LOYOLA UNIVERSITY HEALTH SYSTEM

VA

# Hypoglossal Nerve Stimulators For Obstructive Sleep Apnea

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## Disclosure

- I have no actual or potential conflict of interest in relation to this program/presentation.



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## Learning Objectives

- Understand obstructive sleep apnea (OSA) and its prevalence
- Discuss previous treatment options for OSA
- Knowledge of location and mechanics of upper airway stimulation (UAS) devices
- Review UAS data, patient care and therapy options
- Anesthesia considerations



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## The Basics.....

- Obstructive sleep apnea (OSA) is characterized by repetitive upper airway collapse during sleep which leads to oxygen desaturation and hypercarbia.
- These intermittent desaturations lead to nighttime awakening; manifesting into chronic sleep deprivation and subsequent daytime somnolence.




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## The Numbers....

- OSA is extremely common. Prevalence = diabetes or asthma worldwide.
- 25 million in the USA. Over 1 billion people worldwide.
- Only 25% are currently being treated.
- Gold standard is Continuous Positive Airway Pressure (CPAP)



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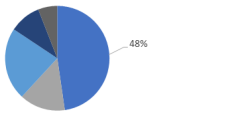
The Numbers....

Global Sleep Disorder
Market Share, by Disorder Type, 2022 (%)




- Sleep Apnea
- Restless Legs Syndrome (RLS)
- Insomnia
- Narcolepsy
- Others



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## Why Do We Need An Alternative To CPAP?

•≥10 million patients own CPAP machines in North America.

•Studies have shown that **almost half do not comply with CPAP** (Weaver et al. 2008)

1. Mask discomfort
2. Claustrophobia
3. Pressure intolerance
4. Dry or irritated nasal membranes
5. Eye irritation from air leakage around the mask (Pavwoski & Shelgikar, 2017).



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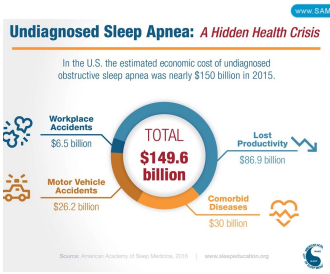
## Untreated OSA

- If left untreated, OSA can result in
  - Hypertension
  - Diabetes mellitus
  - Coronary artery disease
  - Stroke
  - Congestive heart failure
  - Atrial fibrillation
  - Death
- Increased cancer incidence, increased mortality, and increased neurodegeneration (Lim & Pack, 2017)



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## Alternatives To CPAP For Treating Sleep Apnea

1. Weight Loss and Exercise
2. Sleep Position
3. Avoiding Alcohol
4. Mandibular Advancement Devices
5. Tongue Retaining Devices
6. Myofunctional Therapy
7. Surgery (variable success 35-75%)
   a) Maxillomandibular advancement
   b) Uvulopalatopharyngoplasty (UPPP)
   c) Adenotonsillectomy



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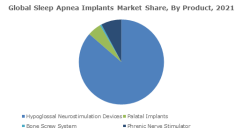
## Introduction Of The Hypoglossal Nerve Stimulator (HGNS)

- Initial patents filed in the 1990s with Inspire founded in 2007 and FDA approval in 2014 for the treatment of OSA.

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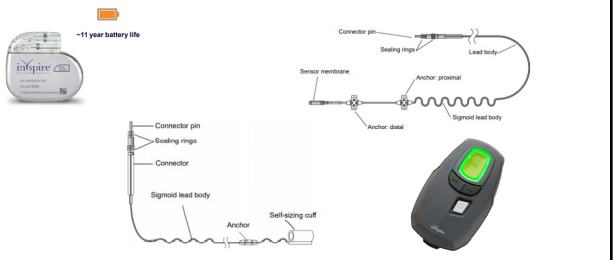
## Components Of The Inspire System



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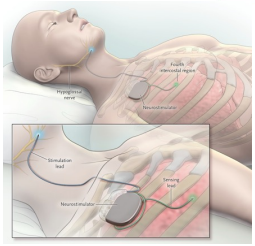
## How It Works

- The stimulation electrode is placed on the hypoglossal nerve to recruit tongue-protrusion function
- The sensing lead is placed between the internal and external intercostal muscles to detect ventilatory effort
- The neurostimulator is implanted in the right ipsilateral mid-infraclavicular region.





