

# Updates on Upper Airway Stimulation

September 9, 2020

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Principal, Post Implant Care, Inspire Medical Systems

Special Guest, An Inspire Patient Implanted in 2016

David Edelstein

# Conflict of Interest / Disclosures

- **Inspire Medical Systems employee since 2012**

# Upper Airway Stimulation Companies

- **3 Companies Developing Hypoglossal Nerve Stimulation or Upper Airway Stimulation**

- Inspire Medical Systems

- FDA approved April 30, 2014, currently the only FDA approved UAS device in the United States

- ImThera – still undergoing clinical trials, now owned by LivaNova

- Nyxoa – March 2019, gained CE mark in Europe. Recently received Investigational Device Exemption from the FDA for the purpose of conducting its clinical trial in the United States.

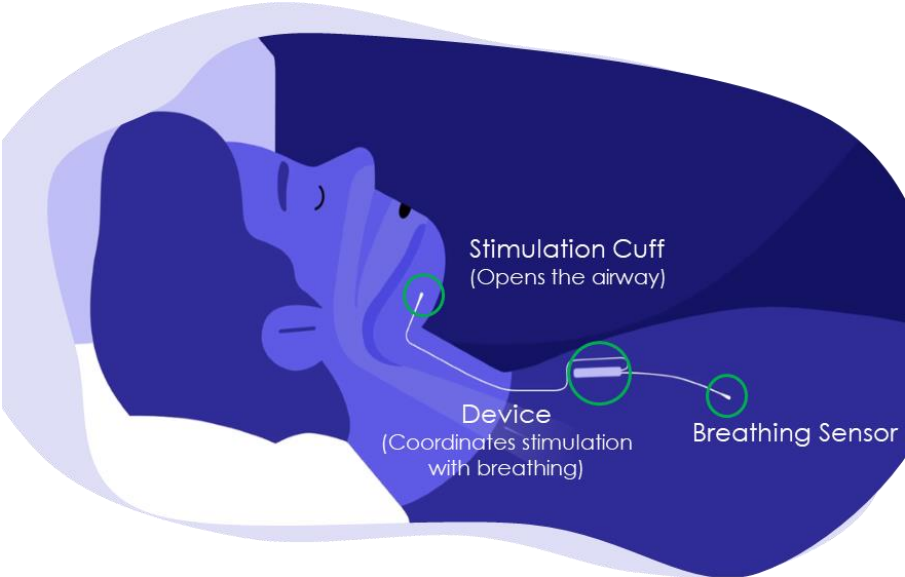
# Agenda

- **Short overview**
- **Scientific Background & Clinical Evidence – latest and greatest!**
- **Patient Care Pathway Updates**
- **Technology & Reimbursement Updates**
- **A Patient's Perspective – Discussion with an Inspire Patient**

# Inspire Therapy

A Treatment for Obstructive Sleep Apnea Patients Who Are Unable to Use CPAP

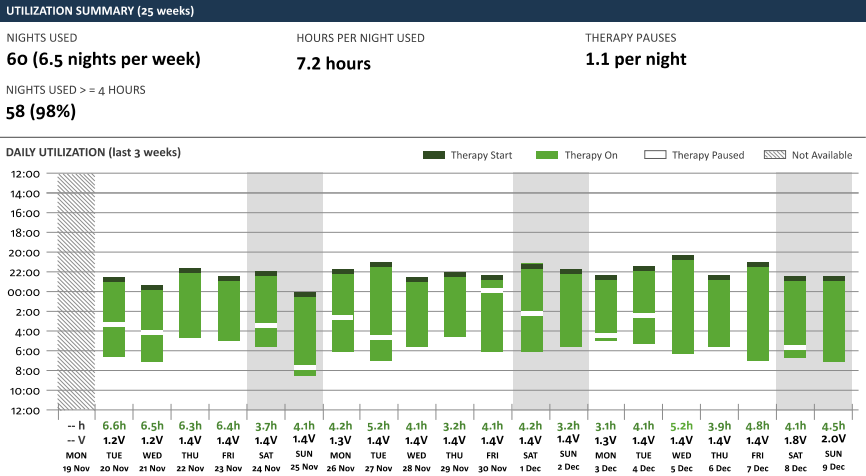
## Safe Outpatient Procedure



## Sleep Remote



## Nightly Adherence Monitoring (Quality Measures)

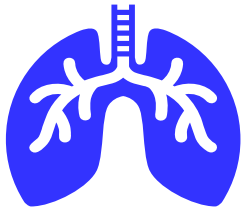


# Inspire Eligibility Requirements: Expanding to More Patients



Adults 18 years of age and older

**+** Updated from 22 years of age



Diagnosed with Moderate to Severe OSA  
(AHI 15-65)

**+** Updated from 20-50



CPAP failure or inability to tolerate CPAP



Appropriate airway anatomy &  
< 25% Central + Mixed Sleep Apnea

*Inspire is not for everyone. Talk to your patients about risks, benefits and expectations associated with Inspire. Risks associated with the surgical implant procedure may include infection and temporary tongue weakness. Some patients may require post implant adjustments to the system's settings in order to improve effectiveness and ease any initial discomfort they may experience. Important safety information and product manuals can be found at [inspiresleep.com/safety-information/](https://inspiresleep.com/safety-information/), or call 1-844-OSA-HELP.*

