Help Your CPAP Intolerant Patients

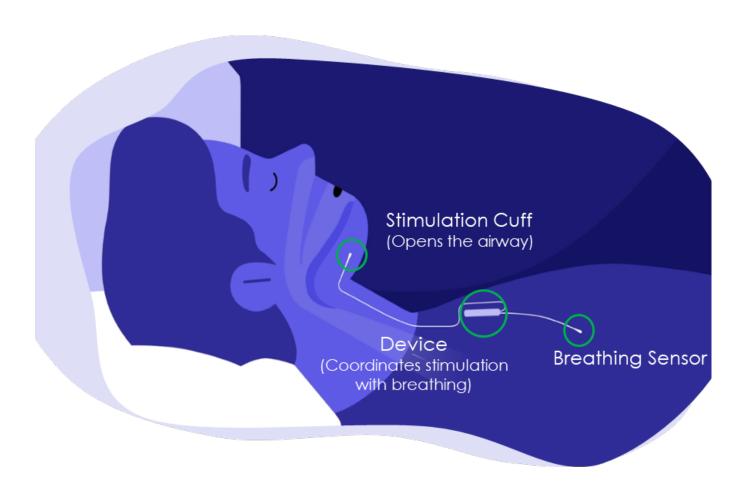
Talk to them about Inspire



Inspire Therapy

A Treatment for OSA Patients Who Are Unable to Use CPAP

Safe Outpatient Procedure



Sleep Remote



Digital Health – Quality Measures (Nightly Adherence Monitoring)





Growing Adoption

Sustained Clinical Results

The NEW ENGLAND JOURNAL of MEDICINE

Upper-Airway Stimulation for Obstructive Sleep Apnea

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BACKGROUND

Obstructive sleep apnea is associated with considerable health risks. Although con- The authors' affiliations are listed in the tinuous positive airway pressure (CPAP) can mitigate these risks, effectiveness can

Appendix Address reprint requests to Dr.

Strollo at University of Pittsburgh Medical be reduced by inadequate adherence to treatment. We evaluated the clinical safety

Center Montefiore, Suite \$639.11, 3459 and effectiveness of upper-airway stimulation at 12 months for the treatment of Fifth Ave., Pittsburgh, PA 15213-2582, or moderate-to-severe obstructive sleep apnea.

Using a multicenter, prospective, single-group, cohort design, we surgically implanted an upper-airway stimulation device in patients with obstructive sleep apnea who had difficulty either accepting or adhering to CPAP therapy. The primary at NEJM.org. outcome measures were the apnea-hypopnea index (AHI; the number of apnea or hypopnea events per hour, with a score of ≥15 indicating moderate-to-severe apnea) and the oxygen desaturation in dex (ODI; the number of times per hour of sleep that Copyright to 2014 Manuschaster Medical the blood oxygen level drops by ≥4 percentage points from baseline). Secondary outcome measures were the Epworth Sleepiness Scale, the Functional Outcomes of Sleep Questionnaire (FOSQ), and the percentage of sleep time with the oxygen saturation less than 90%. Consecutive participants with a response were included

- 100+ Peer-Reviewed Publications
- 5-Year Follow-Up Data; STAR Trial
- Enrolment goal of 5,000pts in ADHERE Registry

Broad Coverage



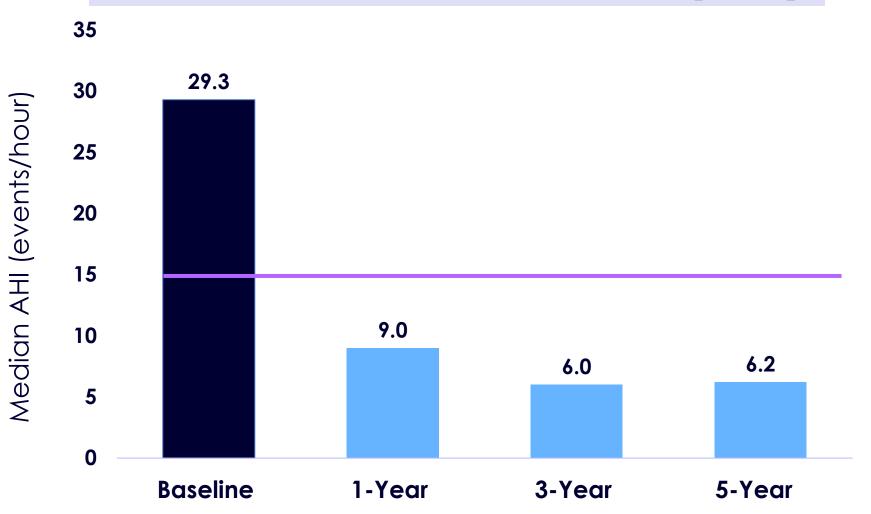
- 400+ sleep practices managing Inspire patients
- Broad private and Medicare coverage
- Many VA and military hospitals