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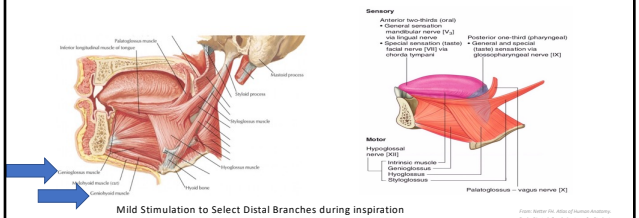
## The Hypoglossal Nerve Innervation

- All the intrinsic muscles and all but one of the extrinsic muscles (genioglossus, styloglossus, and hyoglossus) of the tongue.




Mild Stimulation to Select Distal Branches during inspiration

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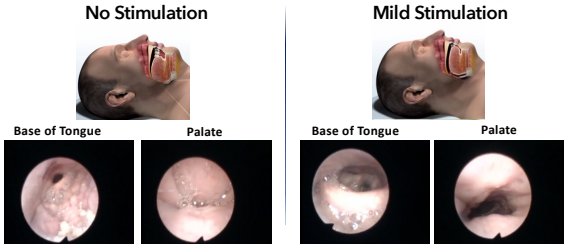
## Hypoglossal Nerve Stimulation Effect An Increase In Cross Sectional Size Of Airway

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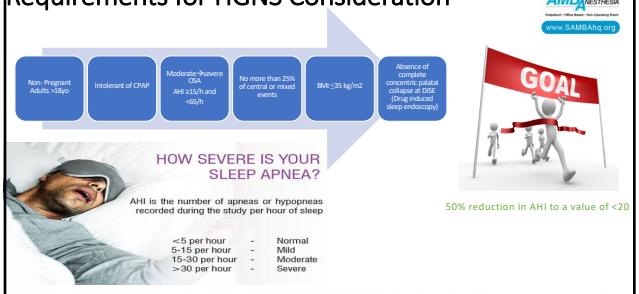
## Requirements for HGNS Consideration




50% reduction in AHI to a value of <20

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## Pre-op Anatomical Assessment Drug Induced Sleep Endoscopy (DISE)

- Used to determine eligibility for device implantation.
  - patients are excluded if DISE reveals complete concentric collapse
  - tongue's protrusion will not resolve this pattern of airway obstruction. (Gupta et al., 2018).
- Propofol (midazolam and dexmedetomidine) are the drugs of choice for DISE.
- The degree of sedation is important (BIS score in the mid 60's); a light sedation that most closely mimics sleep is ideal for accurate assessment of the upper airway.
- Collaborate with surgery PRIOR to the procedure.

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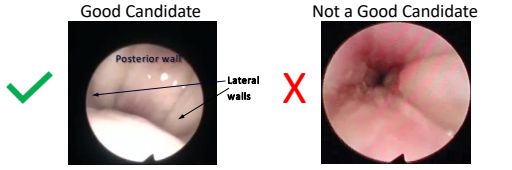
## Pre-op Anatomical Assessment Drug Induced Sleep Endoscopy (DISE)




AP collapse at palate

Complete concentric collapse at palate

Assess lateral wall collapse at genu of the soft palate

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## Inspire STAR Trial (The Stimulation Therapy for Apnea Reduction Trial) Multicenter trial