# Hypoglossal Nerve Stimulation – targets mechanism of airway collapse

No Stimulation

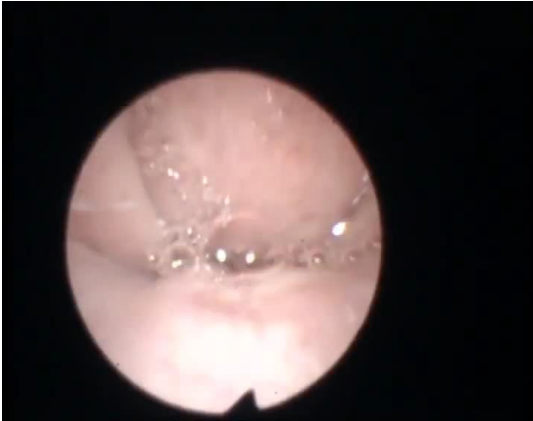


Mild Stimulation



Base of Tongue

Palate

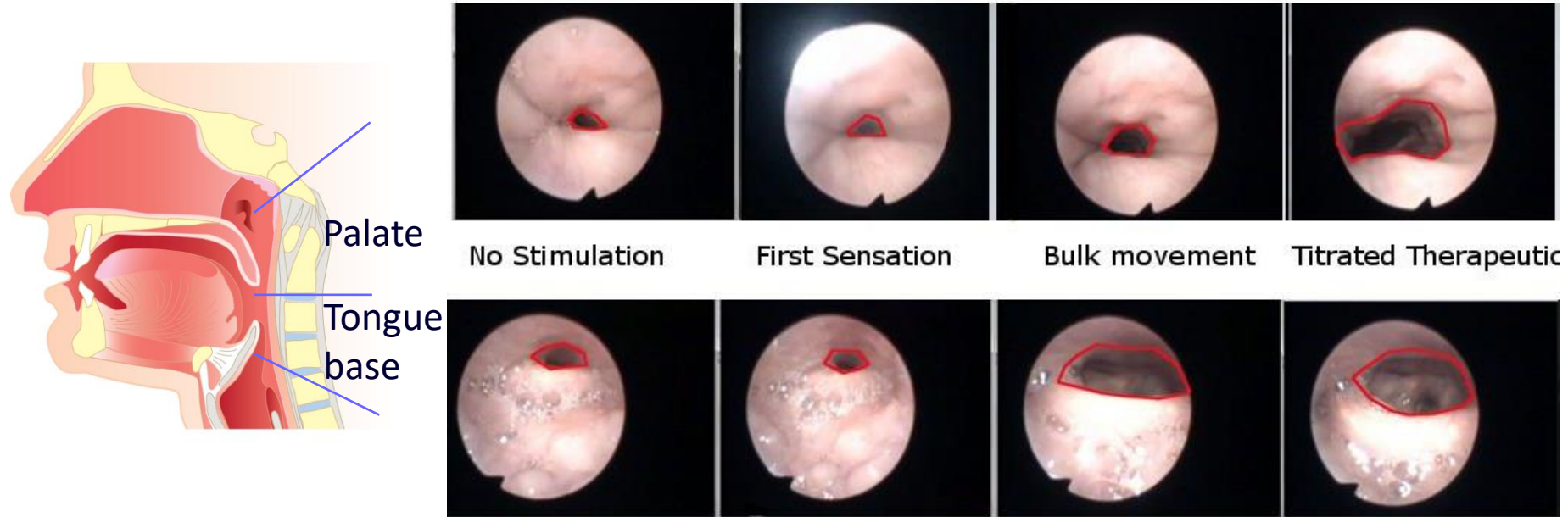


Base of Tongue

Palate

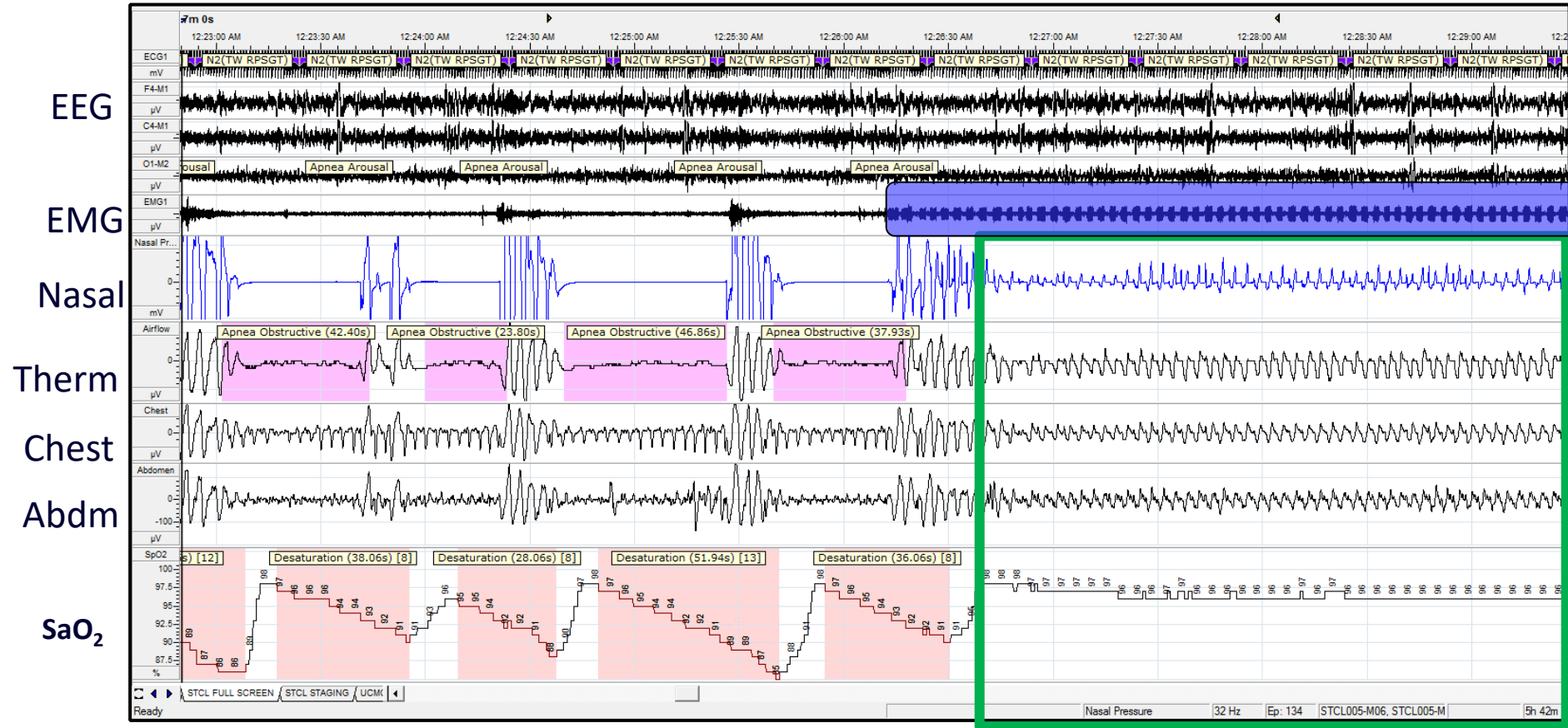


# Stimulation is titratable, with multi-level effect



- Effects are observed at palate and tongue-base
- Airway size increases with stimulation amplitude

