9-2015

Upper Airway Stimulation for Treatment of Obstructive Sleep Apnea

Maurits Boon, MD
Thomas Jefferson University

Upper Airway Stimulation for Treatment of OSA

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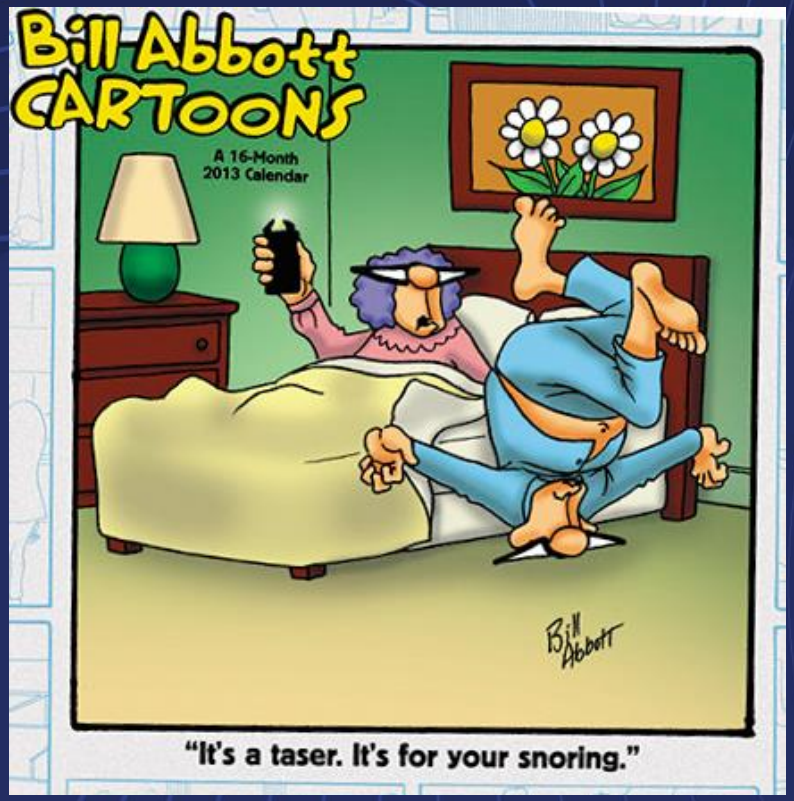
Introduction:

- What is OSA
  - Consequences of untreated OSA
- CPAP therapy
- Why do we need alternatives to positive airway pressure (PAP) therapy
- How do we evaluate a patient for alternative treatments
- Who is a candidate
- What are the alternatives



Obstructive Sleep Apnea

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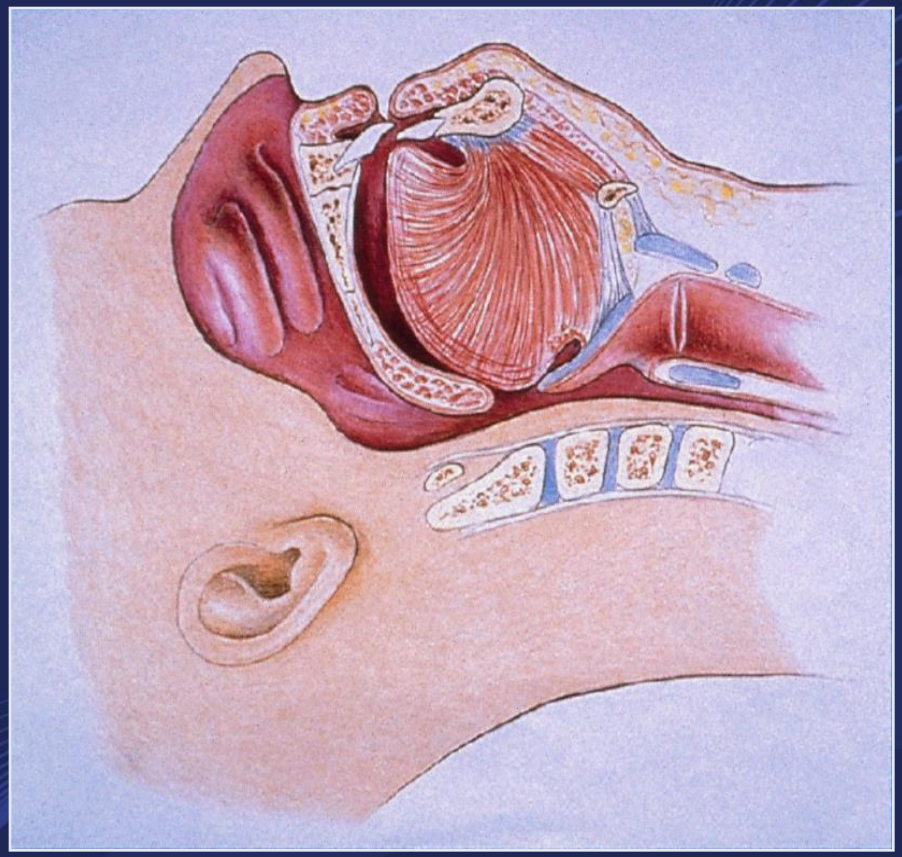
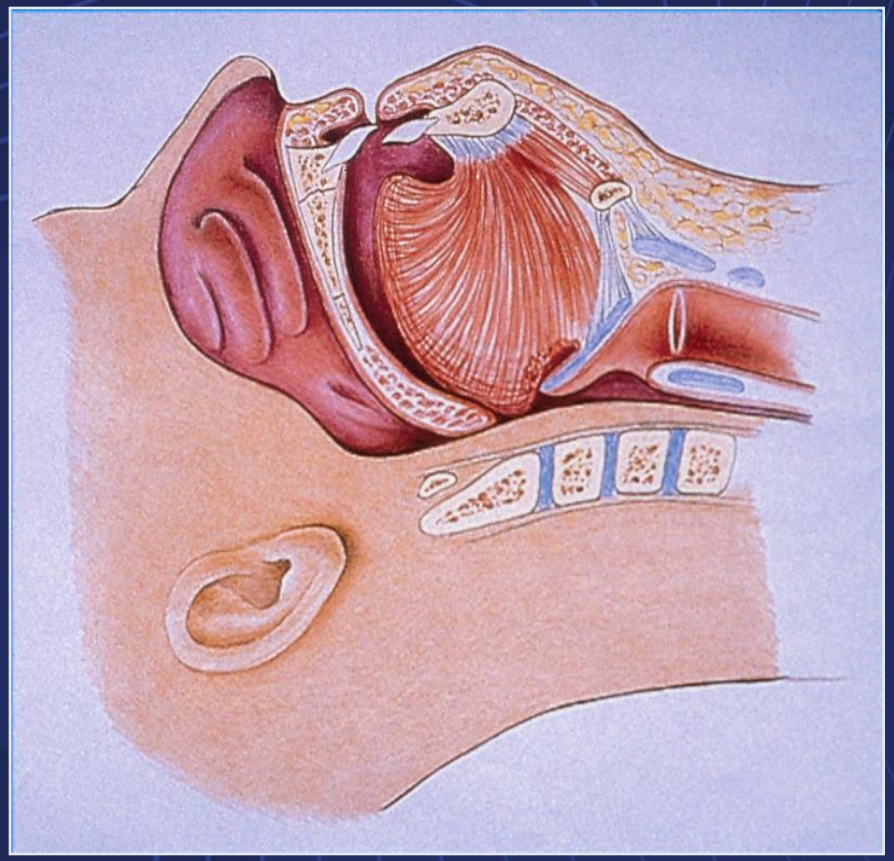




How we Measure OSA

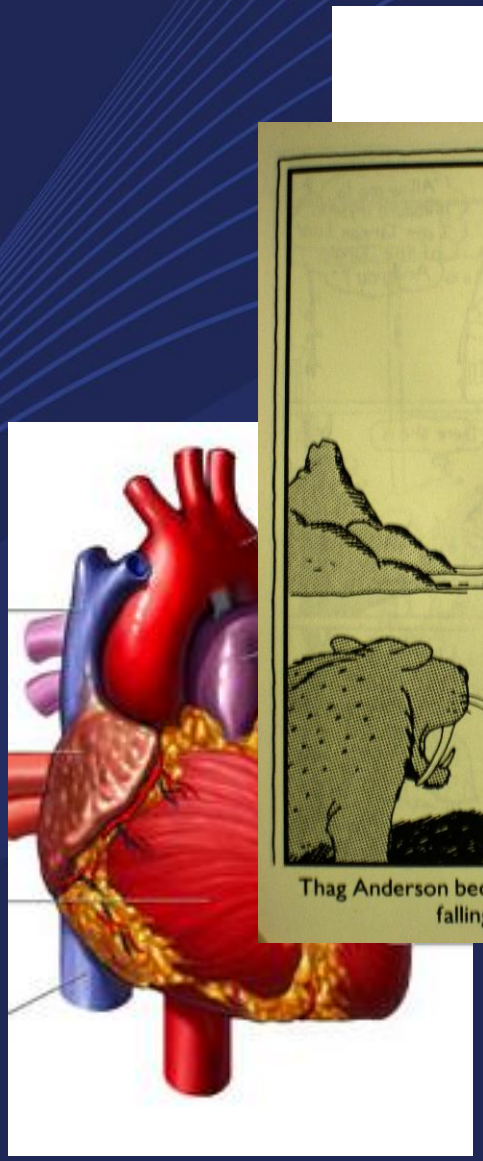
- Hypopnea:
  - Reduction in airflow of 30% for 10 seconds with corresponding desaturation of 4%
- Apnea:
  - Cessation of breathing for 10 seconds
- RERA:
  - Respiratory event related arousal
- Apnea Hypopnea Index (AHI)
  - Average of apneas and hypopneas per hour
- Respiratory Disturbance Index (RDI)
  - Apneas, hypopneas and RERA on average per hour

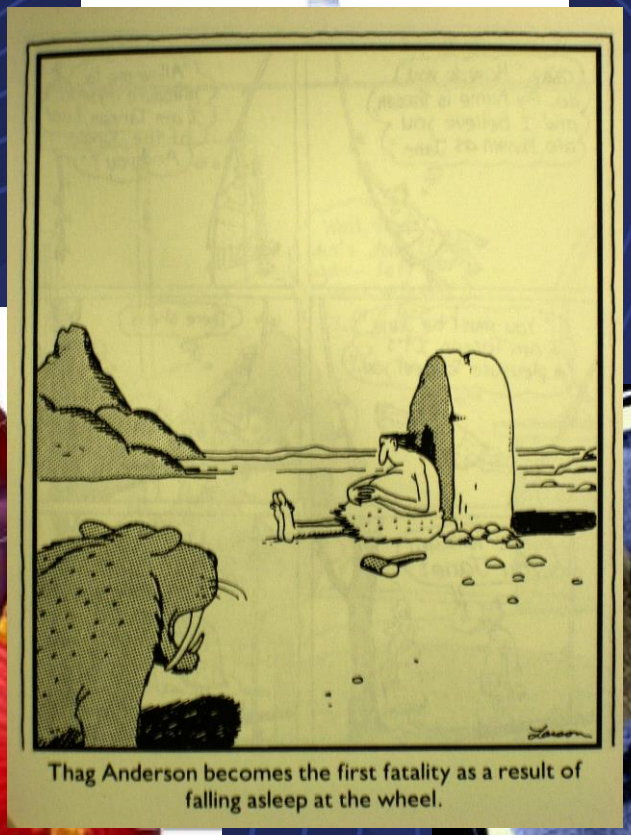
Scoring Sleep Studies

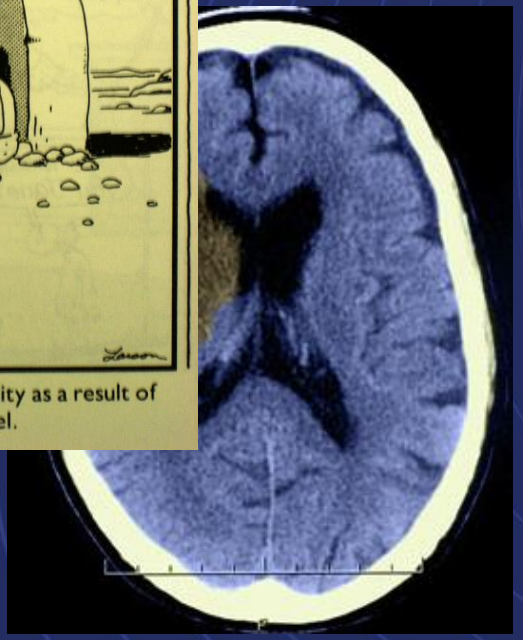
- <5 Normal
- >5-15 Mild
- >15-30 Moderate
- >30 Severe

What are the consequences of untreated OSA?