Table 1. Characteristics of the Study Population at Baseline.*

| Characteristic | Participants (N=126) |
|---|---|
| Age — yr | 54.5±10.2 |
| Male sex — no. (%) | 105 (83) |
| White race — no. (%)† | 122 (97) |
| Body-mass index‡ | 28.4±2.6 |
| Neck size — cm | 41.2±3.2 |
| Blood pressure — mm Hg | |
| Systolic | 128.7±16.1 |
| Diastolic | 81.5±9.7 |
| Hypertension — no. (%) | 48 (38) |
| Diabetes — no. (%) | 11 (9) |
| Asthma — no. (%) | 6 (5) |
| Congestive heart failure — no. (%) | 2 (2) |
| Uvulopalatopharyngoplasty — no. (%) | 22 (17) |

68%

70%

Table 2. Primary and Secondary Outcome Measures.*

| Outcome | Baseline | 12 Months | Change | P Value |
|---|---|---|---|---|
| Primary outcomes | | | | |
| AHI score† | 32.0±11.8 | 15.3±16.1 | −16.4±16.7 | <0.001 |
| Median | 29.3 | 9.0 | −17.5 | |
| Interquartile range | 23.7 to 38.6 | 4.2 to 22.5 | −26.4 to −9.3 | |
| ODI score‡ | 28.9±12.0 | 13.9±15.7 | −14.6±15.8 | <0.001 |
| Median | 25.4 | 7.4 | −15.7 | |
| Interquartile range | 19.5 to 36.6 | 3.5 to 20.5 | −24.0 to −8.6 | |
| Secondary outcomes | | | | |
| FOSQ score§ | 14.3±3.2 | 17.3±2.9 | 2.9±3.1 | <0.001 |
| Median | 14.6 | 18.2 | 2.4 | |
| Interquartile range | 12.1 to 17.1 | 16.2 to 19.5 | 0.7 to 4.7 | |
| Epworth Sleepiness Scale score¶ | 11.6±5.0 | 7.0±4.2 | −4.7±5.0 | <0.001 |
| Median | 11.0 | 6.0 | −4.0 | |
| Interquartile range | 8.0 to 15.0 | 4.0 to 10.0 | −8.0 to −1.0 | |
| Percentage of sleep time with oxygen saturation <90% | 8.7±10.2 | 5.9±12.4 | −2.5±11.1 | 0.01 |
| Median | 5.4 | 0.9 | −2.2 | |
| Interquartile range | 2.1 to 10.9 | 0.2 to 5.2 | −6.6 to −0.3 | |

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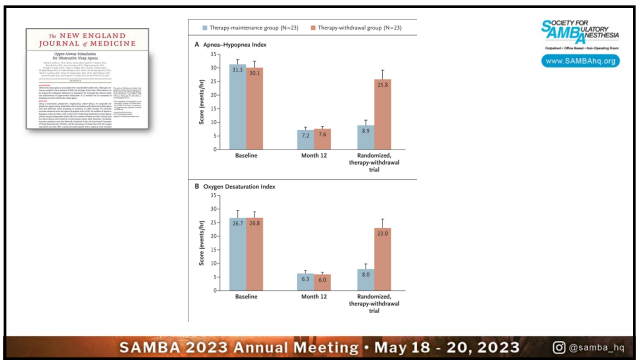


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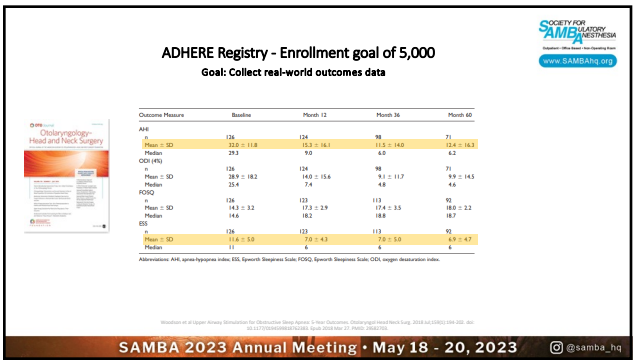