# Inspire Therapy Effect – Sleep Study



No Stimulation

Stimulation Active

# Rigorous Clinical Evidence

## Over 5 years of data, 100+ publications

### PHASE 1

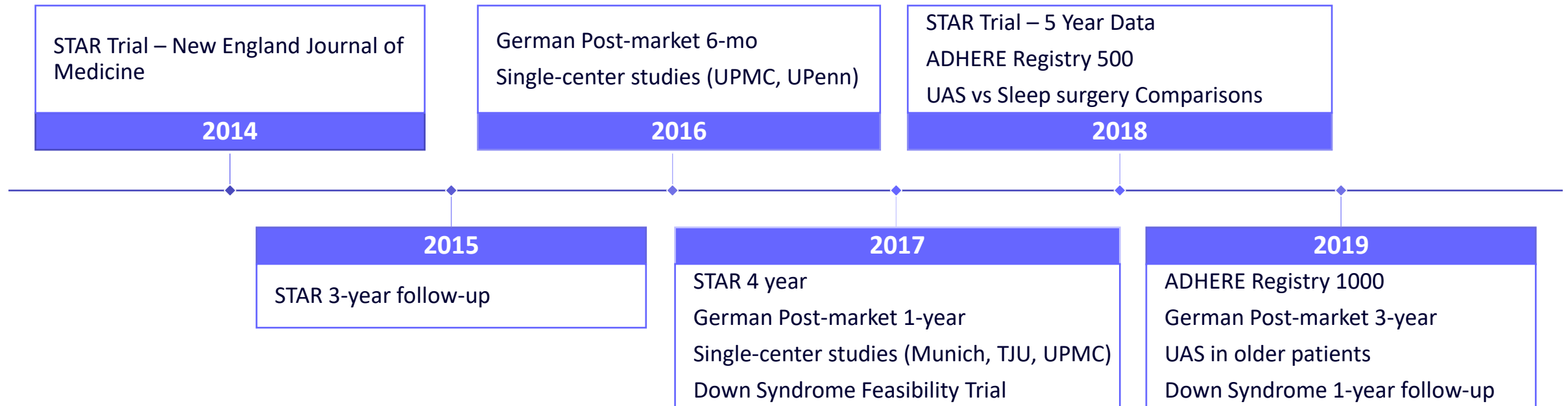
Foundational data for therapy approval

### PHASE 2

Long-term outcomes, post-market studies

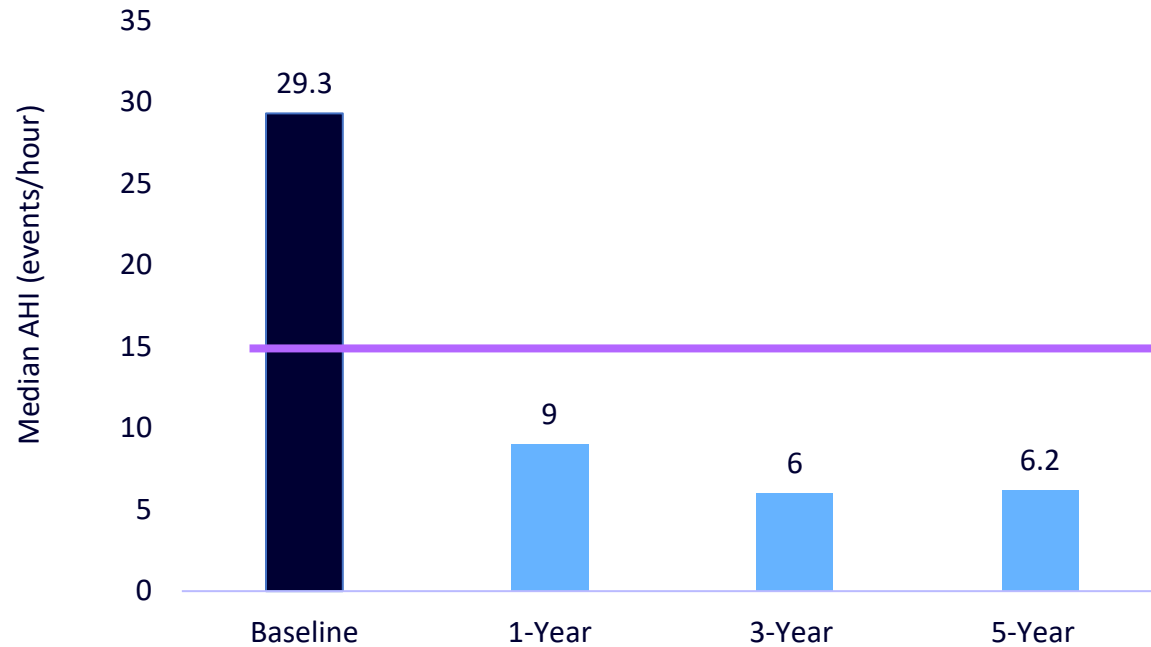
### PHASE 3

Real world data, indications, comparisons

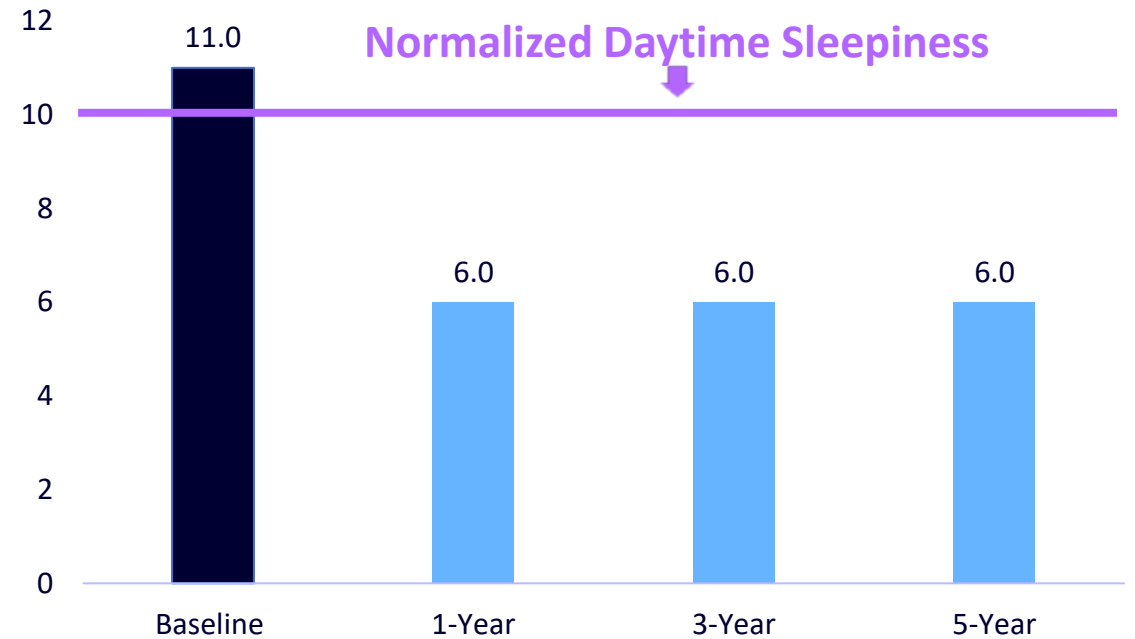


# STAR Trial Overview: 5-Year Follow-Up Complete

## Apnea Hypopnea Index (AHI)

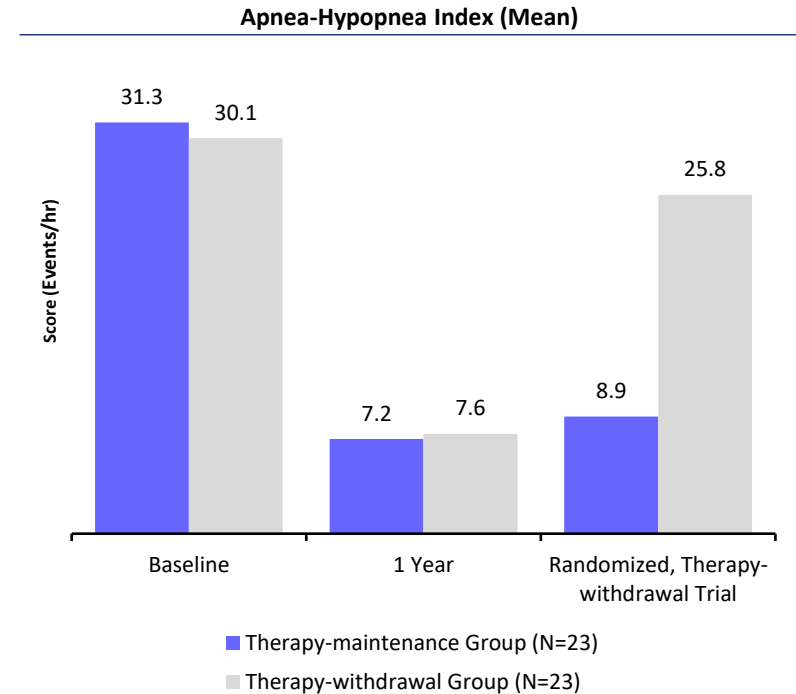
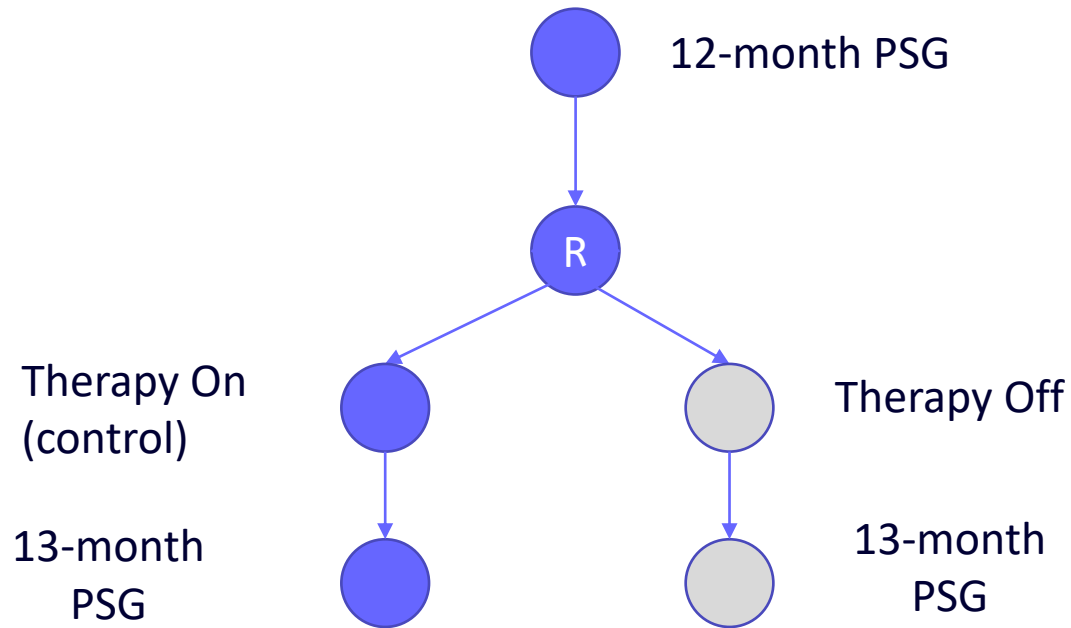