- Cardiovascular
  - Hypertension
  - Heart failure
  - MI
  - Arrhythmia
  - Stroke
- Pulmonary
- Endocrine
  - Diabetes
- Other
  - Reflux
- Functional







Treatment

- Surgical treatments predate medical treatments
  - Tracheotomy
  - UPPP
- CPAP shortly thereafter

Positive Airway Pressure

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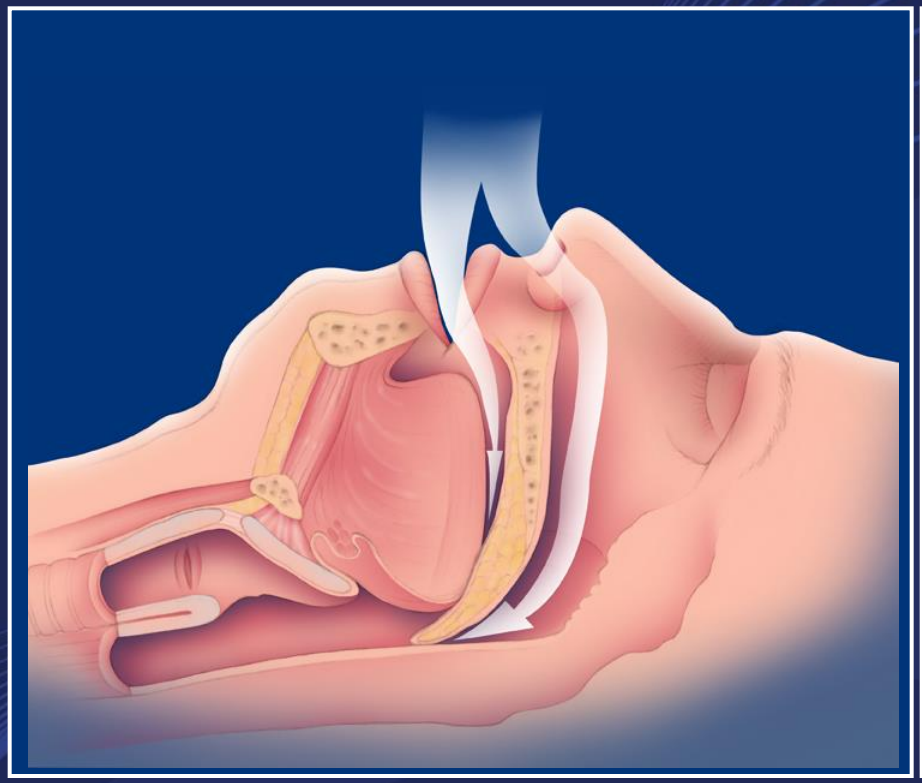
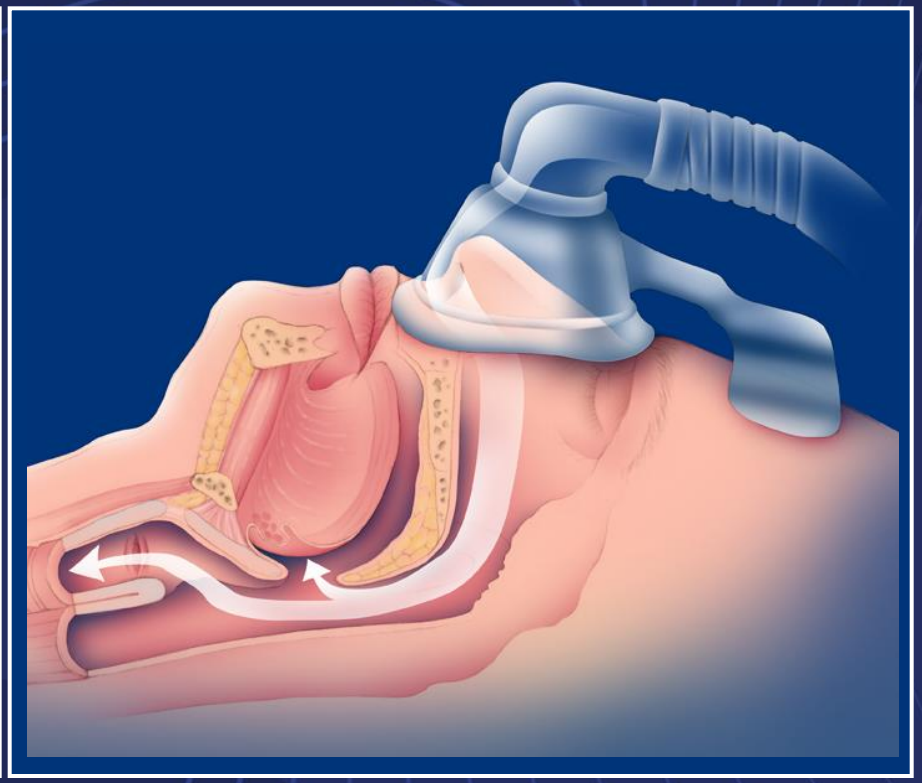
OSA



CPAP-Treated Airway



CPAP = continuous positive airway pressure.

Benefits of CPAP

- Sleep quality
- Reduced snoring
- Alertness
- Reduced GERD
- Depressive symptoms
- Blood pressure control
- Heart function, esp atrial fibrillation
- Mortality rate

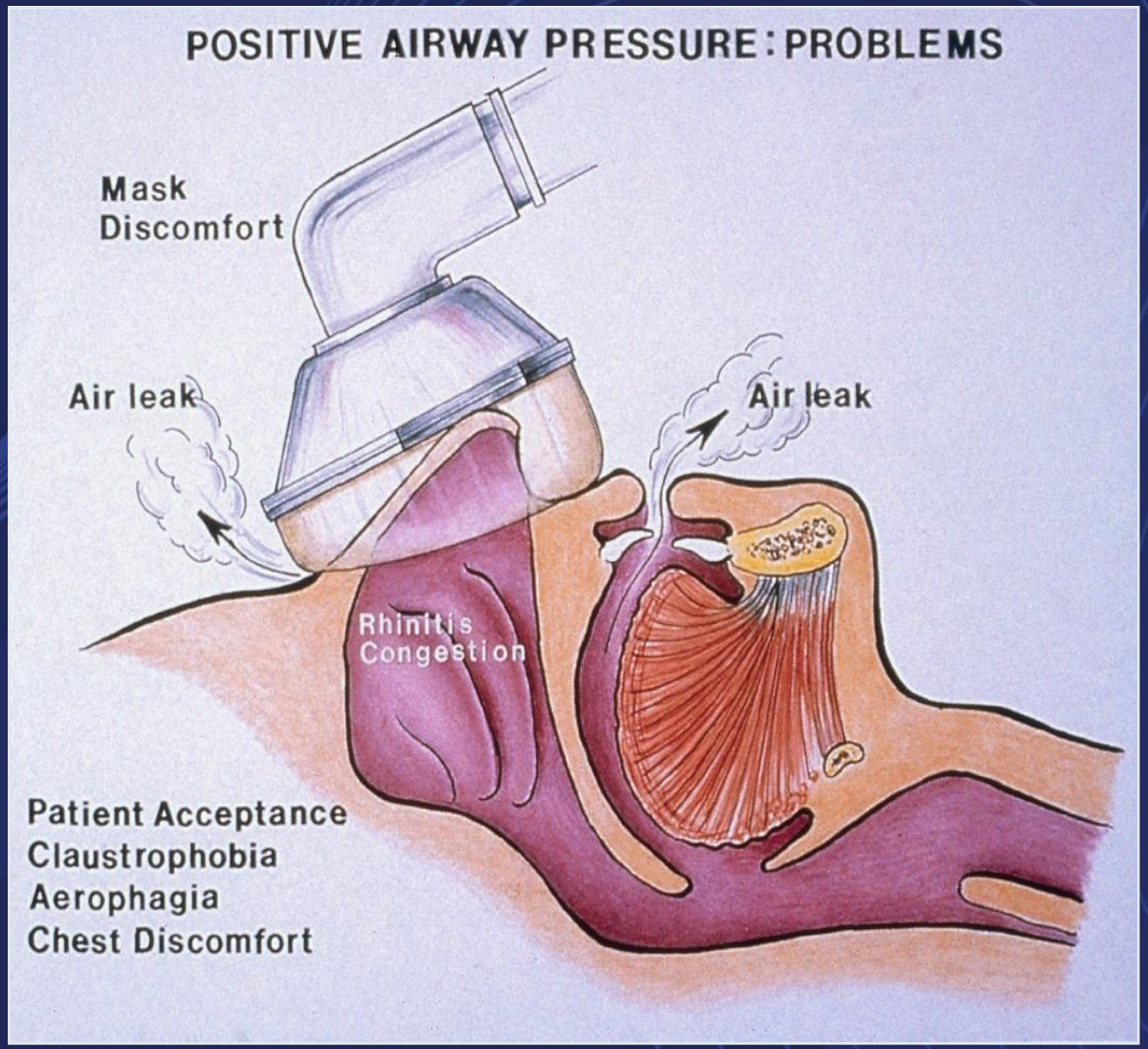
Kanathur et al. Therapy in Sleep Medicine, 2012

Adverse Effects of CPAP

Hoffstein V, Viner S, Mateika S, et al. Am Rev Respir Dis 1992;145(4 Pt 1):841-45.

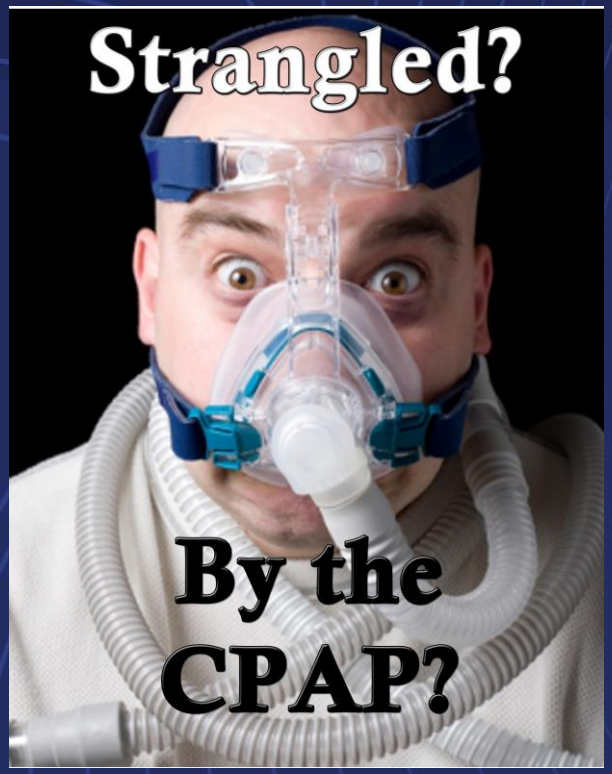
Waldhorn RE, Herrick TW, Nguyen MC, et al. Chest 1990;97(1):33-38.

Nino-Murcia G, Mc Cann CC, Bliwise DL, et al. West J Med 1989;150(2):165-69.



Why do we need alternatives?

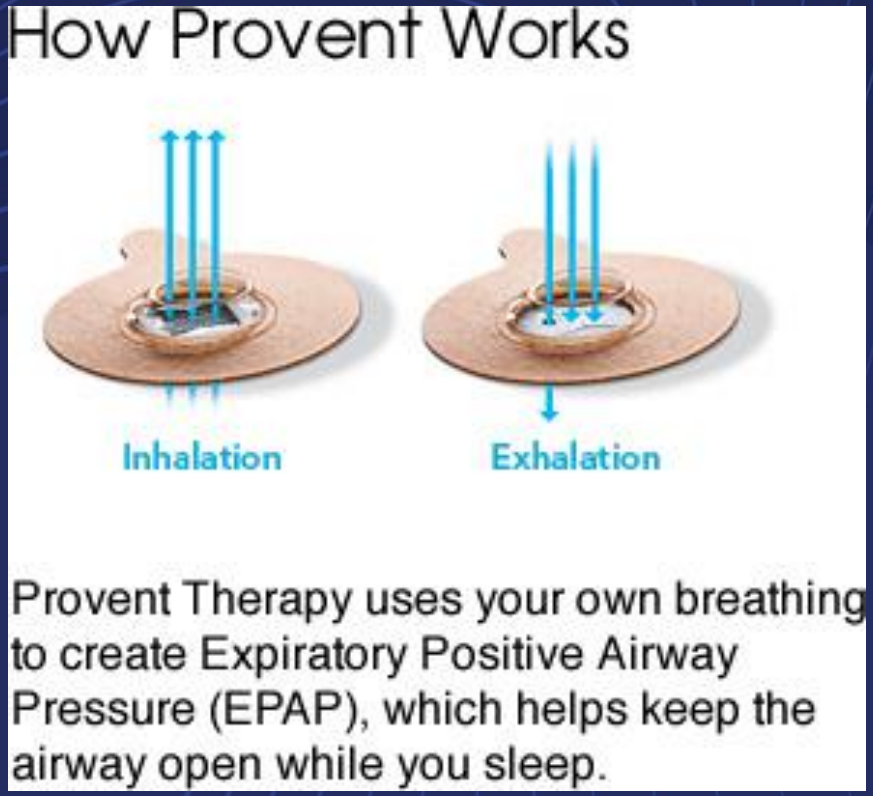
- Patients who cannot tolerate CPAP
  - Non-adherence 46-83%
  - Better response with more severe symptoms



Weaver, TE et al. Adherence to Continuous Positive Airway Pressure Therapy: The Challenge to effective treatment. Proceedings of the American Thoaracic Society. 5(2). Feb 173-8

Expiratory Positive Airway Pressure (EPAP)

- Theravent®
- Provent®
  - Imposes expiratory resistance
  - Stent open airways
  - 94% compliance



Rosenthal, L. et al. A. JCSM 5(^) 2009

Provent®

- Well tolerated
- Decrease in AHI by 42.7% (vs 10% sham)
- Further research is required to identify the ideal candidates.