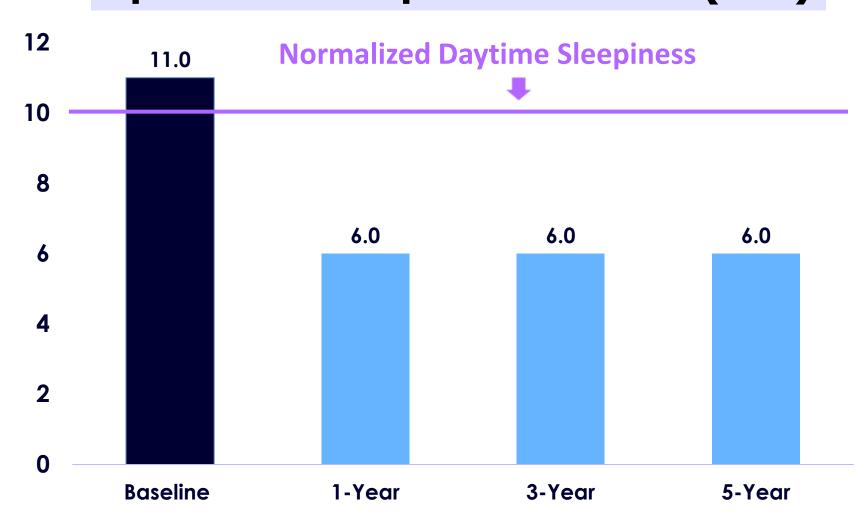
STAR Trial Overview

5 Year Follow-up Complete

Apnea Hypopnea Index (AHI)



Epworth Sleepiness Scale (ESS)



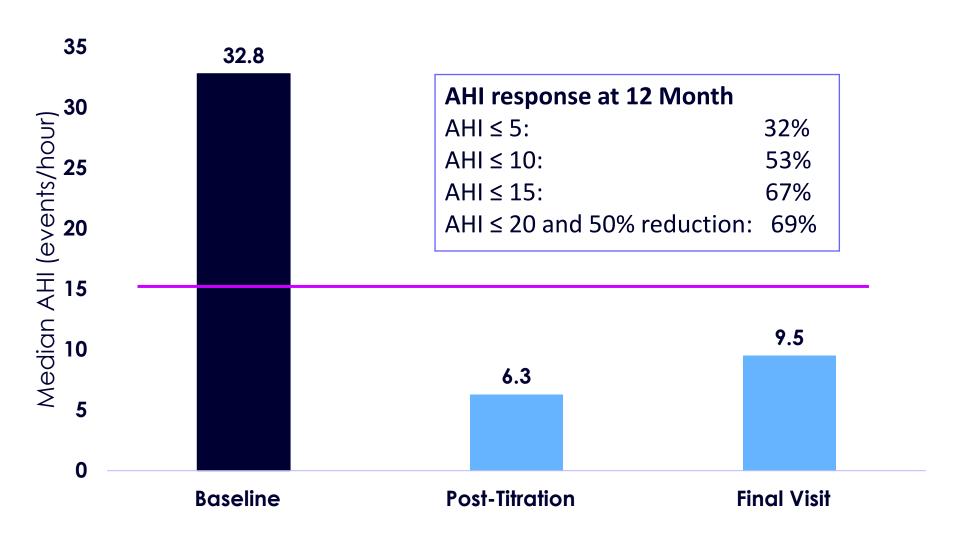
Multi-Center Prospective, 126 Patients, Randomized Control Tx, Withdrawal ARM