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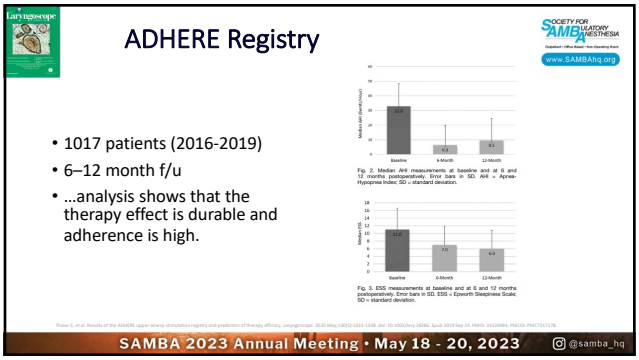


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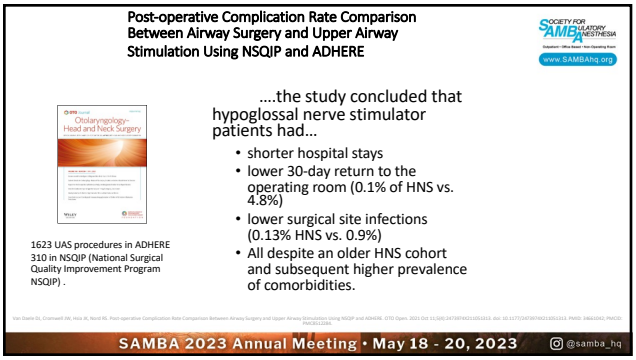


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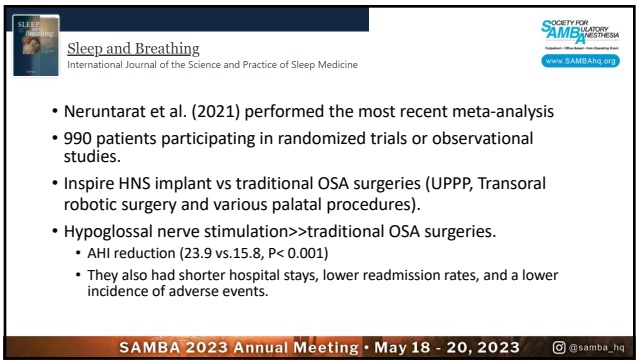


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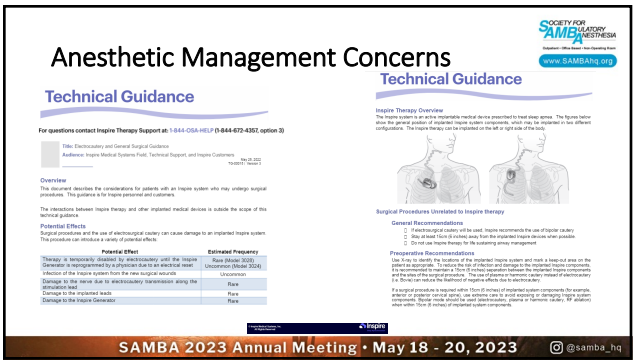


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## Anesthetic Management concerns

- Similar to a patient with a cardiac pacemaker
- Preoperative radiologic films



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## Anesthetic Management concerns

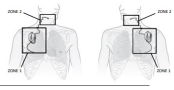
**Table 1.** Generator Scan Eligibility

| Model* | X-ray ID** | Serial Number Prefix | Eligibility Details |
|---|---|---|---|
| 3028 | IMS1 | AIR0000000X | MR Conditional at 1.5T |
| 3024 | NCR | NCR0000000X | **Not eligible for MRI** |

* All Inspire lead model numbers are MR conditional and are eligible for the scan conditions defined in this manual
** Reference "Appendix B: X-ray ID Tag" on page 18 for location and examples of the X-ray ID tag

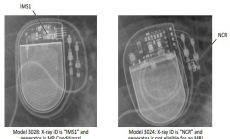
The following table lists the approved locations for implanted components. Sensor location does not impact MR eligibility. Generator and stimulation lead can be implanted on either the right or left side of the body.

**Table 2.** Approved Locations for Implanted Components




**Appendix B: X-ray ID Tag**

The X-ray images below show Generator Models 3028 and 3024, with specific reference to the location of the X-ray identification tag.




