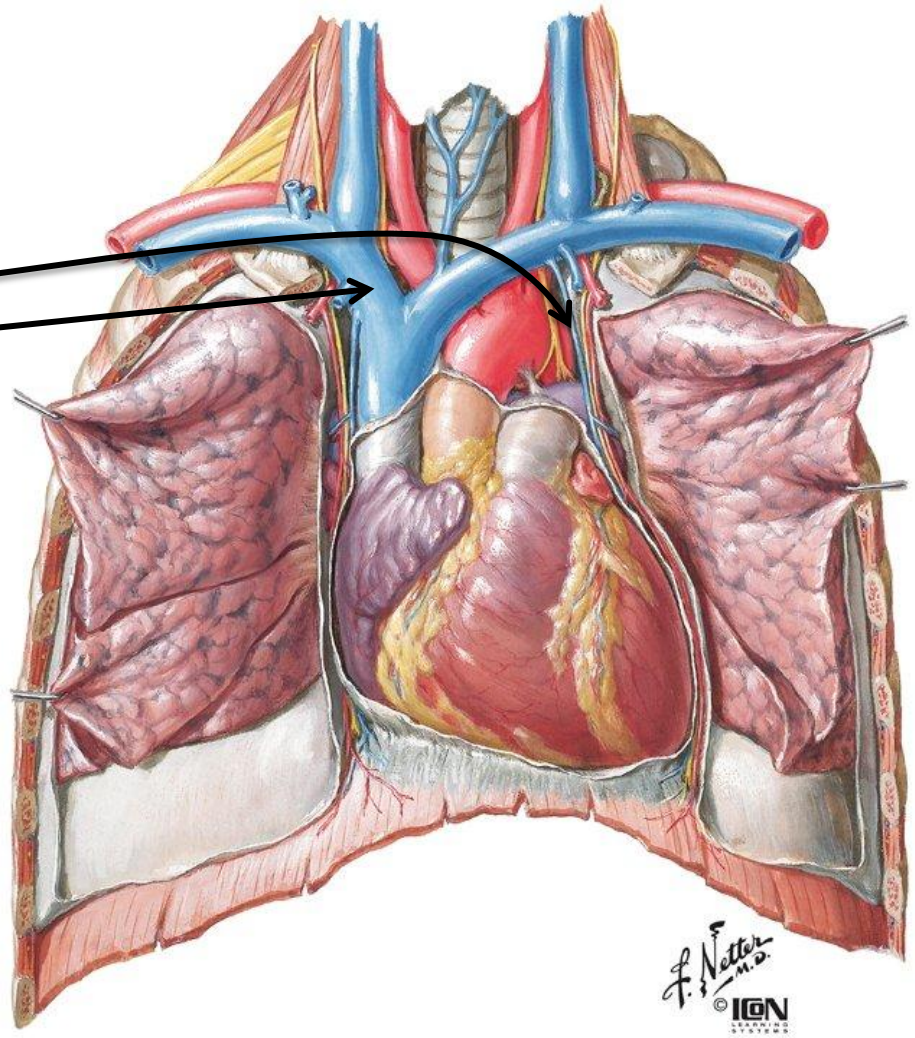
- System Includes:
  - Implantable Neurostimulator
  - Stimulation Lead
  - Sensing Lead
  - Programmer and Wand
- Implanted by an Electrophysiologist



- Provides transvenous unilateral stimulation of the phrenic nerve to treat central sleep apnea using sophisticated set of algorithms

Two Venous Locations are available for Unilateral Transvenous Stimulation of the Phrenic Nerve

- Left Pericardiophrenic Vein or Right Brachiocephalic Vein
- Placement dependent on patient's anatomy
- Clinical outcomes are comparable for either stimulation location