1. Berry, B. et al. A novel nasal expiratory positive airway pressure device For the treatment of OSA: A randomized controlled trial. Sleep 2011 34(4)479-85
2. Rosenthal, L. et al. A Multicenter, Prospective Study of a Novel Nasal EPAP Device in the Treatment of Obstructive Sleep Apnea: Efficacy and 30-Day Adherenence. JCSM 5(^) 2009

Oral Appliances:

- Useful in primary snoring and OSA
- 2 Types:
  - Tongue retaining
  - Mandibular advancing

Oral Appliances:

- Success in treatment
  - Mild to moderate OSA
  - AHI <10 in 52%
- Treatment adherence 76%

- Adverse events:
  - Tooth movement
  - Changes in occlusion
  - TMJ pain
  - Salivation
  - Gum irritation
  - Tongue pain (tongue retaining devices only)

Ferguson, et al, Oral appliances for snoring and obstructive sleep Apnea: A review. Sleep 29(2):244-62 2006

Body Positioning Devices

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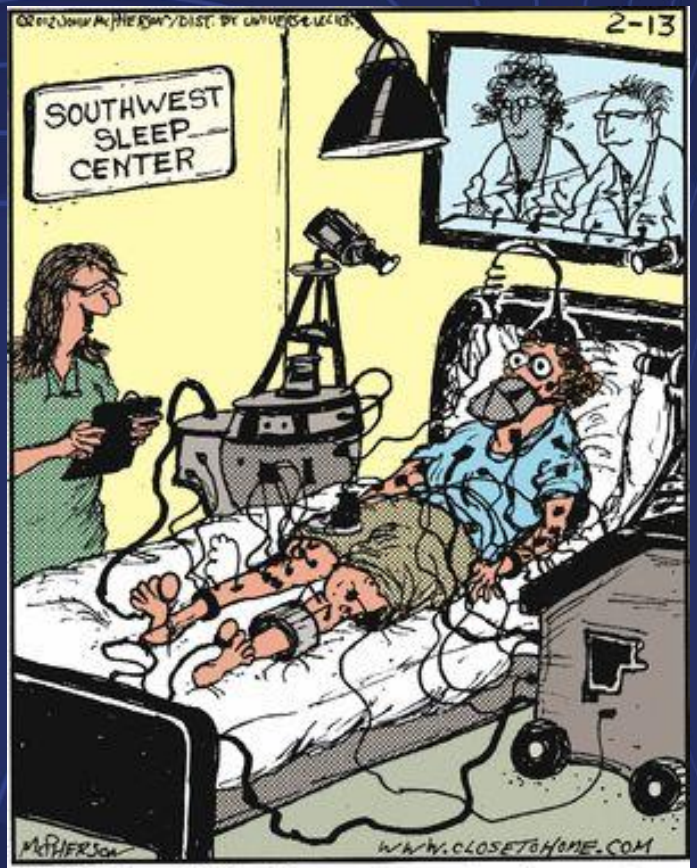
What is sleep surgery?

- Surgery to facilitate other modalities of treatment
  - Improve tolerance of CPAP
  - Improve use of oral appliances or EPAP
- Surgery to definitively treat OSA
  - Bariatric surgery
  - Modification of the upper airway
  - Upper airway stimulation (Inspire®)

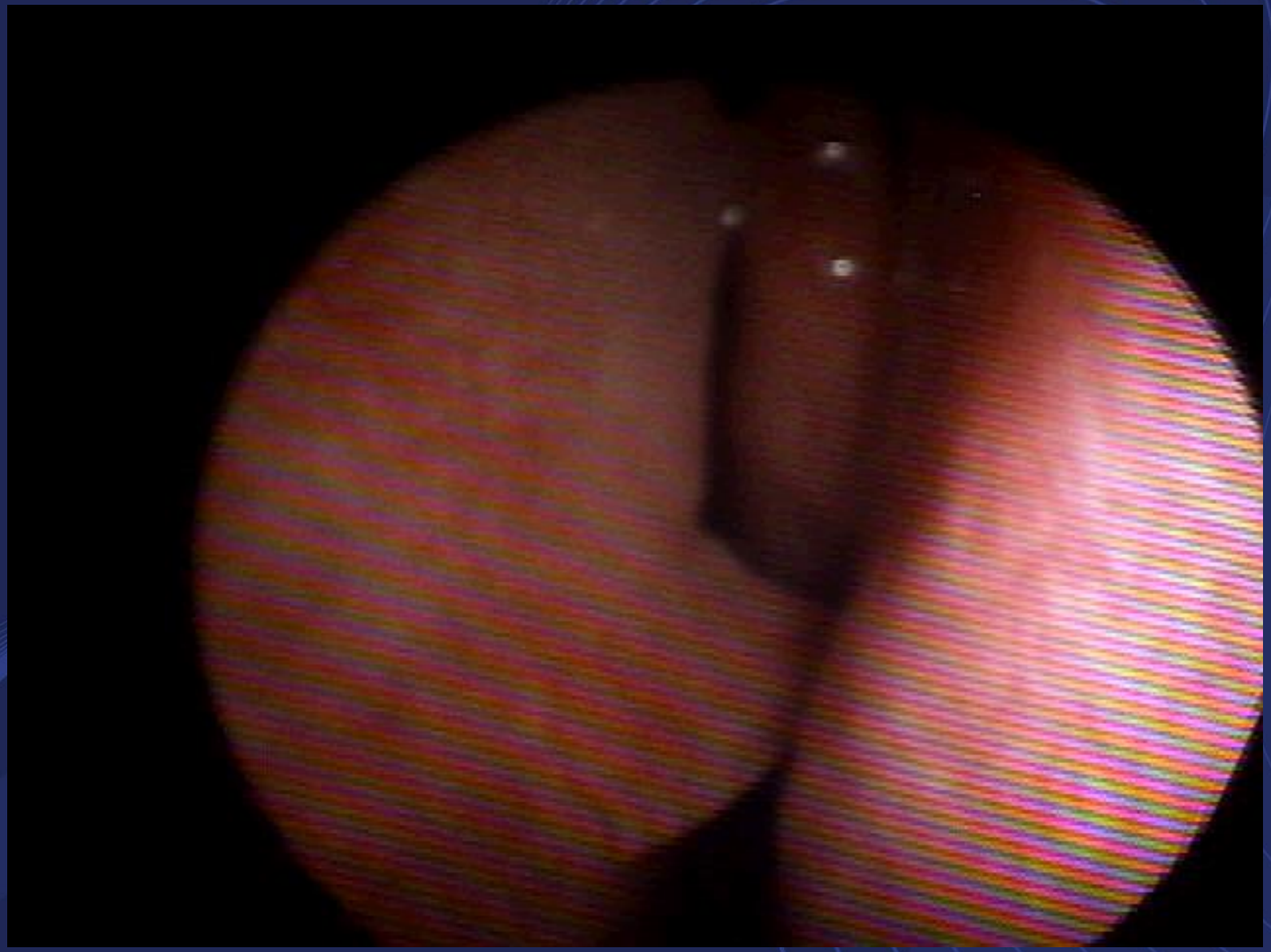
Who is a candidate?

- Diagnosed OSA by appropriate PSG screening
- BMI (<40)
- Willing to undergo postoperative PSG to objectively assess outcome of alternative treatment

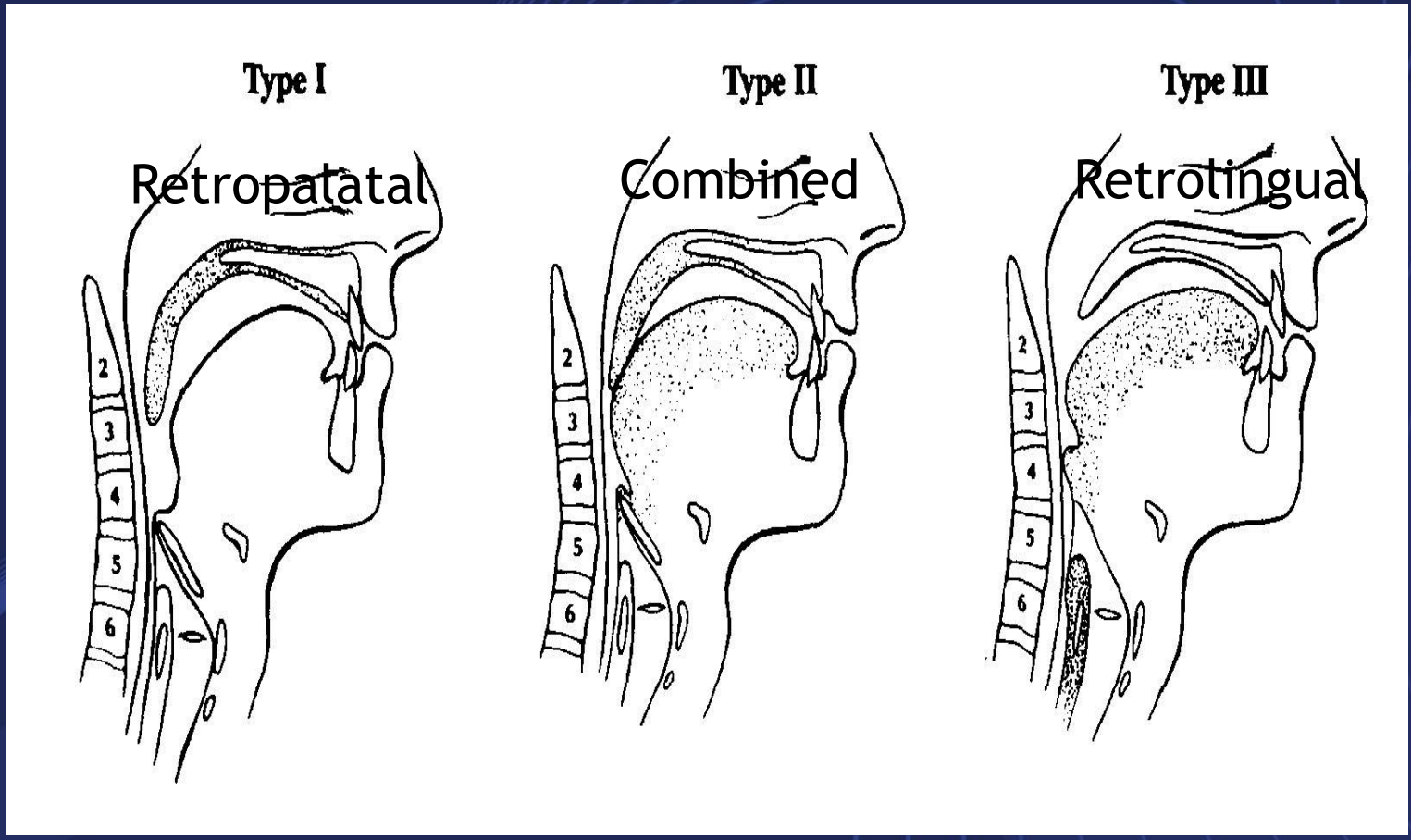


"OK, Mrs. Tully. We want you to relax, get a good night's sleep, and we'll evaluate any sleep issues that you have."

Mueller's Maneuver



Evaluation: Fujita Classification



Sleep Endoscopy

- Flexible fiberoptic examination of patient with sedation
- Assesses airway under more “true” to sleep circumstances
- ?Better assessment of site of obstruction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DR BOON

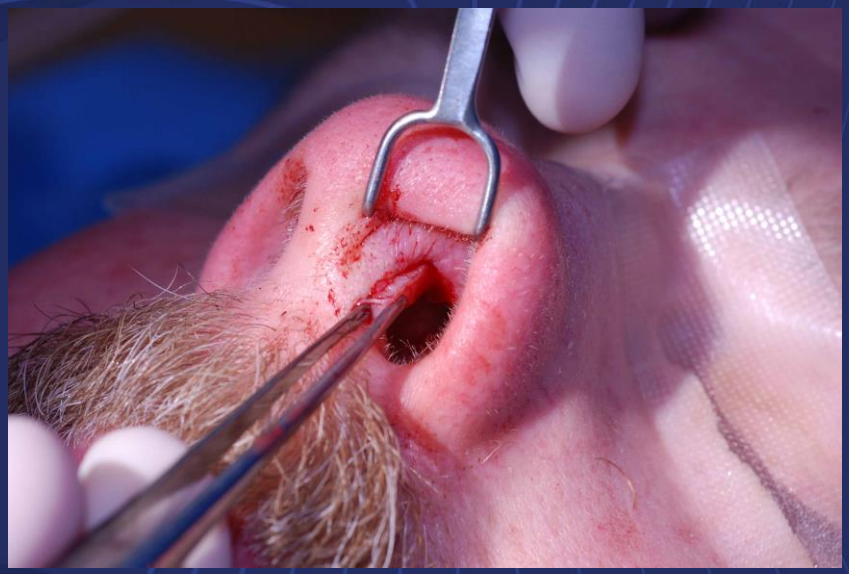
Surgical Management:

- Addressing different sites of obstruction
  - Nose
  - Palate
  - Tongue base / Hypopharyngeal

Surgical Management

Nasal Obstruction Surgery

- <20%successful in mild OSAS with nasal obstruction
- Facilitate CPAP compliance
  - Decreased CPAP pressures
  - Tolerance of different masks



Poirier J. Et al. The effect of of nasal surgery on nasal continuous Postive airway pressure compliance. Laryngoscope. 2013 epub ahead of print

Palatal Procedures

- Laser assisted Uvuloplasty
- Injection snoreplasty
- Cautery Assisted Palatal Stiffening Operation (CAPSO)
- Tonsillectomy
- Pillar implants
- UvuloPalatoPharyngoPlasty (UPPP)
- Anterior Palatoplasty
- ZP3
- Expansion sphincteroplasty
- Palatal advancement
- Lateral pharyngoplasty

Management: Tongue Base

- Radiofrequency reduction
- Laser midline glossectomy
- Laser Lingualplasty
- Lingual tonsillectomy
- SMILE procedure
- TORS