Model 3028: X-ray ID is "IMS1" and generator is MR Conditional

Model 3024: X-ray ID is "NCR" and generator is not eligible for an MRI

**Figure 6.** X-ray ID Tag Locations



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## Anesthetic Management concerns

### MRI Conditional Guidelines

**Overview**
Patients implanted with the Inspire 3028 generator may undergo an MRI if specific guidelines are followed. These guidelines allow for imaging of the head, neck, arms, and legs with the use of a transmit-receive RF coil. The ability to achieve a medically relevant scan of a particular structure will vary based on imaging goals, patient anatomy, patient comfort, scan sequence, and available MRI equipment.

**Potential Risks**
The complete Inspire MRI guidelines including risks associated with MRI and RF power limits can be found at manuals.inspiresleep.com.

**Scan Regions**
With the use of a transmit-receive RF coil the head, neck, arms, and legs of a patient implanted with the Inspire 3028 generator can be scanned with MRI. MRI of the patient's neck can be performed with the use of a transmit-receive head coil lowered onto the patient's shoulders.

**Required MRI Equipment**
A transmit-receive RF coil is required for all scans. A MR system that displays B1+RMS is required for head and neck scans.

**Implant Configurations**
Patients with Inspire leads not connected to a generator cannot be scanned with MRI. Refer to the complete Inspire MRI guidelines for additional information: manuals.inspiresleep.com.

**MRI INCLUSION:**
- Brain
- Lower Extremities
- Neck
- Upper Extremities

**MRI EXCLUSION:**
- Abdomen
- Back
- Chest
- Hip
- Pelvis
- Shoulder

Clinically effective imaging of included anatomy is dependent on the specific MRI hardware available, patient anatomy, and imaging requirements and will vary

**MRI conditional labeling provides patients access to MRI scans at 1.5T***



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## Anesthetic Management concerns

- To avoid the risk of infection and damage to the implanted components, a 15cm (6 inches) separation between the components and the surgical procedure site is recommended by the manufacturer.
- If less call manufacturer for device interrogation
- Bipolar cautery preferred. If mono used→placement of pad important
- Postoperatively, electrolyte disturbances can affect lead sensing, and as such, checking a basic metabolic panel after surgery may be indicated. (Preston et al. Am J Cardiology)
- Check the device function post op prior to discharge!!!



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## Anesthetic Management concerns

PERIOPERATIVE MEDICINE

ANESTHESIOLOGY

**Evaluation of Diaphragmatic Function after Interscalene Block with Liposomal Bupivacaine: A Randomized Controlled Trial**

Aaron A. Berg, D.O., James M. Flaherty, M.D., Jason M. Habeck, M.D., Alicia K. Harrison, M.D., Jonathon P. Braman, M.D., Alexander M. Kaizer, Ph.D., Jacob L. Hutchins, M.D.

*Anesthesiology 2022; 136:531–41*

**Hemi-diaphragmatic Transient Phrenic Nerve Palsy**

Paralysis resulting from local anesthetic traveling over the anterior scalene muscle to the phrenic nerve.

Decrease in diaphragm function of 0 to 25% normal
Decrease of 25 to 75% is partial paralysis
Decrease of 75% or greater defines complete paralysis.



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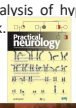
## Anesthetic Management concerns


- Leuzinger K et al. (2021)
  - Hypoglossal nerve palsies, both isolated and in conjunction with other nerves, have been linked to numerous anesthesia-related iatrogenic etiologies including laryngeal manipulation during intubation or with ENT suspension cases, prolonged placement of the endotracheal tube, use of laryngeal mask airways, bronchoscopy, and shoulder surgery with utilization of chin straps.


Bharati S et al. (2014) Ipsilateral paralysis of hypoglossal nerve following interscalene brachial plexus block.




Fritz et al. (2014)
…compression of the lateral tongue base during prolonged surgery or intubation.



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