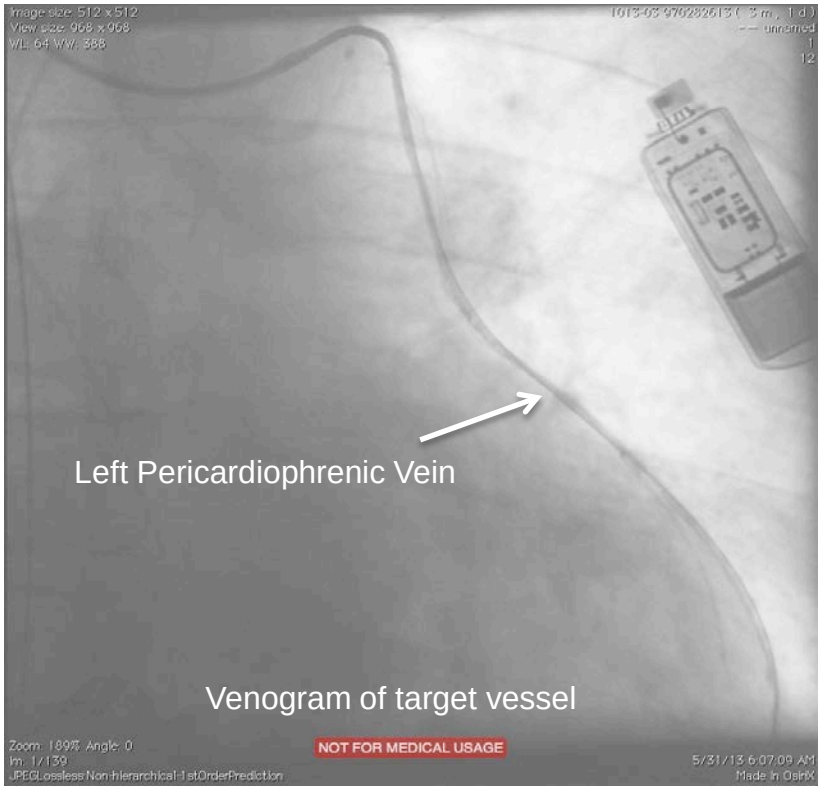


remedē® System Implant Procedure – Left Stimulation Lead Placement

The Left Stimulation lead is placed into the left pericardiophrenic vein, which is anatomically adjacent to the left phrenic nerve.

Procedure:

1. Gain venous access
2. Locate target vessel
3. Deploy the Left Stimulation lead
4. Test for nerve capture

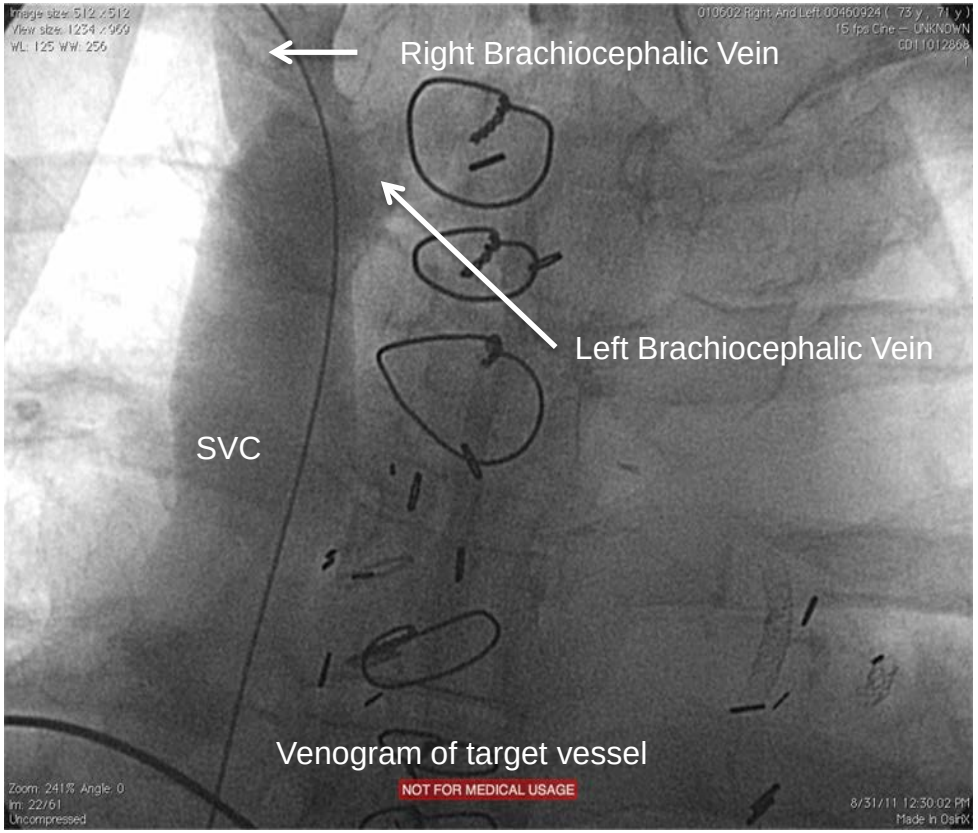


remedē® System Implant Procedure – Right Stimulation Lead Placement

The Right Stimulation lead is placed into the right brachiocephalic vein, which is anatomically adjacent to the right phrenic nerve.

Procedure:

1. Gain venous access
2. Access target vessel
3. Deploy the Right Stimulation lead
4. Test for nerve capture

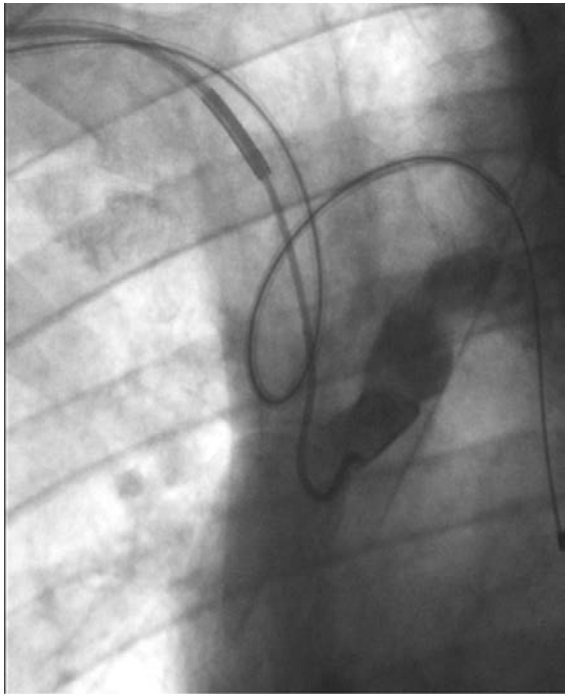


remedē® System Implant Procedure – Sensing Lead Placement

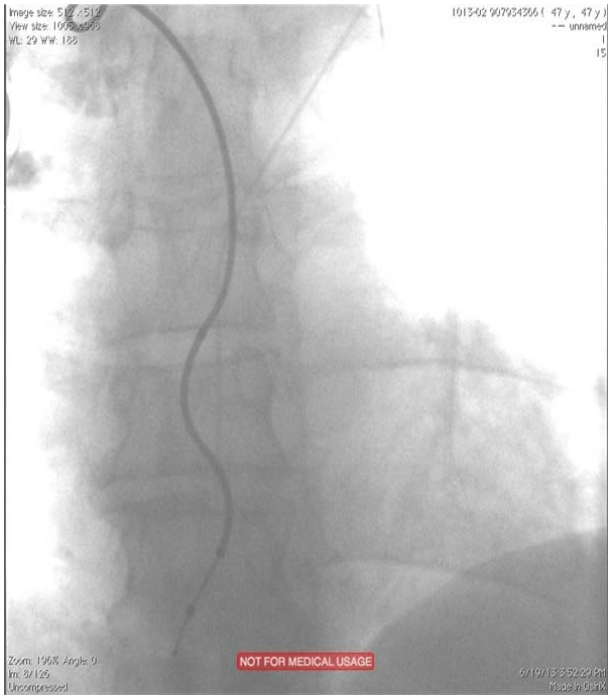
The Sensing lead is placed into the azygos vein after the Stimulation lead is placed.