The ADHERE Registry

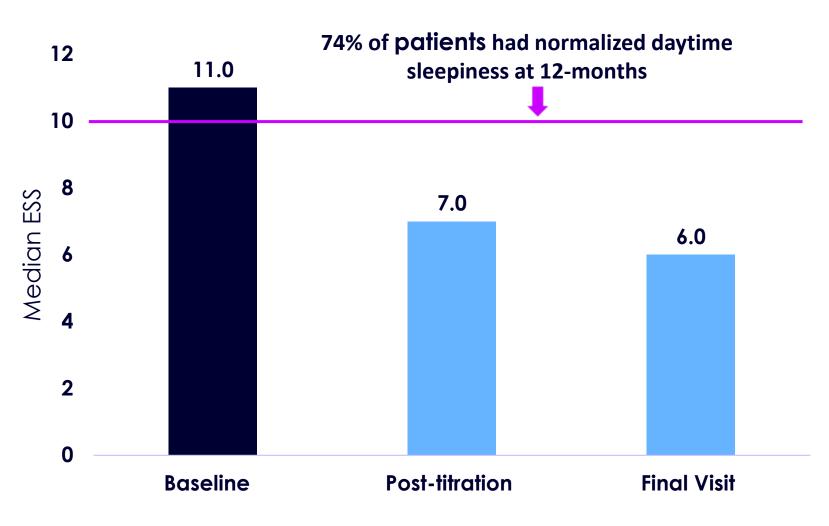
1000 Patient Data

Apnea Hypopnea Index (AHI)



Results in median; Mean AHI reduced from 35.8 at baseline to 11 at post-titration and 14.2 at 12 months

Epworth Sleepiness Scale (ESS)



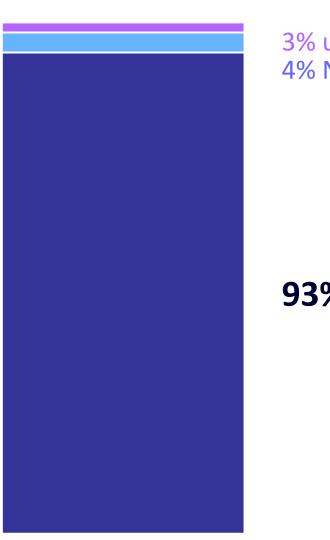
Results in median; Reference: ESS < 10 considered free of symptoms for excessive daytime sleepiness