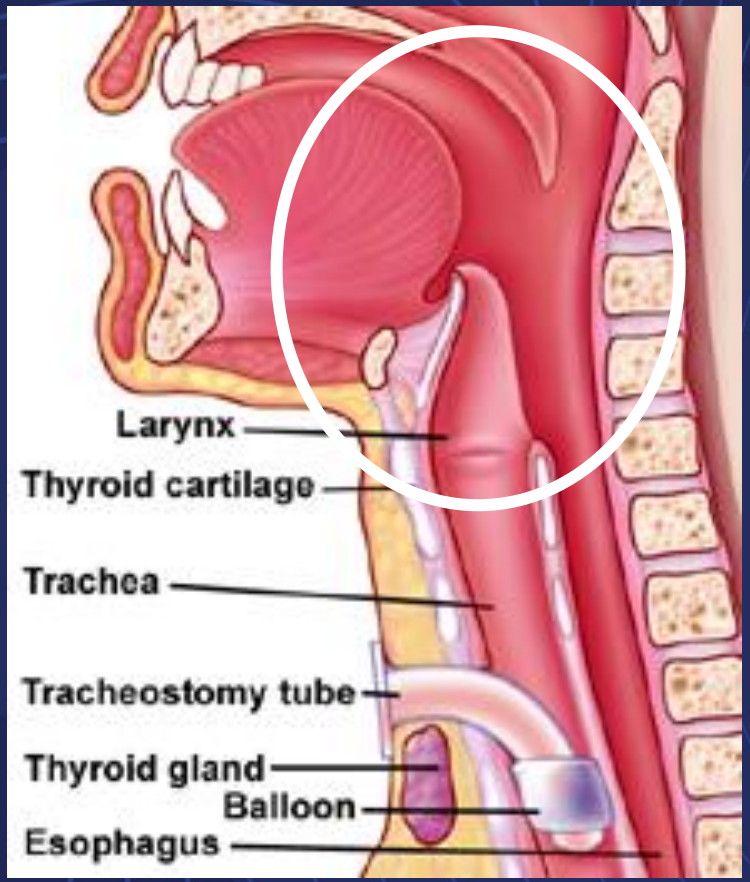
- Hyoid Myotomy and advancement +/-Tongue base suspension
- Genioglossus advancement
- Hypoglossal Nerve Stimulator

Bimaxillary Advancement

- Osteotomies of maxilla and mandible
- Addresses oropharyngeal and hypopharyngeal airway
- Can be used after failed “phase 1” sleep surgery
- 90-95% success
- Limited by patient acceptance

Tracheotomy

- “Gold Standard”
- Temporary adjunct to procedures in severe cases

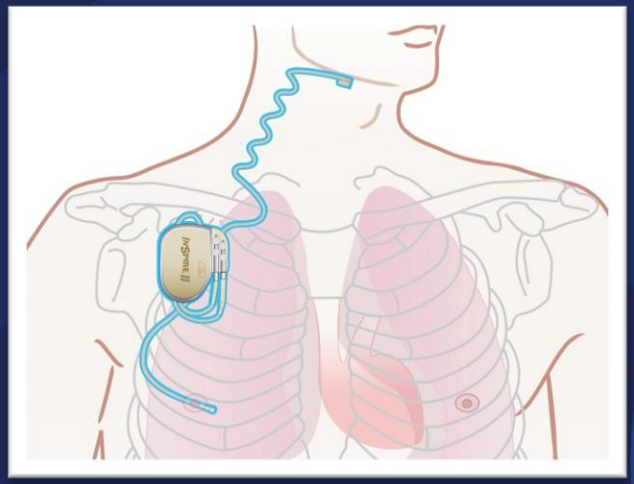


Upper Airway Stimulation:

- Surgically implanted device
- Does not alter native anatomy of pharynx and tongue base

How Does Inspire Therapy Work?

- Inspire therapy:
  - Is fully implanted
  - Senses breathing
  - Delivers mild stimulation to key airway muscles
  - Turns on and off with a handheld remote



Inspire Therapy

Inspire System

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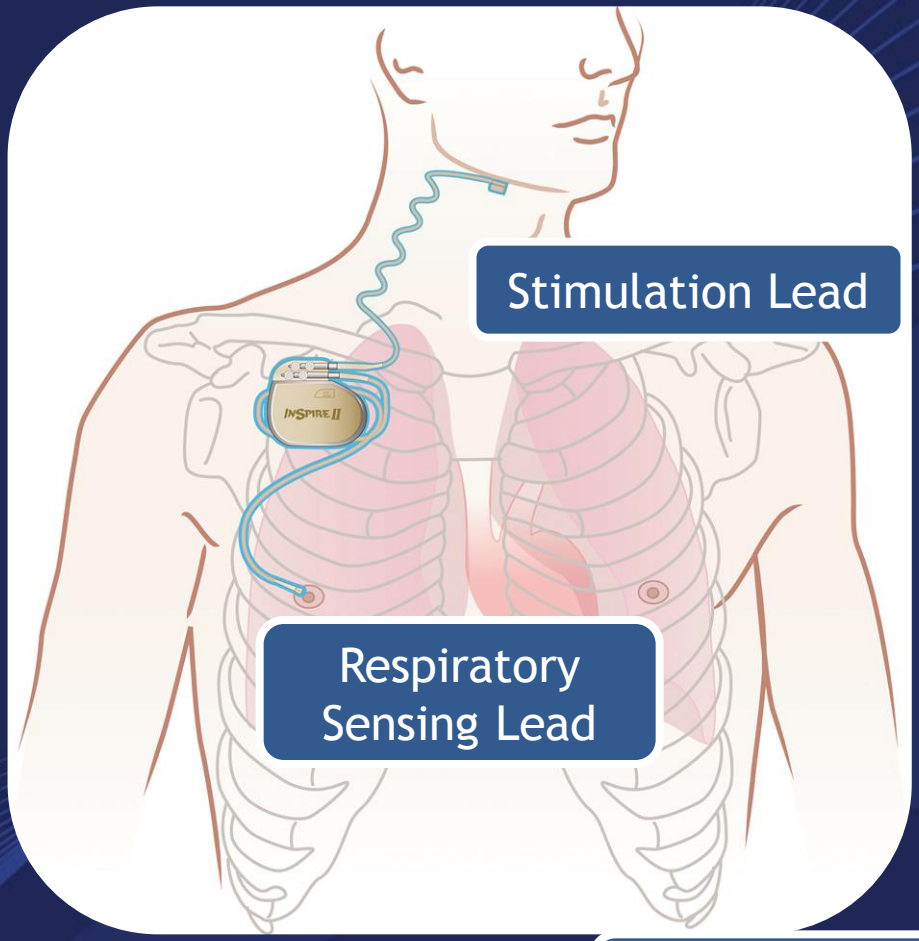


Stimulation Lead

Respiratory Sensing Lead

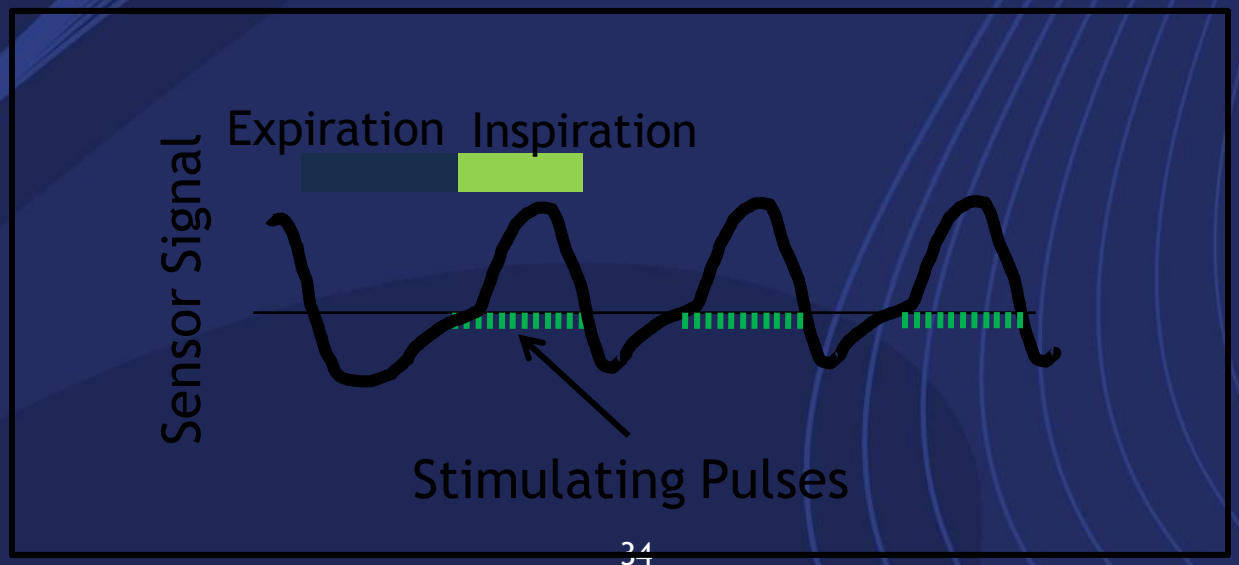
Implantable Pulse Generator

Patient Sleep Remote

Physician Programmer

Adjustability of Device

- Implantable neurostimulation systems are adjustable to optimize therapy
- Inspire is a closed-loop system measuring respiration and providing stimulaton
- Titration occurs during an in-lab sleep study



Upper Airway Stimulation Effect

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EEG

EMG

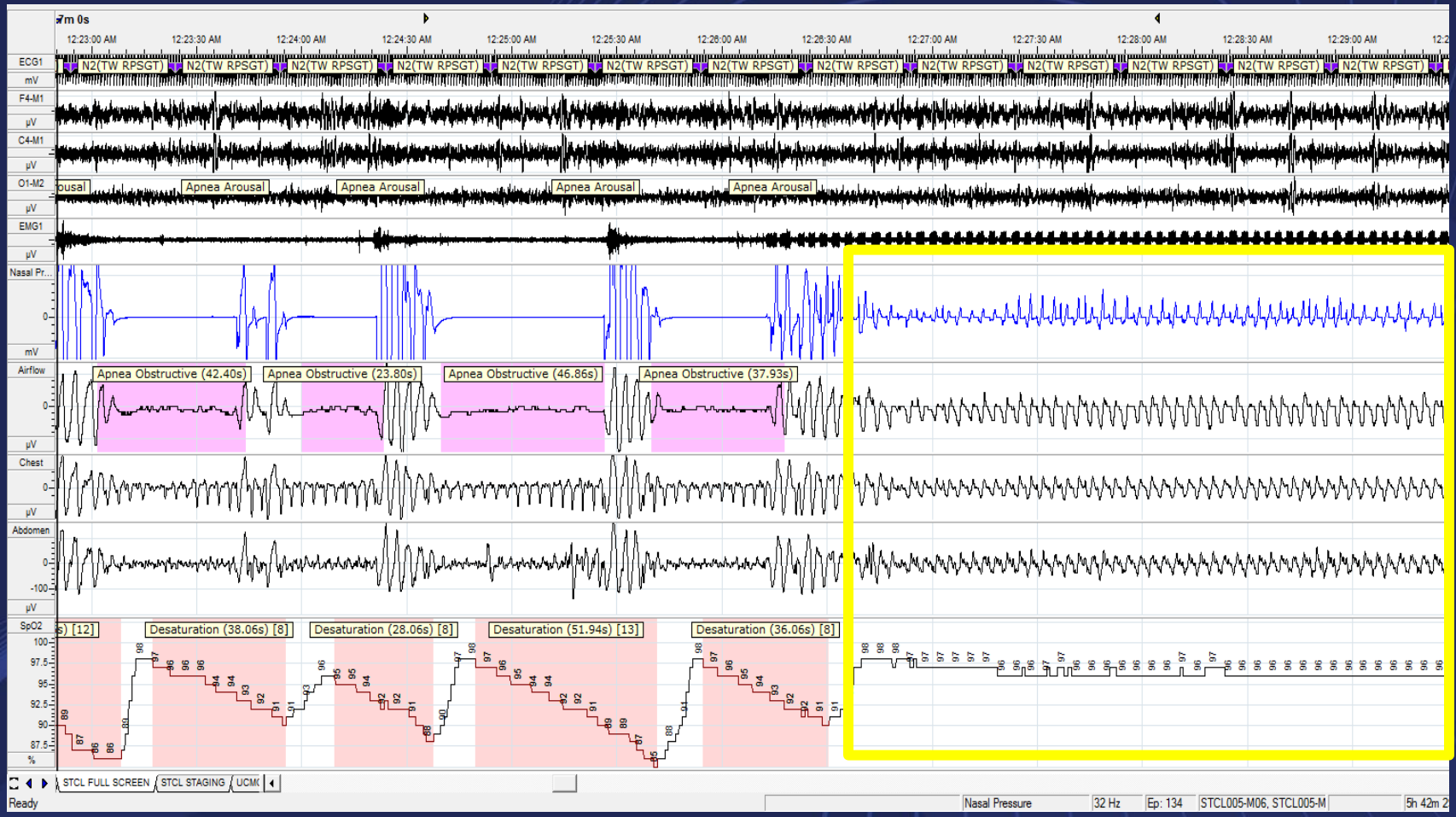
Nasal

Therm

Chest

Abdm

SaO_2



No Stimulation

Stimulation Active

Inspire Therapy affects the airway at multiple-levels

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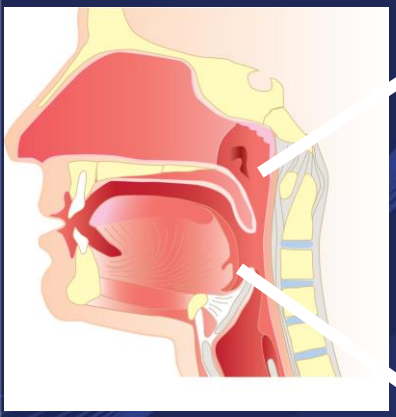

Tx OFF - Palate

Tx ON - Palate

OFF - Tongue Base

ON – Tongue Base

Star Trial: Stimulation for Treatment of Apnea Reduction

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Upper-Airway Stimulation for Obstructive Sleep Apnea