Procedure:

1. Gain venous access
2. Locate target vessel
3. Deploy the Sensing lead into the azygos vein
4. Perform final stabilization and electrical testing of leads



Venogram of target vessel (RAO Projection)



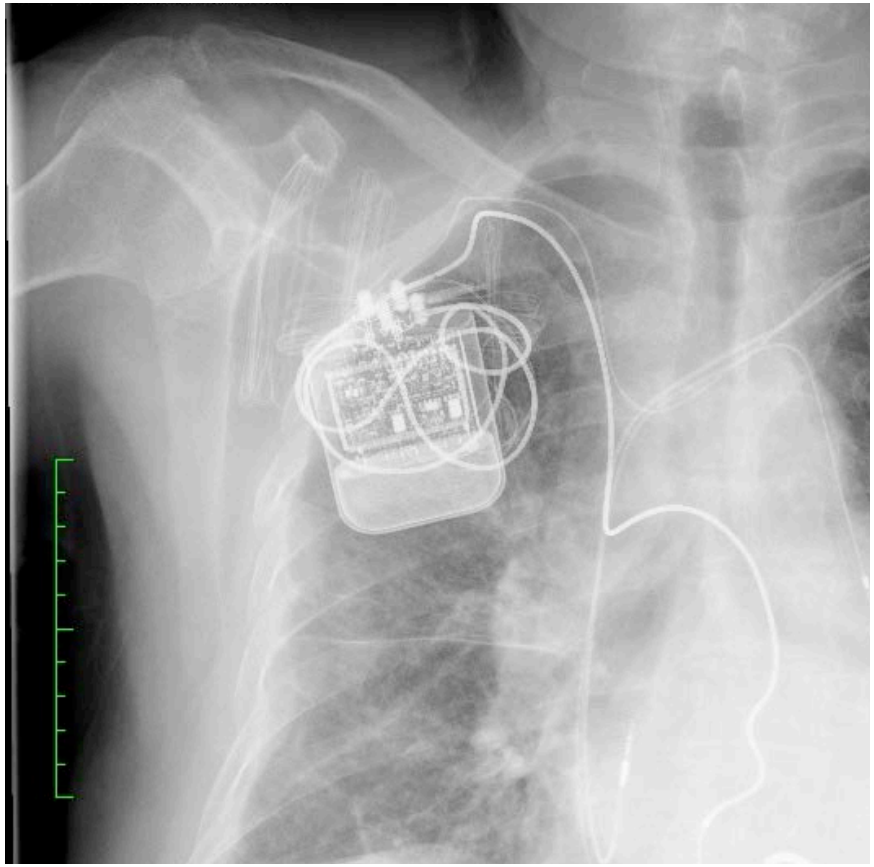
Sensing lead implanted in target vessel

remedē® System Implant Procedure – Neurostimulation Device Placement

The stimulator is implanted via a submuscular or subcutaneous approach in the pectoral region.

Procedure:

1. Form device pocket
2. Connect leads to the device
3. Place device in pocket
4. Perform Concomitant Device Testing (when required)
5. Close device pocket
6. Perform final electrical test



remedē® System Removal

- The removal of the **rem**edē® System should only be performed by qualified personnel for indications consistent with the HRS guidelines[1]
- The equipment utilized to remove the stimulation lead and sensing lead would be the common equipment used for other transvenous leads including: locking stylet, removal sheaths and fluoroscopy
- Removal procedure similar to removal of other implantable transvenous leads

1 **Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications and Patient Management**

Medicare Beneficiaries

- Central Sleep Apnea is associated predominantly with **structural heart disease** and **symptomatic heart failure**
- Risk factors include
  - Male
  - Elderly
  - Arrhythmias
  - Heart Failure Hospitalizations

Rationale for new ICD-10-PCS codes

- Currently there are no ICD-10 codes that describe the transvenous placement of a stimulating lead into the right brachiocephalic or left pericardiophrenic vein or a sensing lead into the azygos vein

- We request CMS develop ICD-10 PCS codes that describe the implantation and removal of both the stimulating and sensing leads

Questions
&
Discussion