## Epworth Sleepiness Scale (ESS)



Multi-Center Prospective, 126 Patients, Randomized Control Tx, Withdrawal ARM

# Randomized Design Confirms Therapy Effect



## Conclusions:

- Efficacy due to stimulation – therapy withdrawal causes AHI reversion to baseline
- BMI was similar between groups baseline and follow-up

# ADHERE Registry

- Goal: Collect **real-world outcomes** data
- International multi-center, standard-of-care registry
- Eligibility – prospective patients receiving UAS for OSA
  - CPAP intolerant or non-compliant
  - AHI between 15-65, and fewer than 25% central + mixed apneas
  - Absence of velum complete concentric collapse on DISE

**2,000+ enrollments** as of September 2020

Enrollment Goal: 5,000 patients

44 SITES IN THE US & EUROPE



# ADHERE Registry

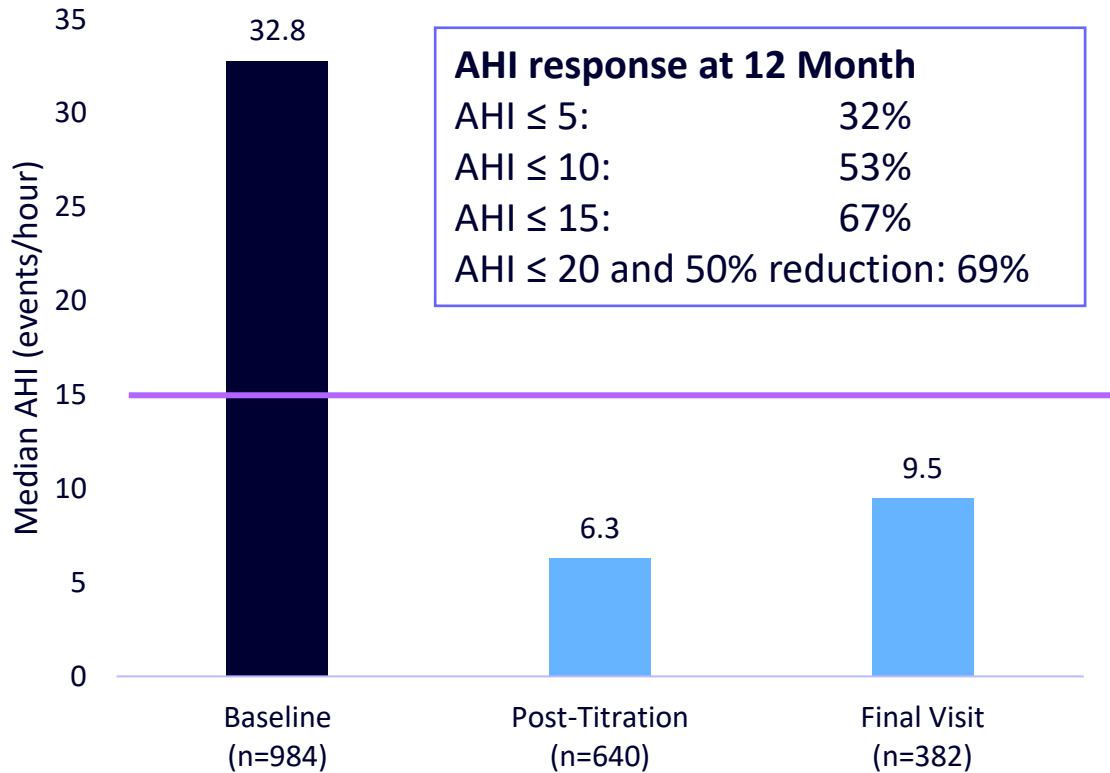
Demographics: middle aged, male, severe OSA (n=1,017)

Patient Characteristics	Value
Age	60 ± 11 (22-86)
Sex	74% Male
Ethnicity	96% Caucasian
Body Mass Index	29.3 ± 3.9
Baseline AHI	36 ± 15

Baseline Co-morbidities	Value
Hypertension	47%
Depression	22%
Diabetes	13%
Atrial Fibrillation	6%
Heart Attack	4%
Stroke	3%

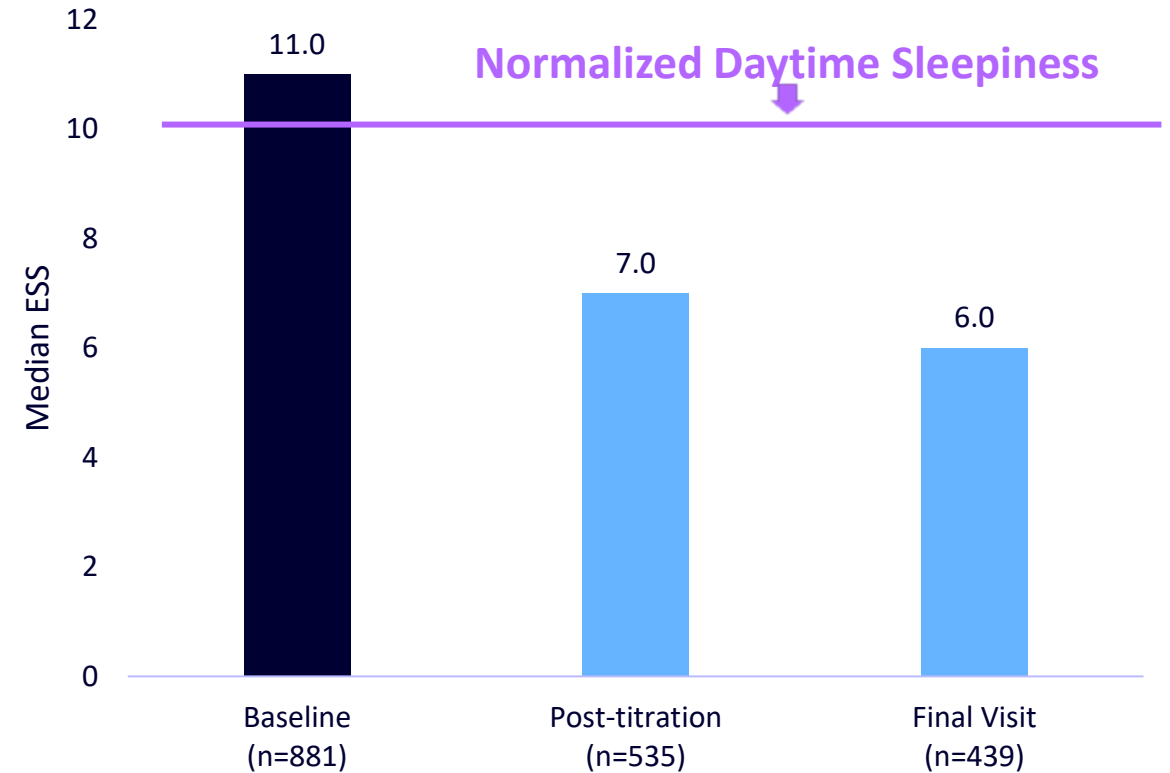
# ADHERE Registry: Consistent effectiveness