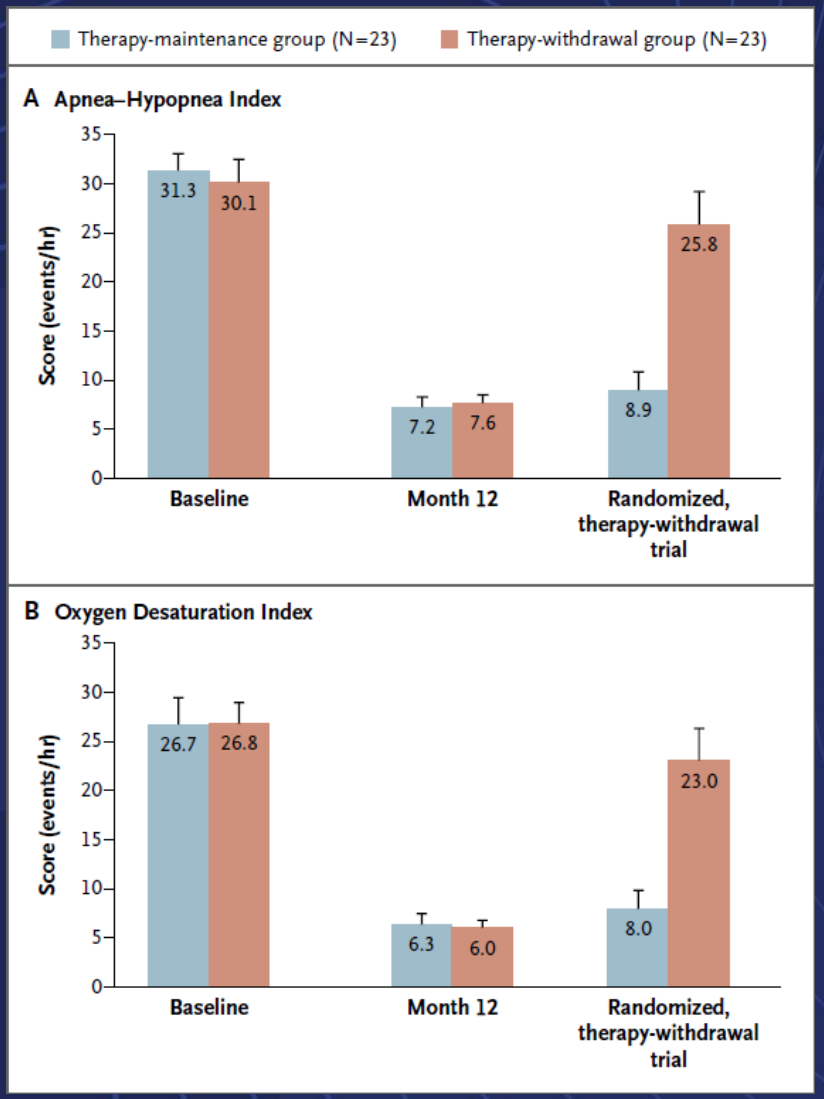
Patrick J. Strollo, Jr., M.D., Ryan J. Soose, M.D., Joachim T. Maurer, M.D., Nico de Vries, M.D., Jason Cornelius, M.D., Oleg Froymovich, M.D., Ronald D. Hanson, M.D., Tapan A. Padhya, M.D., David L. Steward, M.D., M. Boyd Gillespie, M.D., B. Tucker Woodson, M.D., Paul H. Van de Heyning, M.D., Ph.D.,

PRIMARY OUTCOMES

The scores on the AHI and ODI (primary outcome measures) were lower (indicating fewer episodes of sleep apnea) at 12 months than at baseline. The median AHI score decreased 68%,

SECONDARY OUTCOMES

Scores on the FOSQ and Epworth Sleepiness Scale indicated significant improvement at 12 months, as compared with baseline. The increase in the



N Engl J Med 2014;370:139-49; p 143-4; Figure 3, p 147.
Green underlines added for clarity in text excerpts.

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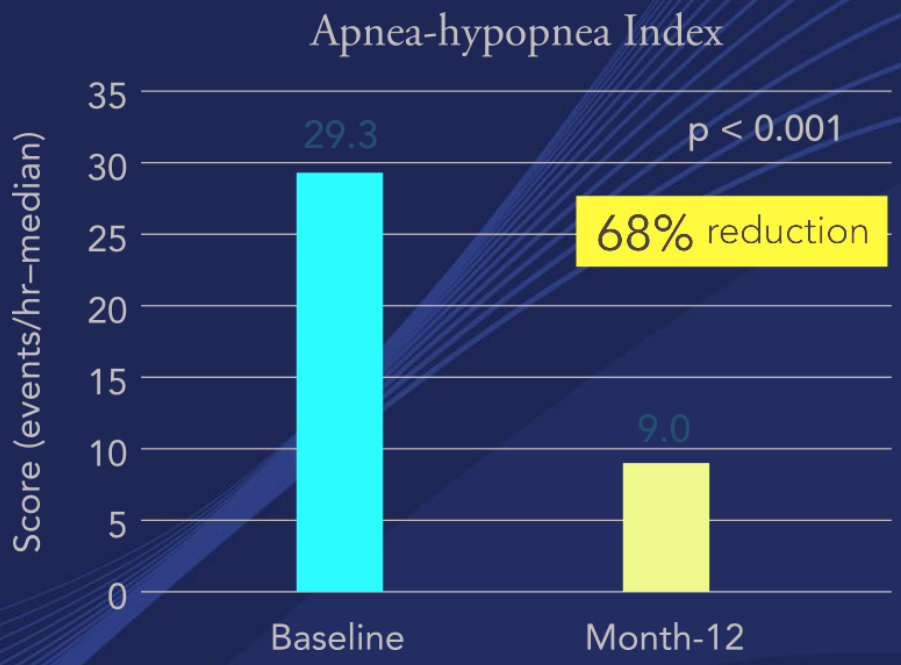
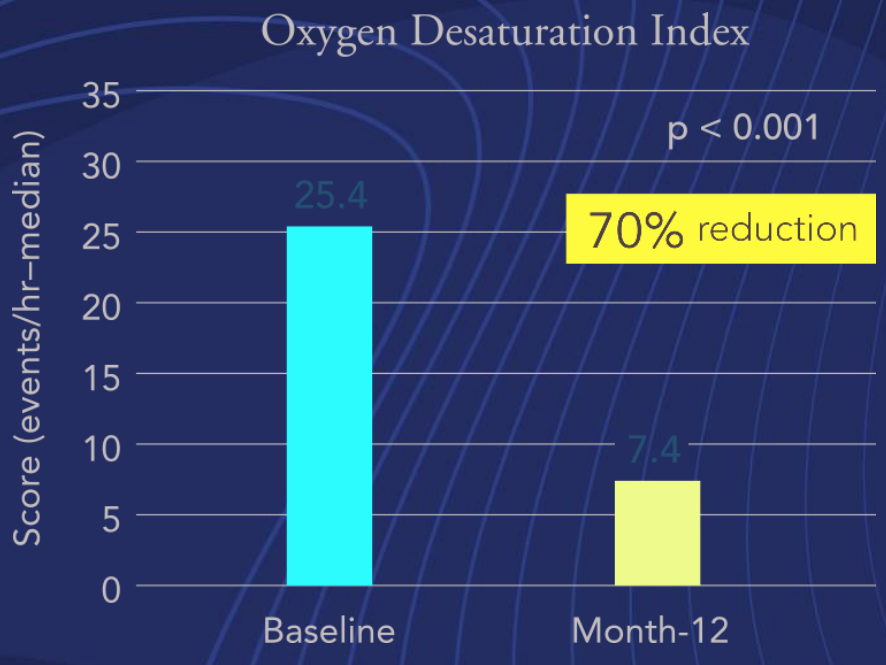
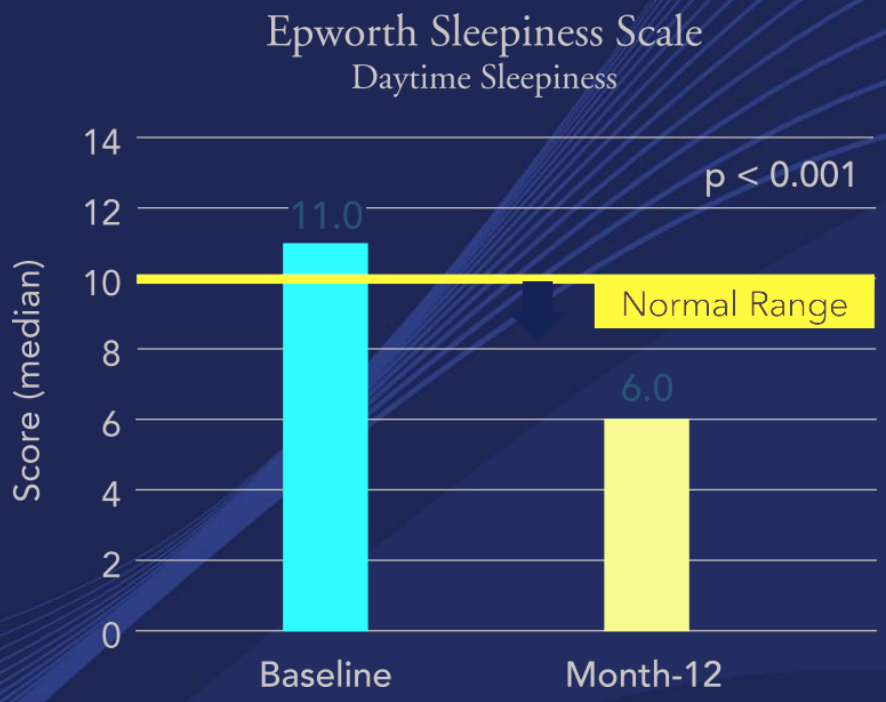
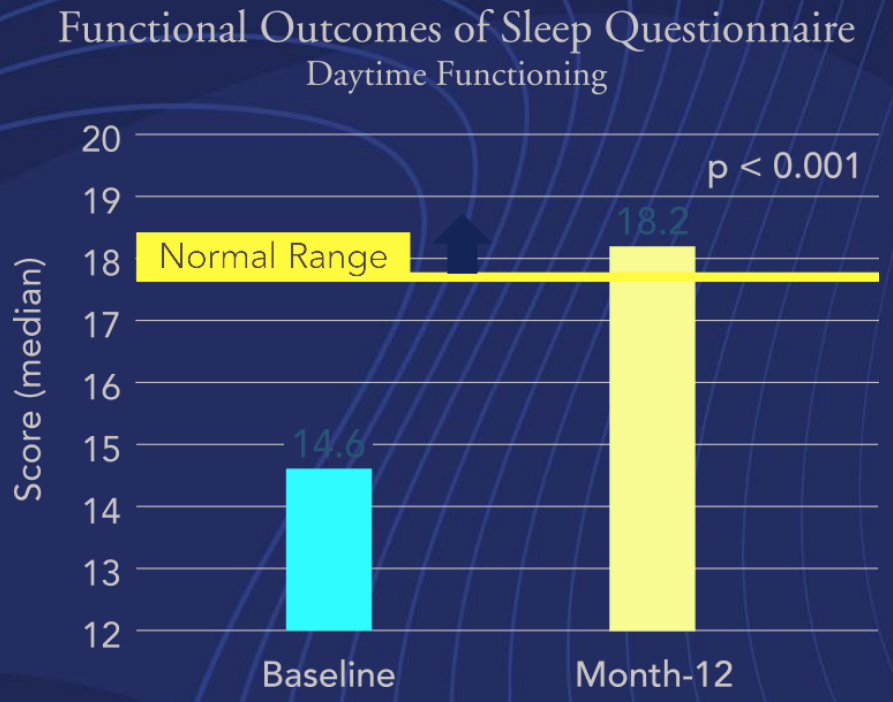
Significant Reduction In OSA Severity



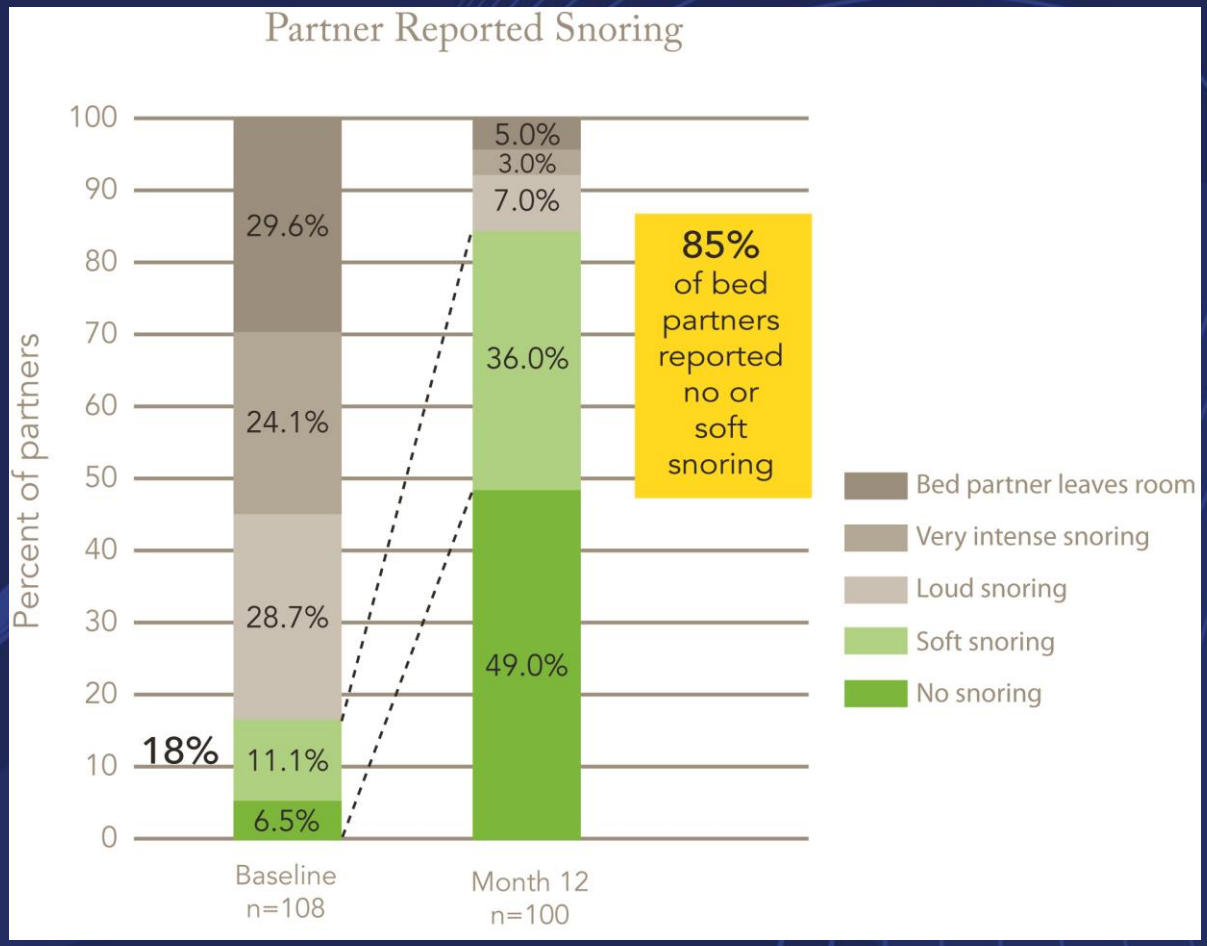


Significant Improvement In Daytime Functioning





Reduction in Snoring



Source: Inspire STAR pivotal trial

Inspire Therapy Visits

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Assessment	Implant	Follow Up
Sleep profile	Typically outpatient	Therapy activation
Anatomy check		Therapy optimization
		Routine annual follow up