Patient Satisfaction and Adherence

Patients Like It

Overall Patient Satisfaction At Final Visit



3% unsatisfied 4% Neutral

93% Satisfied

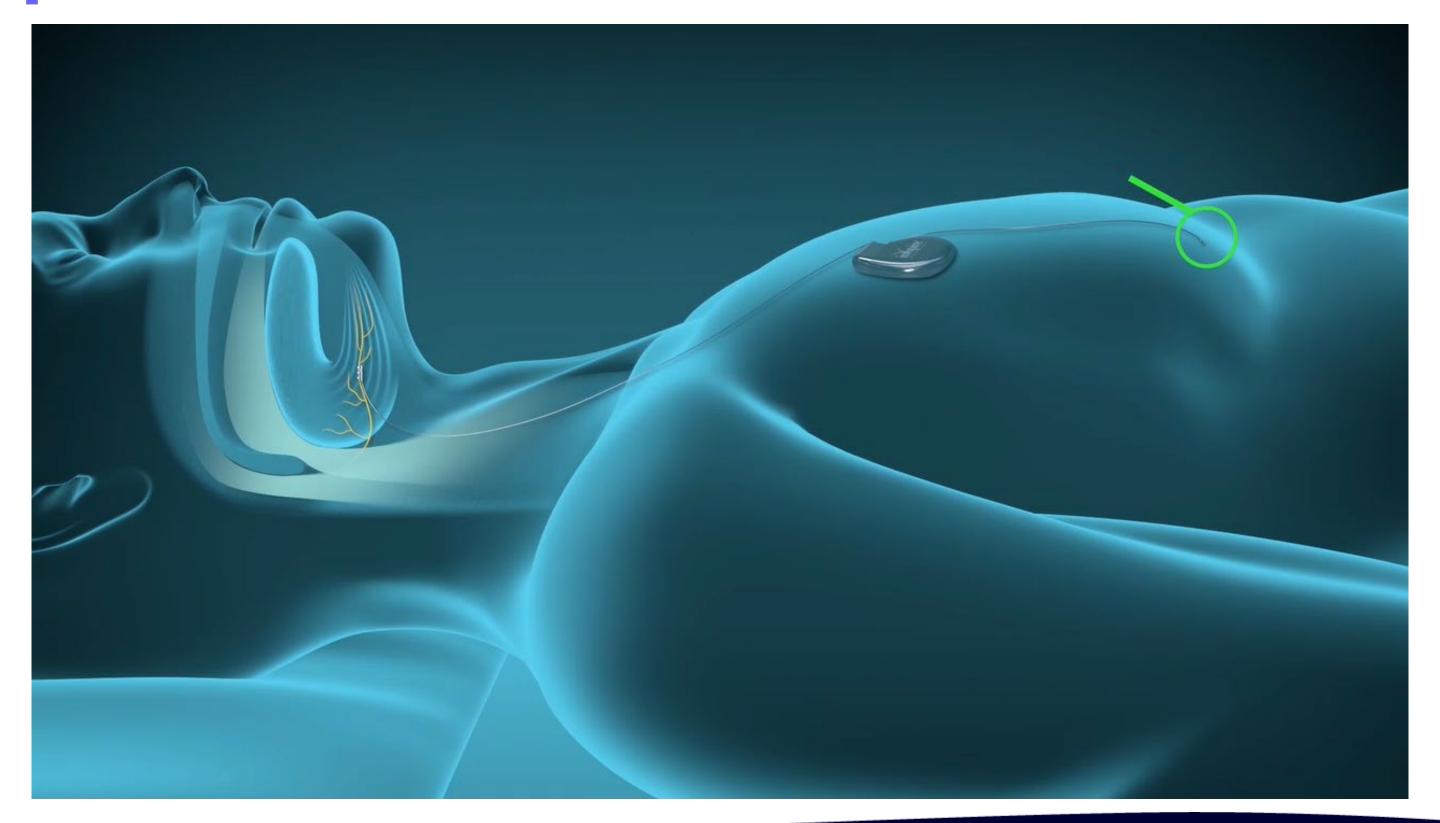
Patients Use It

Patient Adherence At Final Visit

Average 5.6 hours of therapy use/night



Inspire – How It Works





Hypoglossal Nerve Stimulation Effect

No Stimulation



Base of Tongue



Palate



Mild Stimulation



Base of Tongue



Palate





Inspire Care Pathway



Patient
Education and
Screening

Endoscopy
(DISE) & Inspire
Procedure

Activation:
Daytime
Clinic Visit

Fine-Tuning:
Sleep Study and
Adjustments

Long Term Care Management



Patient Eligibility & Education

Patient Eligibility



Adults 18 years of age and older*



Moderate to Severe OSA (AHI 15-65)



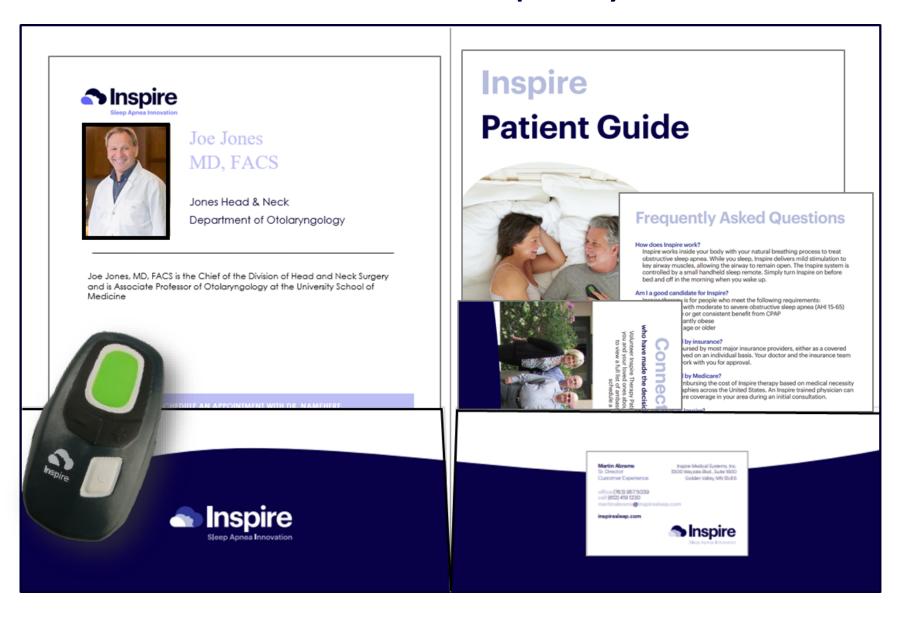
CPAP failure or inability to tolerate CPAP