## Apnea Hypopnea Index (AHI)



Mean AHI reduced from baseline of  $35.8 \pm 15.4$  to  $14.2 \pm 15.0$  at 12 months ( $p < 0.001$ )

## Epworth Sleepiness Scale (ESS)



Mean ESS reduced from baseline of  $11.4 \pm 5.6$  to  $7.2 \pm 4.8$  at 12 months  
Reference: ESS < 10 considered free of symptoms for excessive daytime sleepiness

# ADHERE Registry: Strong safety profile

Type	Post-Titration		Final Visit	
	# of Events	% of Patients	# of Events	% of Patients
Tongue Weakness	3	<1%	0	-
Swallowing or speech related	4	1%	1	<1%
Infection	2	<1%	0	-
Revision interventions (including explant)	1	<1%	2	<1%
<b>Total</b>	<b>10</b>	<b>3%</b>	<b>3</b>	<b>&lt;1%</b>

Type	Post-Titration		Final Visit	
	# of Events	% of Patients	# of Events	% of Patients
Discomfort (incision/scar)	14	4%	8	2%
Discomfort (device)	10	3%	5	1%
Stimulation related discomfort	41	12%	28	8%
Other Discomfort	12	3%	8	2%
Post-Op – Other	14	4%	6	2%
Tongue abrasion	12	3%	14	4%
Insomnia/Arousal	10	3%	17	5%
Activation - Other	37	3%	23	7%
<b>Total</b>	<b>151</b>	<b>43%</b>	<b>110</b>	<b>31%</b>

# Favorable Physician & Patient Satisfaction @ 12-months

92% of physicians reported patient improvement



Q: How much the patient's OSA has improved or worsened relative to Baseline/prior to Inspire Therapy?

More than 9 out of 10 patients are satisfied

95%

of patients said Inspire was better than CPAP (n=378)

94%

of patients said they would choose Inspire again (n=390)

96%

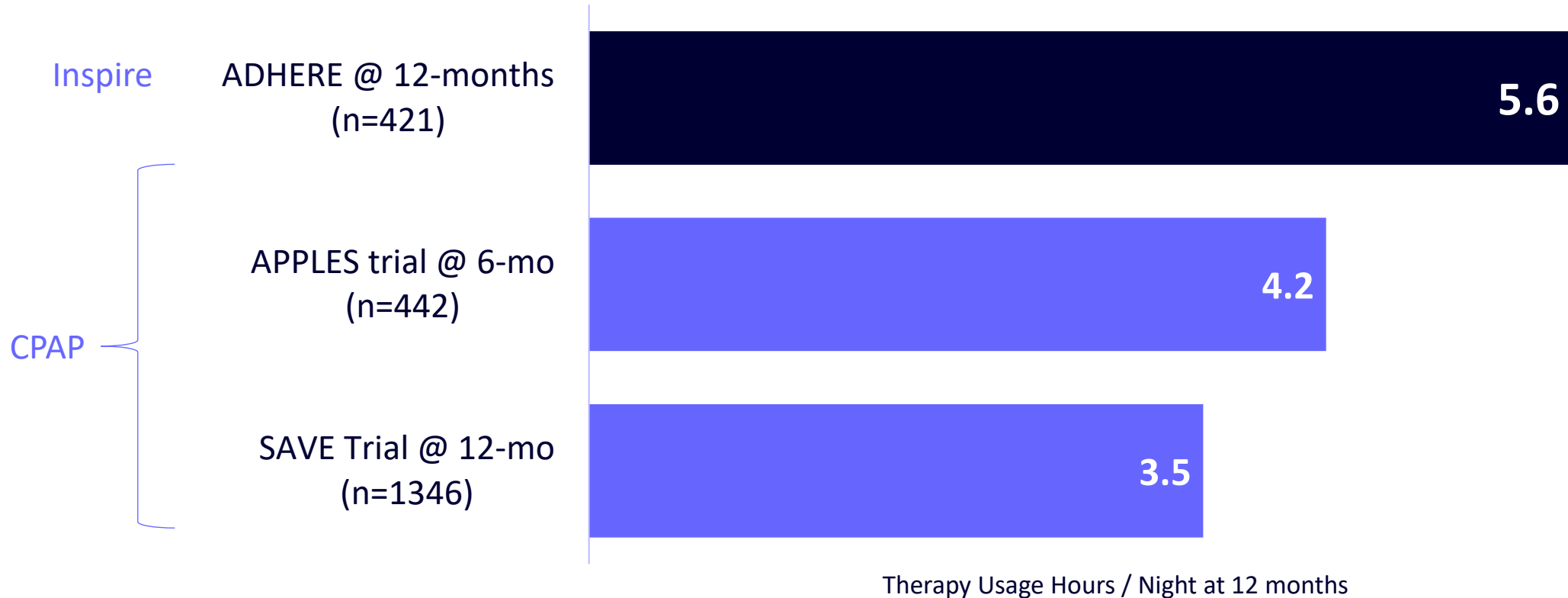
of patients said they would recommend Inspire to a friend or family member (n=390)

93%

of patients said they were satisfied with Inspire (n=391)

# High Patient Adherence

Usage of 5.6 hours/night exceeds most CPAP clinical trials



1. ADHERE-1000: Thaler, Laryngoscope 2019
2. APPLES: Kushida, Sleep 2012
3. SAVE: McEvoy, NEJM 2016
4. Medicare PAP "guideline" is 4 hours / night, 5 nights per week, within a 30 consecutive day period