Who is a candidate for Upper Airway Stimulation

- Moderate to severe OSA with AHI 20 or more
- BMI 32 or less
- No significant central component of apneas
- Appropriate anatomy based on sleep endoscopy


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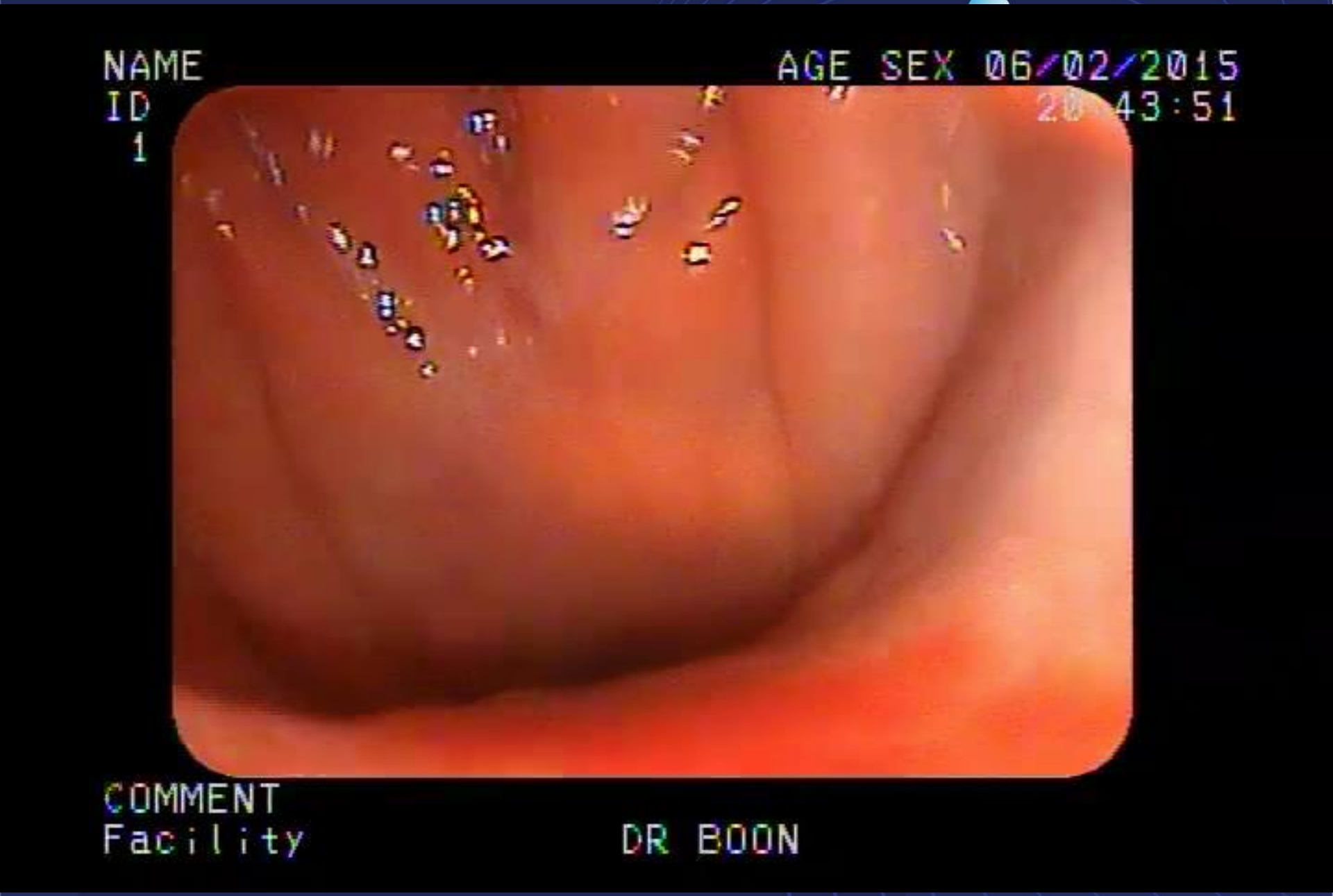
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Inspire Therapy Visits

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Assessment	Implant	Follow Up
Sleep profile	Typically outpatient	Therapy activation
Anatomy check		Therapy optimization
		Routine annual follow up

Surgery:

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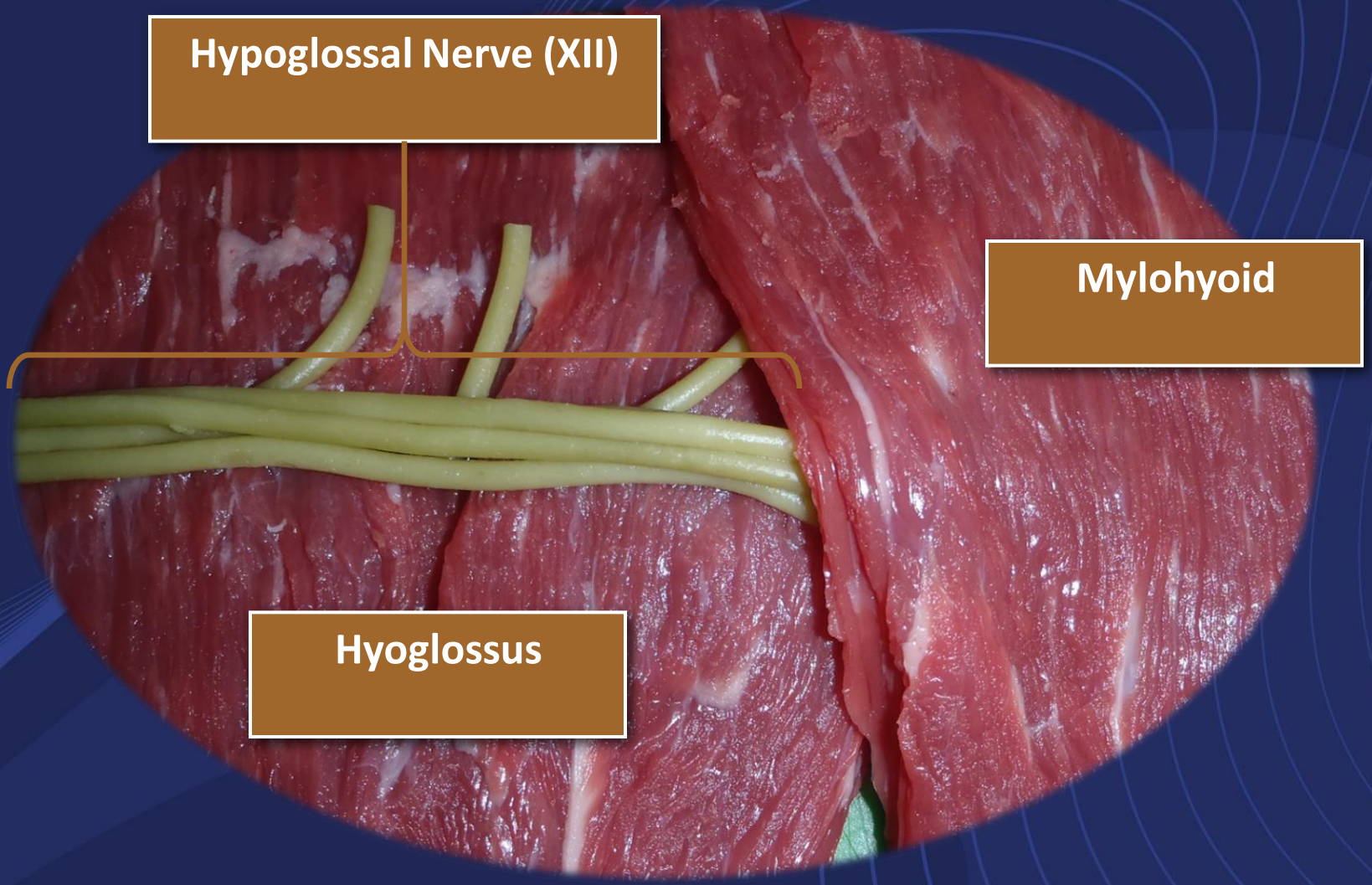
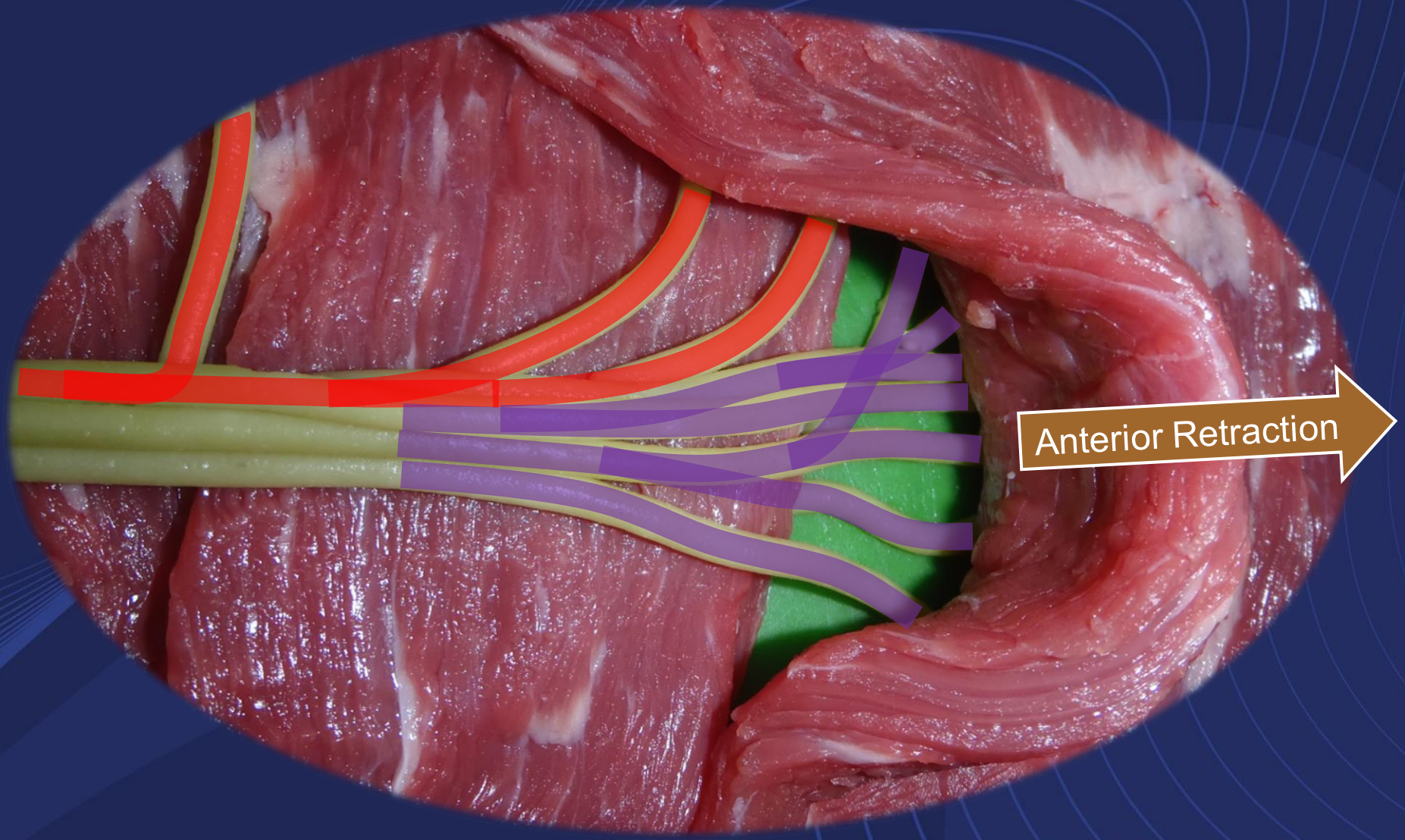
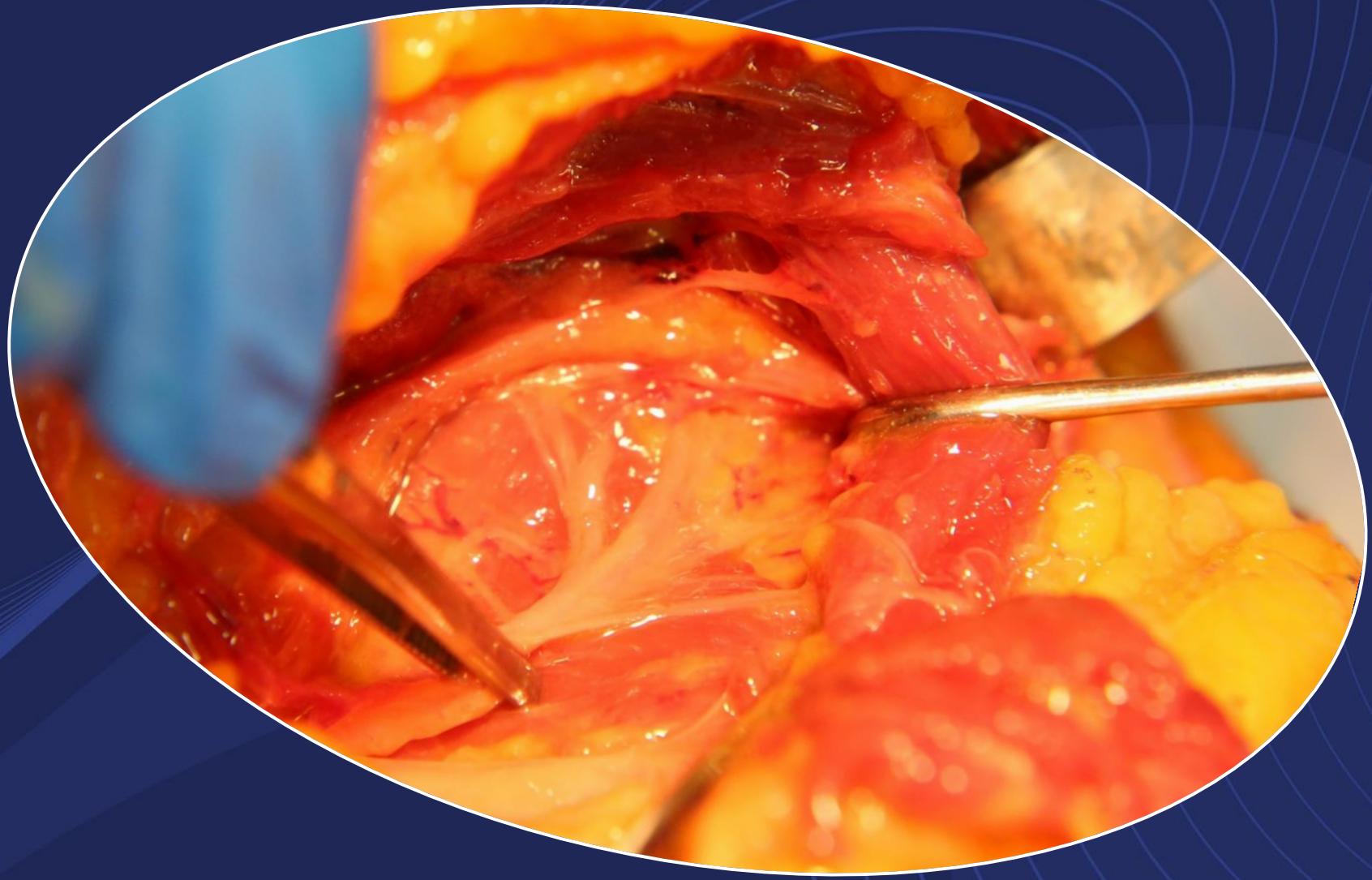

Hypoglossal Nerve (XII)
Mylohyoid
Hyoglossus


Anterior Retraction

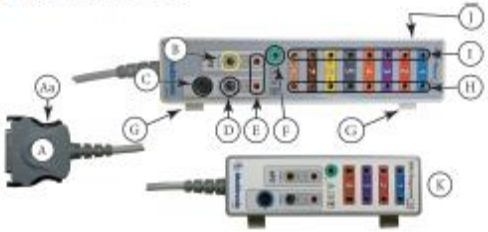
Plunge Point in fresh cadaver
GGh & GGo ramifying



Nerve Integrity Monitor

NIM-Response® 3.0

Patient Interface



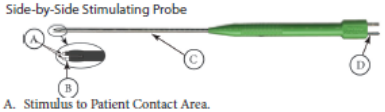
B1 Toggle button normal or at rest.
B2 Increase current.
B3 Decrease current.
B4 Press and hold saves current screen to memory (for Reports) and to selected peripheral device (Printer and/or USB flash drive).

Universal Monopolar Probe Handle

A. Probe Jack.
B. Handle.
C. Stimulus Plug.

Bipolar

Side-by-Side Stimulating Probe



A. Stimulus to Patient Contact Area.
B. Insulating Sleeve.
C. Stainless Steel Tubing.
D. Cable Connection.

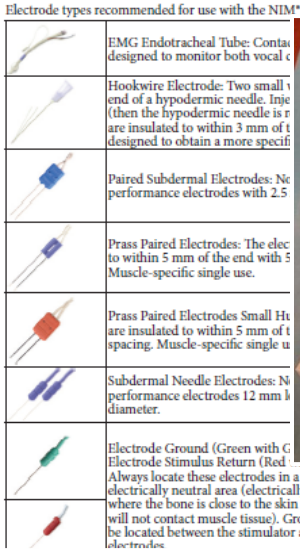
Prass Flush Tip Stimulating Probe

A. Stimulus to Patient Contact Area.
B. Insulating Sleeve.
C. Stainless Steel Tubing.
D. Cable Connection.

A. Thumb Switch
B. Cable

Electrodes

Electrode types recommended for use with the NIM® 3.0 System



EMG Endotracheal Tube: Conta designed to monitor both vocal c

Hookwire Electrode: Two small end of a hypodermic needle. Inje (then the hypodermic needle is r are insulated to within 3 mm of t designed to obtain a more specifi

Paired Subdermal Electrodes: Ne performance electrodes with 2.5

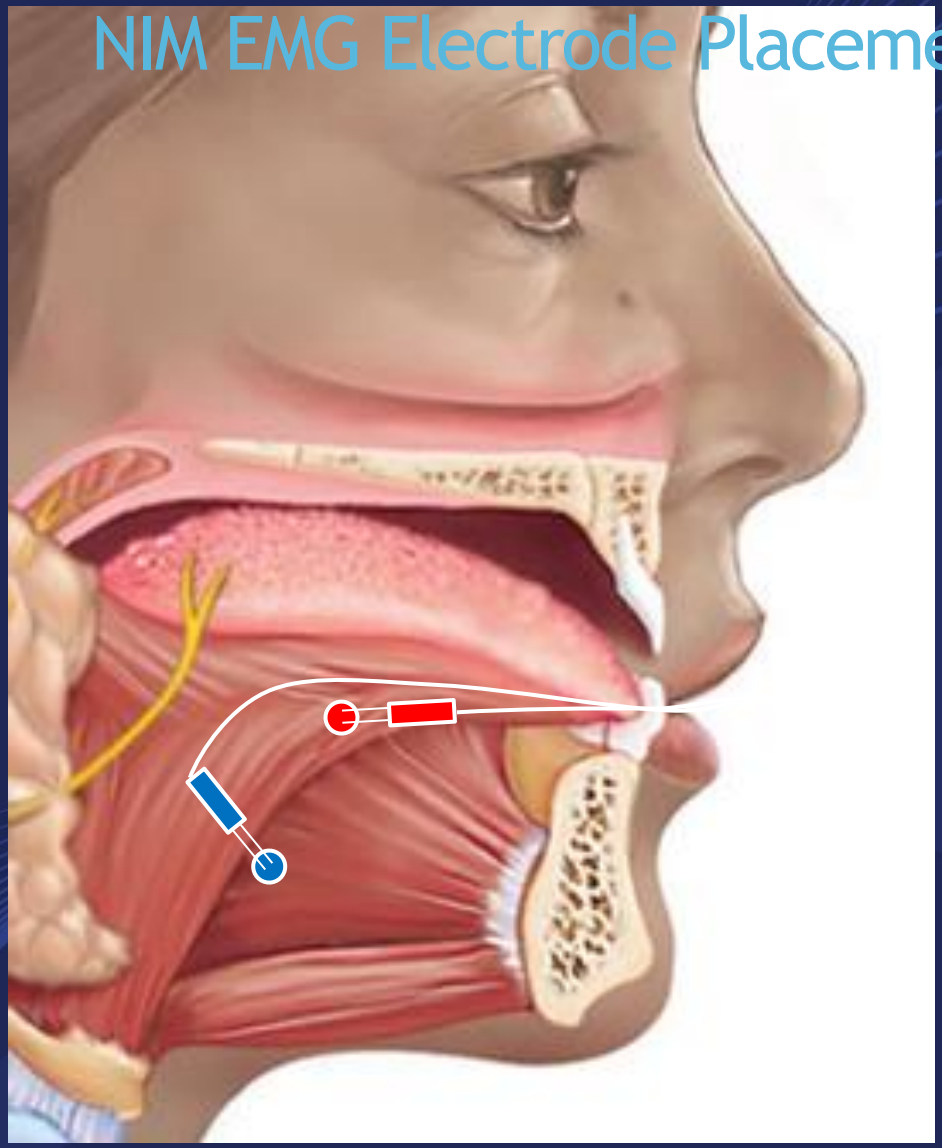
Prass Paired Electrodes: The elec to within 5 mm of the end with 5 Muscle-specific single use.

Prass Paired Electrodes Small Hu are insulated to within 5 mm of t spacing. Muscle-specific single u

Subdermal Needle Electrodes: N performance electrodes 12 mm l diameter.

Electrode Ground (Green with G Electrode Stimulus Return (Red Always locate these electrodes in a non-innervated, electrically neutral area (electrically neutral areas are where the bone is close to the skin and the electrode will not contact muscle tissue). Ground should also be located between the stimulator and monitoring electrodes

NIM EMG Electrode Placement



wikimedia.org

NIM Set up

EMG Monitoring Electrodes:

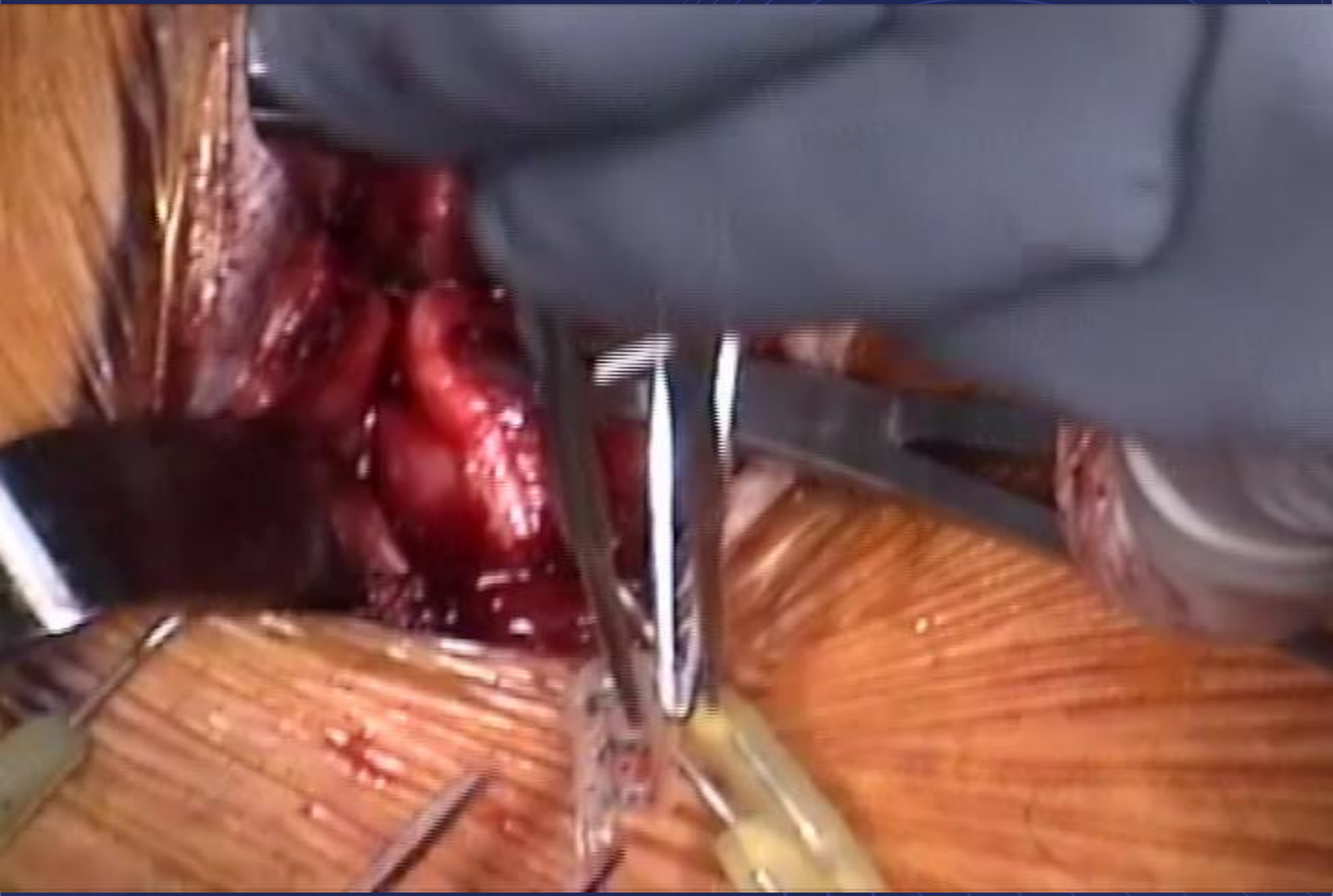
- **Genioglossus**: insert towards mid-inferior section of the tongue along inner molars, underneath the tongue using Prass Paired Electrodes (18 or 12.5 mm)