# Clinical Evidence Summary



Consistent evidence of therapy benefit

Reduce OSA severity  
Improved quality of life  
High patient satisfaction



Multiple Studies and over 100 peer-reviewed publications with consistent results



Long-term sustained outcomes over 5 years



Strong therapy adherence



Superior outcomes compared to airway surgery



Patient  
Screening

Inspire Airway  
Exam

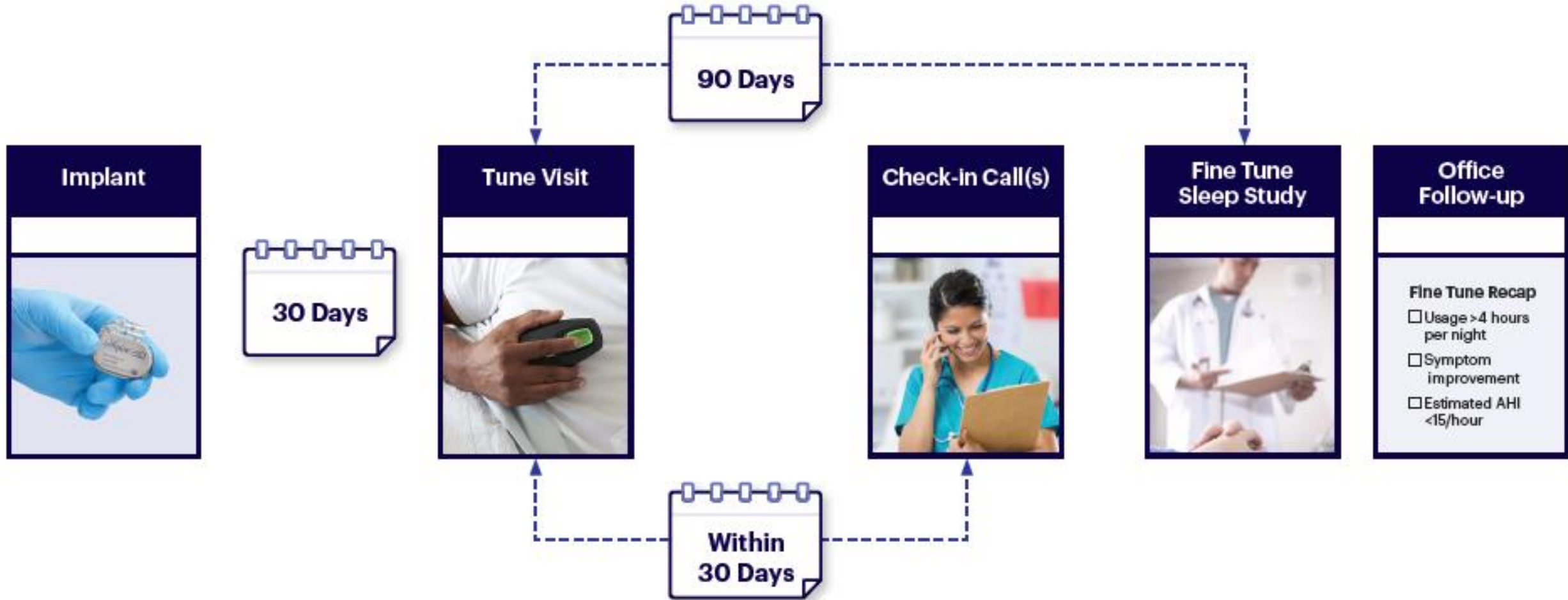
Inspire  
Procedure

Incision Check

Activation

# Patient Journey – Pre-Implant

# A Proven Patient Care Pathway



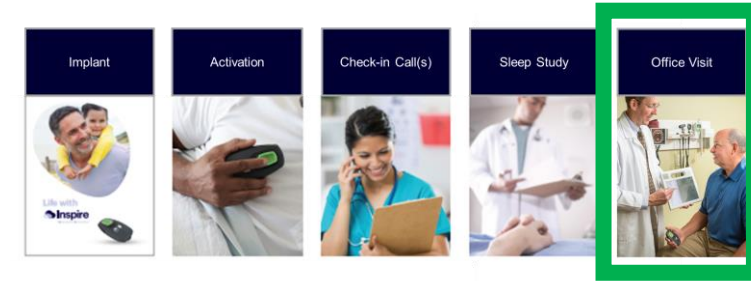
# Green Care Pathway



**Green Patient**  
Good Adherence  
and Good AHI Re-  
duction

70%

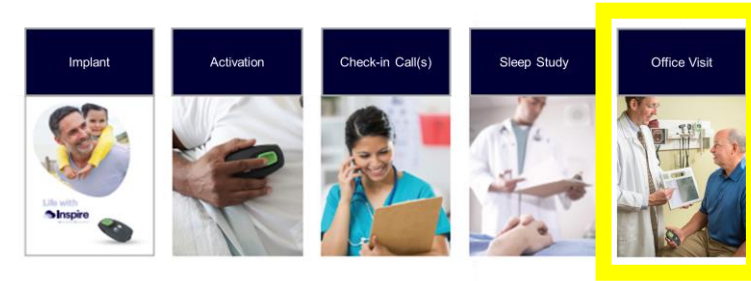
**Fine Tune Recap**  
CHECK ALL BOXES THAT APPLY:  
 1. USAGE: > 4 HOURS PER NIGHT  
 2. SYMPTOM IMPROVEMENT  
 3. ESTIMATED AHI LESS THAN 15/HOUR



## Goals

- ✓ Review sleep study results and finalize programming
- ✓ Regular follow-up every 6 months
- ✓ HST at 12 months for long term monitoring

# Yellow Care Pathway



**Yellow Patient**  
Sub-Optimal AHI  
and/or Sub-Optimal  
Adherence



30%

## Fine Tune Recap

CHECK ALL BOXES THAT APPLY:

- 1. USAGE: > 4 HOURS PER NIGHT
- 2. SYMPTOM IMPROVEMENT
- 3. ESTIMATED AHI LESS THAN 15/HOUR

## Goals

- ✓ Review sleep study results
- ✓ Make adjustments for adherence
- ✓ Make adjustments for AHI



# Technology Updates

# Inspire Digital Health Solutions

Inspire Sleep App  
for Patients  
**Now Available!**



Inspire Cloud  
for Clinicians

Integrated platform designed to improve:

Patient  
**EXPERIENCE**

Practice  
**EFFICIENCY**

Patient  
**OUTCOMES**

# The Inspire Sleep App

The hub for helping **PATIENTS** have the best experience with Inspire

## PRE-IMPLANT CONSIDERATION & EDUCATION

- Sleep Apnea Innovation Series
- 60-90 sec videos answering common questions



## POST IMPLANT SUCCESS

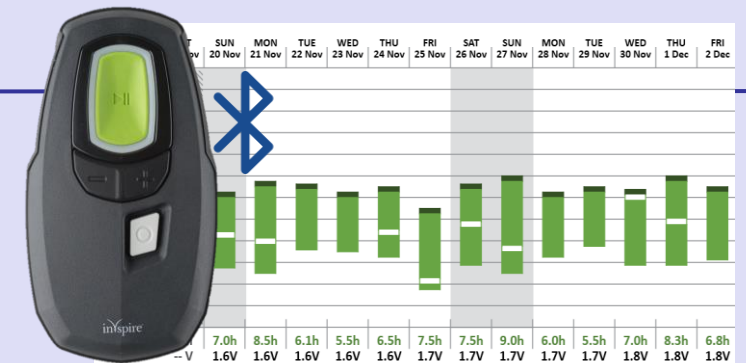
Instructional videos on how to use Inspire and areas to check in with the patient



## Future Capabilities

### LONG TERM FOLLOW-UP

- Automatically send adherence data
- Virtual patient check-ins



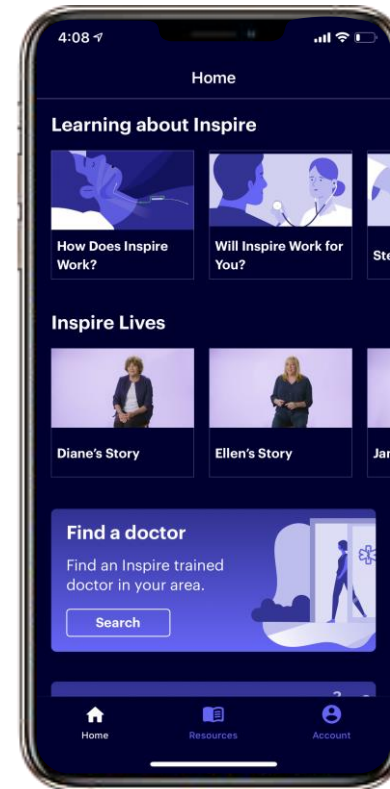
# Inspire App Demo



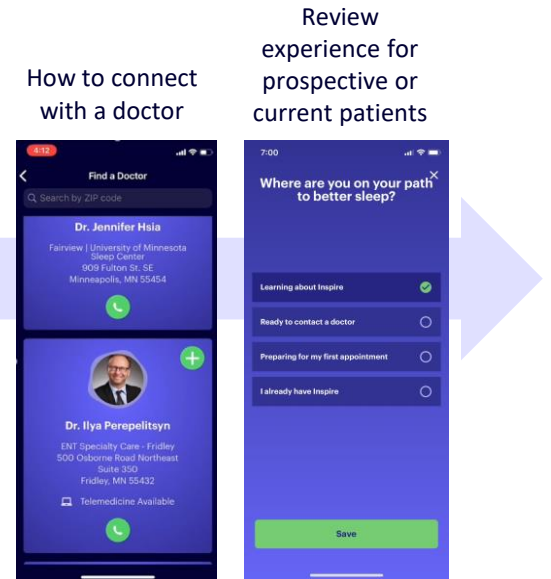
Scan this QR code with  
your phone's camera app  
Or  
Search "Inspire Sleep"  
in the app store?