Goal: Include m-XII branches for optimal protrusor identification/recruitment

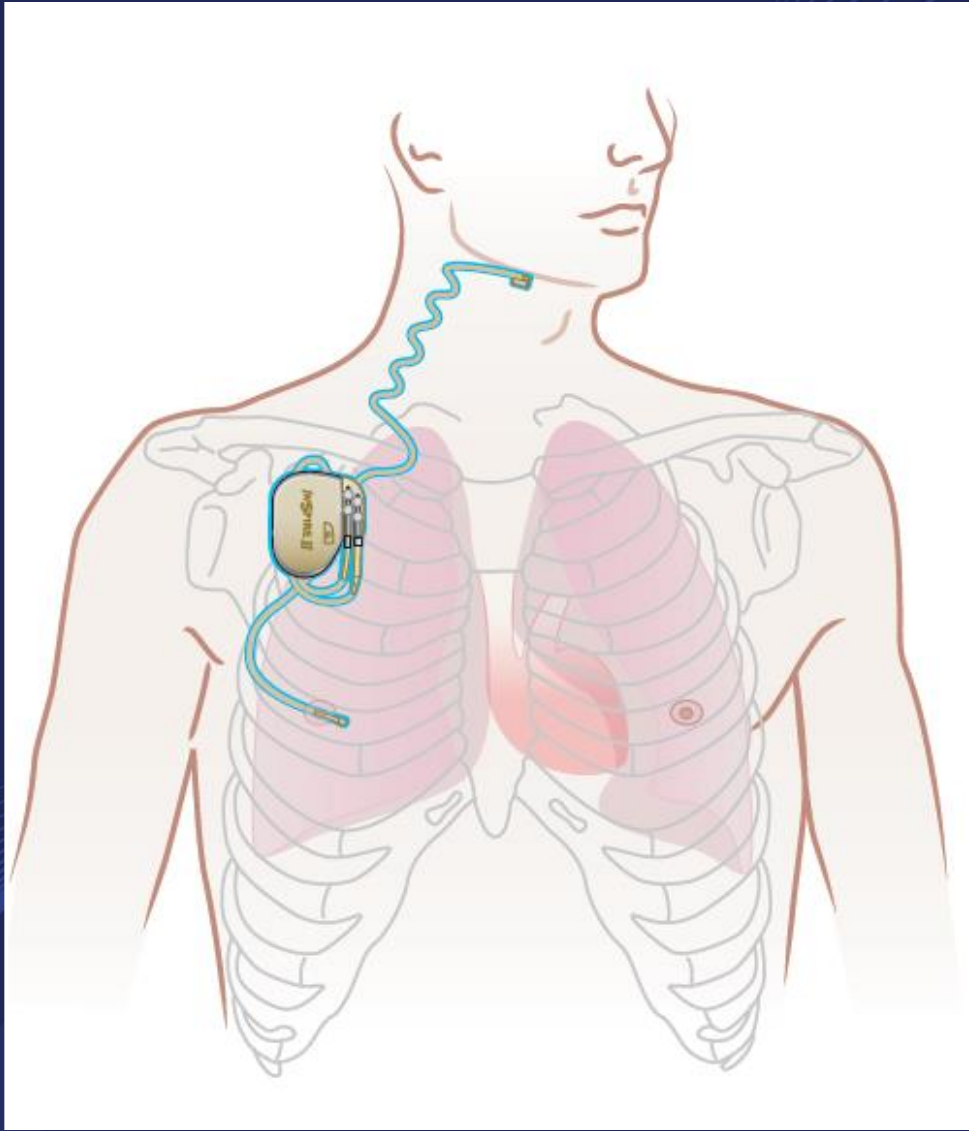
- **Stylo-/Hyoglossus**: insert along ventrolateral aspect, shallow parallel course just beneath the mucosa using Prass Paired Electrodes (12.5 or 18 mm)

Goal: Exclude l-XII branches for optimal retractor identification/exclusion

Stimulation: 0.3 – 0.8 mA
Identify final retractor branch, evaluate challenging branches for inclusion



Respiratory Sensing Lead



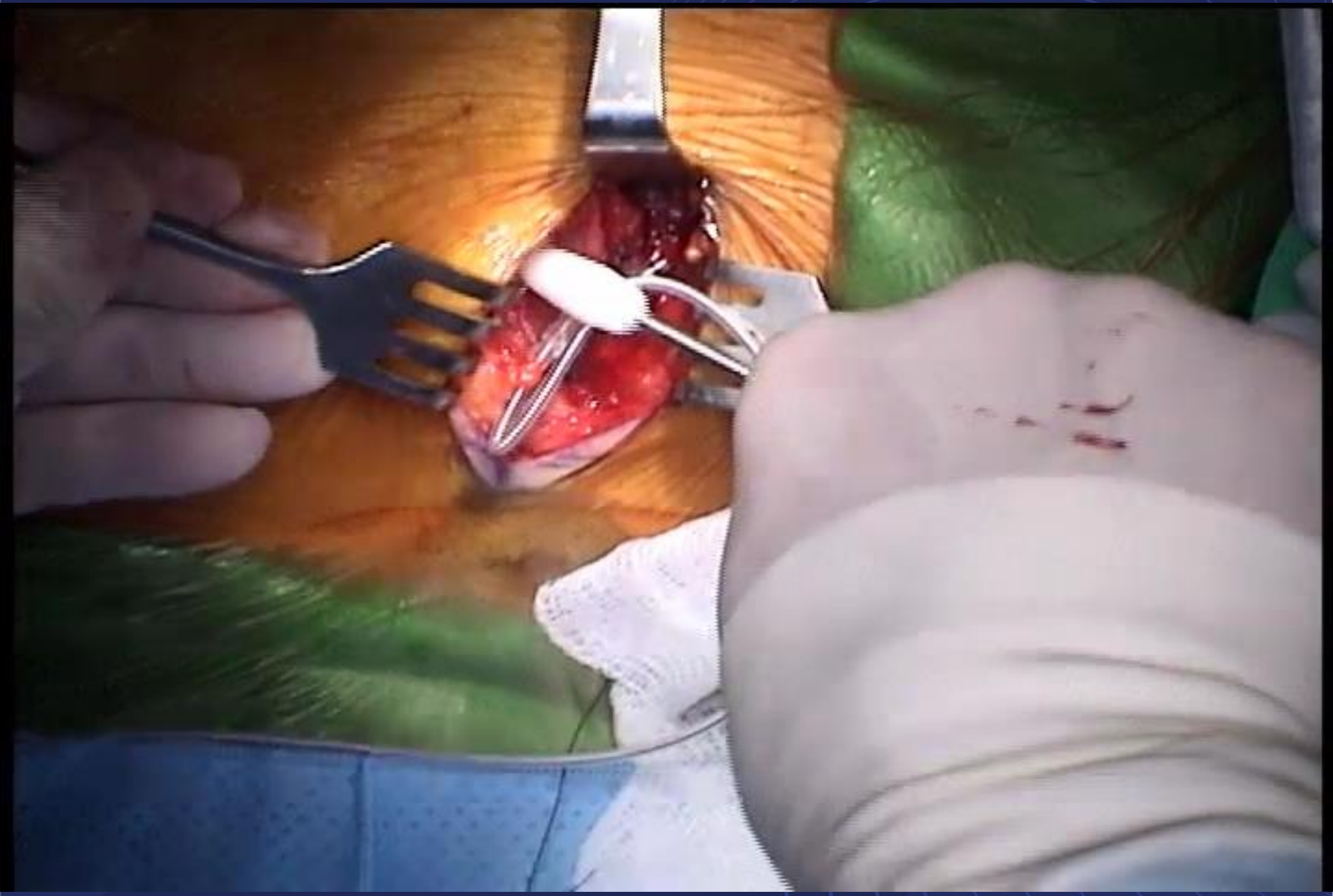
Sensing (Sense) Lead

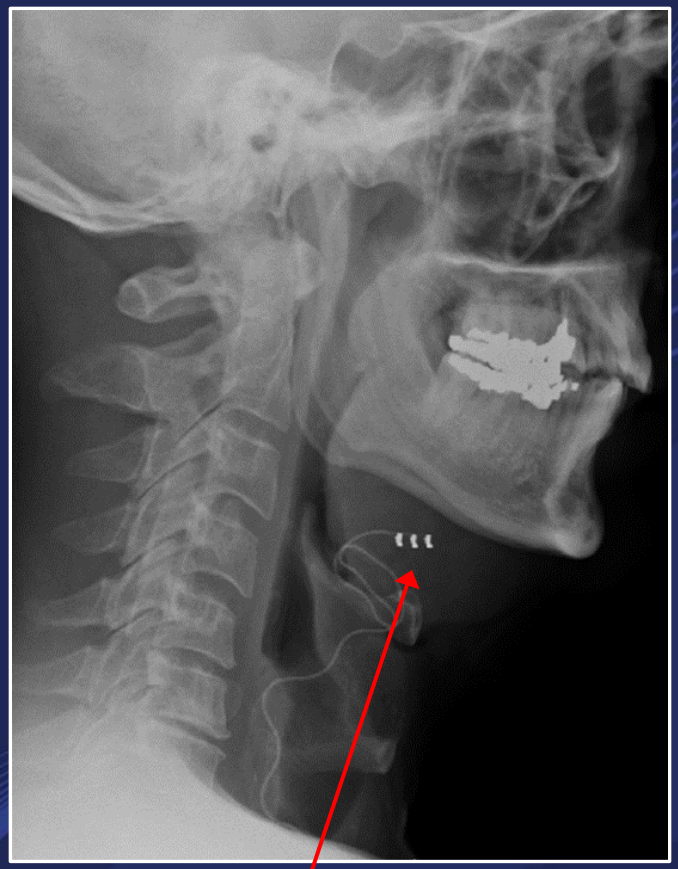
Location

- Inferior to 5th rib, and Superior to 6th rib
- 5 cm interfascial tunnel; deep to external, superficial to internal, intercostal muscle
- Anchor to fascia/muscle

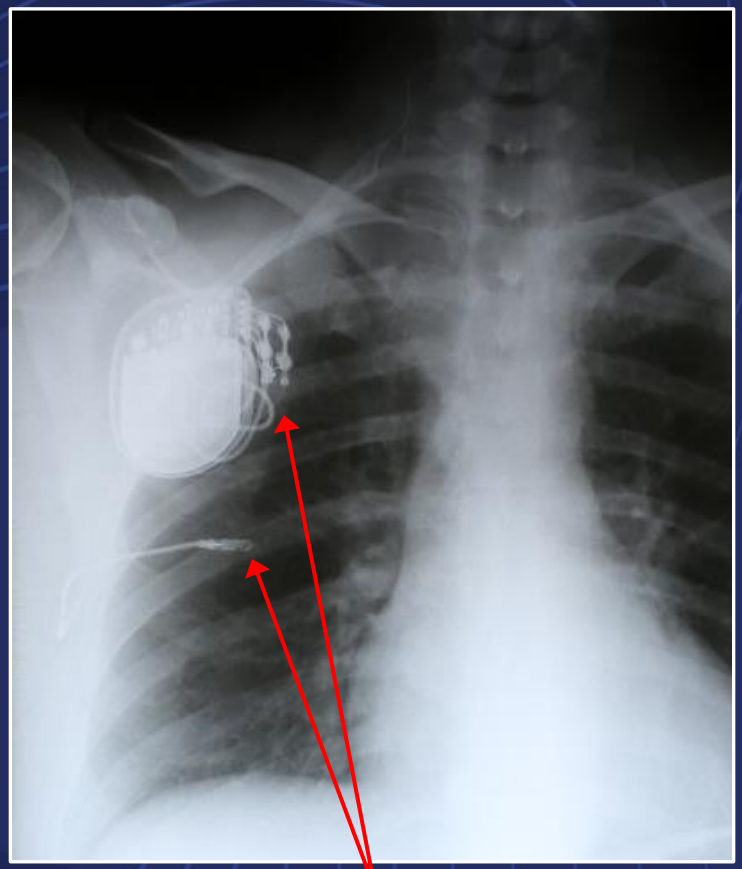
Functions

- Obtain breathing pressures via sensor membrane
- Convert pressure changes to electrical current waveform
- Deliver waveform to IPG for closed-loop therapy





Lateral view, showing stim cuff electrode
include vertebrae and chin



AP view, showing IPG/lead wrap and sensing lead
include IPG and sensor lead

Inspire Therapy Visits

Jefferson
HEALTH IS ALL WE DO

Assessment	Implant	Follow Up
Sleep profile	Typically outpatient	Therapy activation
Anatomy check		Therapy optimization
		Routine annual follow up

Experience To Date

- 14 implants
- 8 post implant titrattions
- First adult Down's syndrome patient implanted in country
- 1 of 10 centers in the post commercial trial

Results

	AHI Pre	AHI Post
• Patient 1:	27.2	1
• Patient 2:	23.0	7.7
• Patient 3:	18.4	5.1
• Patient 4:	25	5.7
• Patient 5:	44	5.1
• Patient 6:	26.3	0
• Patient 7:	86.3	7.7
• Patient 8:	50.1	15*

* = Down's patient with 8 central apneas

- I have but one misgiving. I believe that my characterization of the first generation of this device as a “Model T” was misleading. This really is a Lamborghini, and I am really happy to have one driving my breathing every night. It is making a big difference in my life. In fact, I just now realized as I’m writing this that I have had enough energy in the evening that I’m taking a yoga class that starts at 8 p.m. On January 29, 2015 that would have been impossible because I would have been wiped out before 5:30 p.m. What a gift.

Conclusions

- OSA is a prevalent disease
- Impacts the health of all of our patients
- CPAP remains first line therapy
  - Compliance remains an issue
- Multiple non-PAP therapy options exist and are evolving
  - EPAP
  - Oral appliances
  - Surgery
  - Upper airway stimulation represents one of the most promising therapies for a select group of patients