Click the link that pops  
up on your screen



Let's review the  
app together

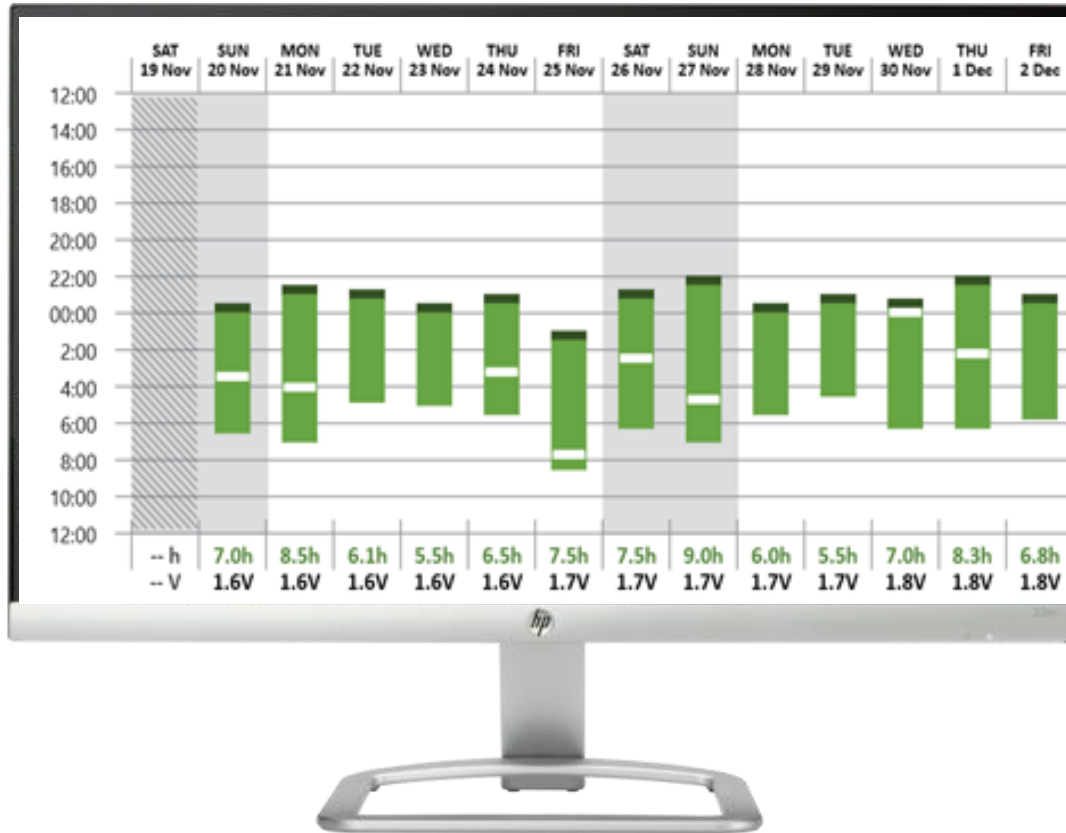


How to connect  
with a doctor

Review  
experience for  
prospective or  
current patients

# Inspire Cloud

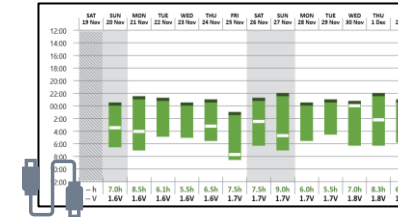
The hub for **MEDICAL PROFESSIONALS** to coordinate the monitoring and management of Inspire patients



Today

Future Capabilities

## ADHERENCE MONITORING

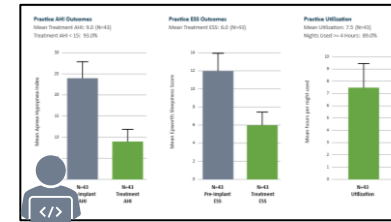


Upload nightly data from patient remote



Automatic remote monitoring

## OUTCOMES & DIAGNOSTICS

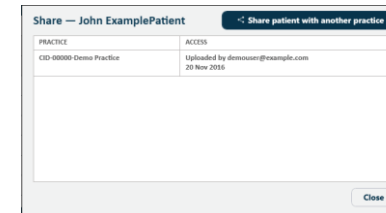


Record AHI & ESS at patient & center level

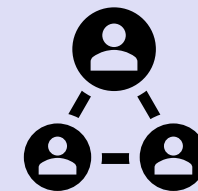


Earlier insight with virtual patient check-ins

## PATIENT & CARE TEAM COORDINATION



Share implanted patient data across providers



Pre-implant patient tracking and referral collaboration

# Reimbursement Updates

# Most US Insurance Covers Inspire



**Broad private insurance coverage**



**Medicare coverage across the US**

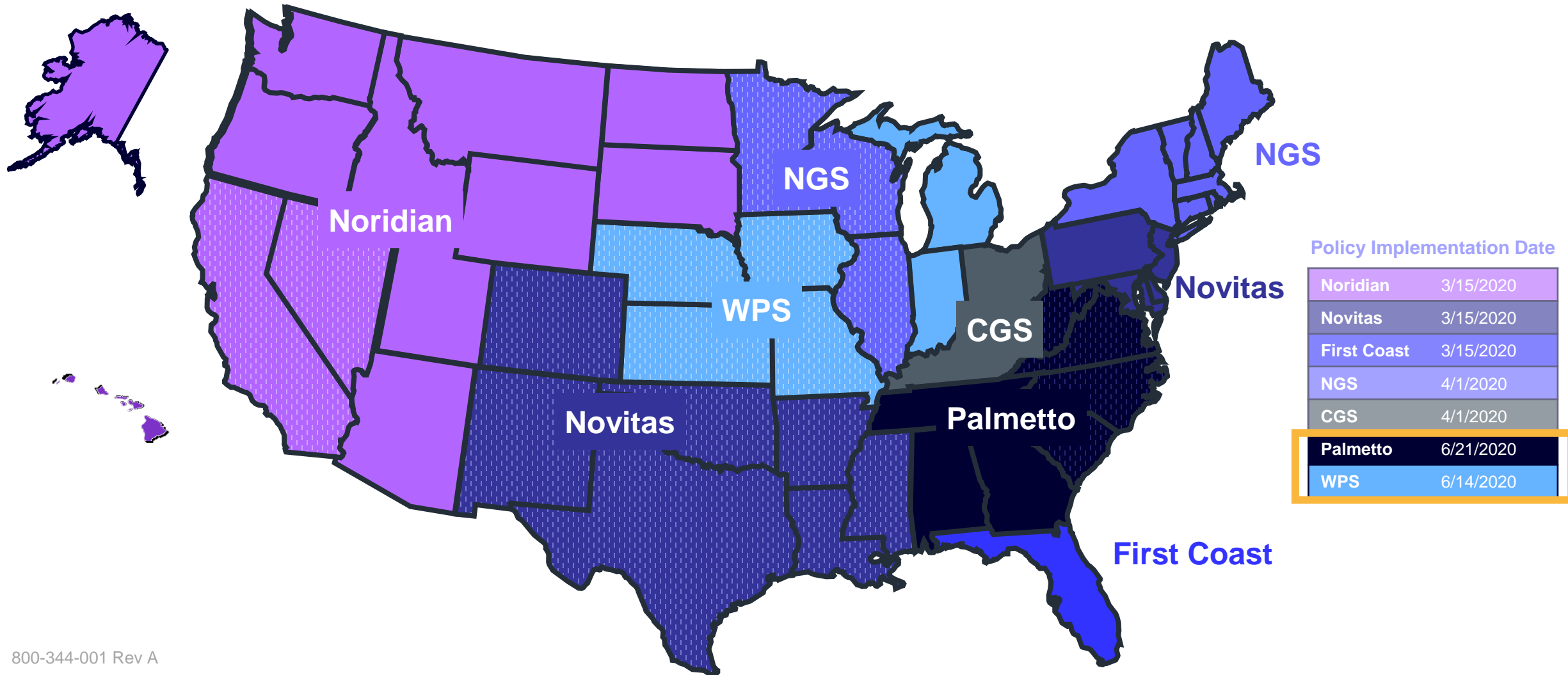


**Many VA and Military Hospitals**



[Link to Reimbursement page and list of Inspire Policies](#)

# Inspire Medicare Coverage is Available Across the United States for Those Who Meet Criteria



# Medicare Coverage Criteria

## The ABCDs of Inspire Medicare Coverage



Medicare coverage is available across the United States for those who meet criteria

- AHI** ..... **15-65**  
Documented central & mixed less than 25% of total
- BMI** ..... **<35**
- CPAP** ..... **Failure or Intolerance**  
Failure defined as AHI > 15 despite CPAP usage  
Intolerance defined as <4 hours per night, 5 nights per week or CPAP returned  
Documentation must include evidence of **Shared Decision Making (SDM)** between the implanting physician and patient  
SDM should indicate patient was intolerant of CPAP despite consultation with a sleep expert
- DISE report** ..... **Certified MD\***  
Free of complete palatal concentric collapse  
Medicare may ask for DISE & Implant certifications provided by Inspire  
Contact the reimbursement hotline for details.
- Sleep study** ..... **<2 yrs old**  
PSG is performed within 24 months of first consultation  
Refer to your local MACs sleep study LCD for guidelines on HST which are generally accepted

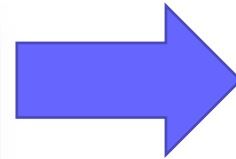
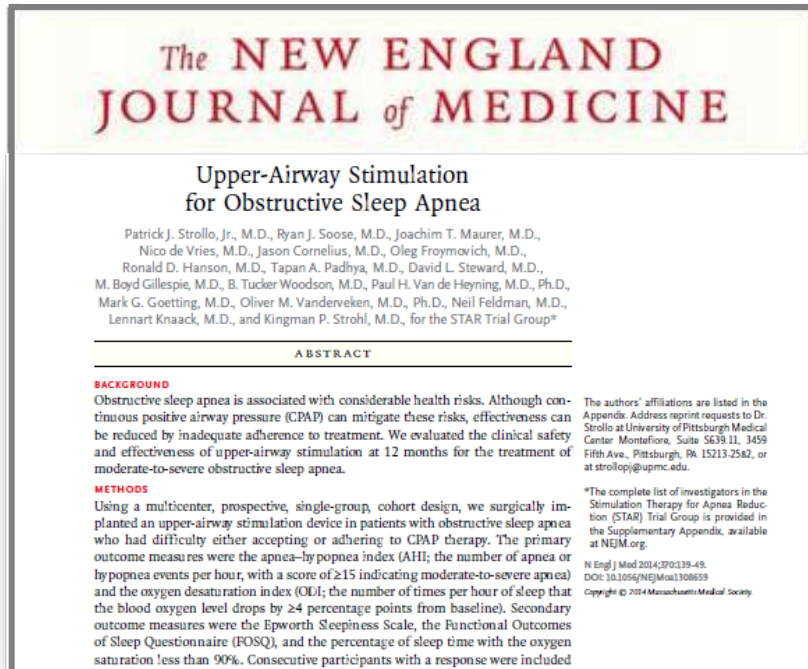
For questions or additional information contact the Inspire reimbursement hotline at 833-897-0939 or visit <https://professionals.inspiresleep.com/reimbursement/>



Inspire is not for everyone. Talk to your patients about risks, benefits and expectations associated with Inspire. Risks associated with the surgical implant procedure may include infection and temporary tongue weakness. Some patients may require post implant adjustments to the system's settings in order to improve effectiveness and ease any initial discomfort they may experience. Important safety information and product manuals can be found at [inspiresleep.com/safety-information/](https://inspiresleep.com/safety-information/), or call 1-844-OSA-HELP.

# Growing Adoption of Inspire

## Sustained Clinical Results

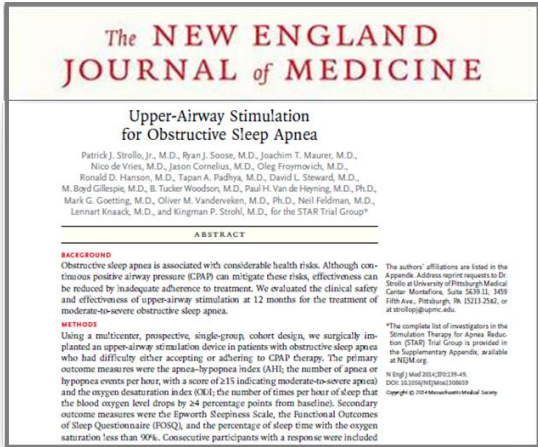


## Coverage from Most Insurers


- Over 185 Million Commercial Covered Live
  - BCBS AL
  - BCBS (27 Regional Plans)
  - United Healthcare
  - Aetna
  - Cigna
  - Palmetto Medicare LCD
- 9000+ patients
- ~400 Insurance Plans have approved patients via prior-auth
- Medicare recently published regional positive draft policies - called Local Coverage Determinations (LCD)
- Over 25 VA / Military Hospitals

- Over 100 Peer-Reviewed Publications
- 5-Year Follow-Up Data; STAR Trial
- ADHERE Registry; Over 1,800 enrolled


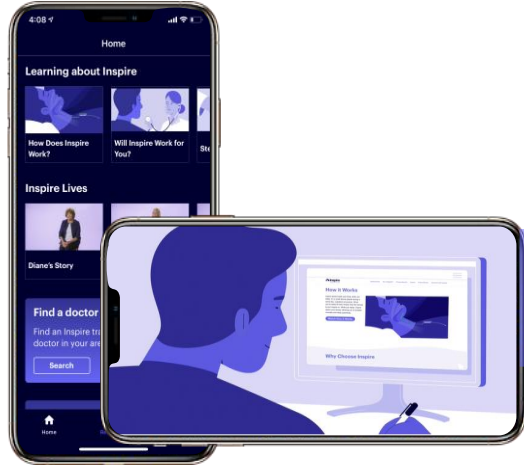
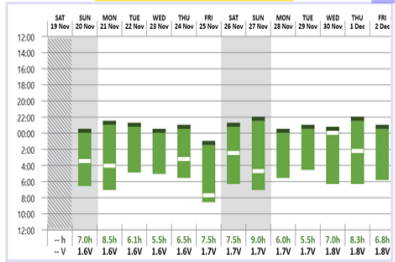
# Growing Adoption: >9000 Inspire Implants



**Green Patient**  
Good Adherence  
and Good AHI Reduction



**Yellow Patient**  
Sub-Optimal AHI  
and/or Sub-Optimal Adherence

**Sustained Clinical Evidence**

**Optimized Clinical Outcomes**

**Enhanced Patient Experience**

**Increased Patient Access**

# Special Guest: Inspire Patient David Edelstein





# Inspire Patient David Edelstein

- Inspire Date: February 18, 2016
- AHI Pre-Inspire: 48
- AHI Post-Inspire: 5

**“I honestly believe Inspire therapy saved my life. I was having very serious complications from AFIB that resulted in 4 surgeries, a pacemaker as well. However, since my implant was activated I am doing great! No more meds need for the AFIB, I have been free of the AFIB for over four years.”**



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