Appropriate airway anatomy & < 25% Central/Mixed sleep apnea

Inspire Discussion

Referral Folder & Squishy Remote





Airway Exam & Procedure

Exam

Good Candidate

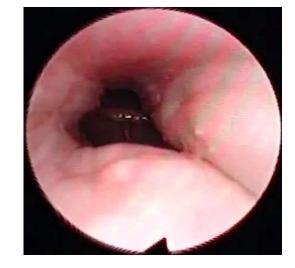




AP Collapse at Palate

Not a Good Candidate





Complete Concentric Collapse at Palate

Implant Procedure

- Safe outpatient procedure
- Fast Recovery
 - Typically, OTC for post-op pain management
 - Return to non-strenuous activities in a few days
- Post-op check 1 week after procedure at ENT Office
- ~11 year battery life
- MRIs can be performed on head, neck & extremities



Patient Support Materials

Inspire Sleep Patient App

The hub for helping patients have the best experience with Inspire

PRE-IMPLANT CONSIDERATION & EDUCATION



POST IMPLANT SUCCESS

Instructional videos on how to use Inspire



Life with Inspire Video Book

GIVEN TO PATIENT POST-PROCEDURE

- Instructional videos
- Guides the patient through the postimplant process

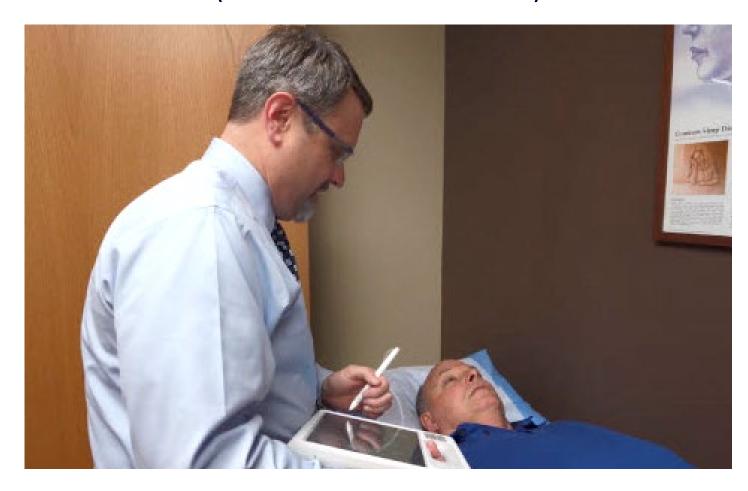




Activation: Office Visit

Establish initial settings

(Comfortable & Effective)



Teach patient to use sleep remote

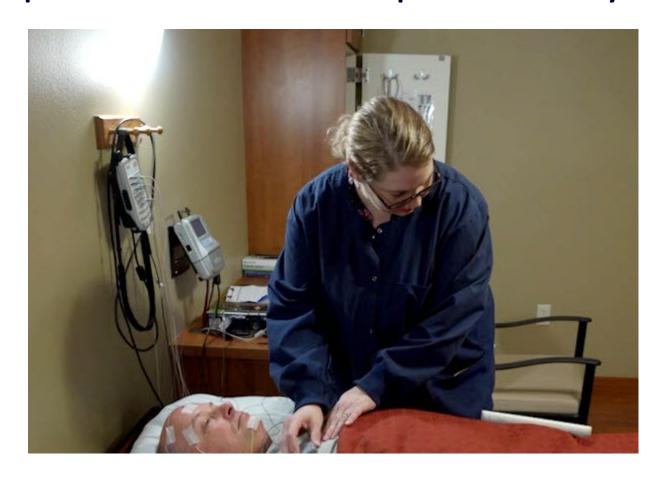


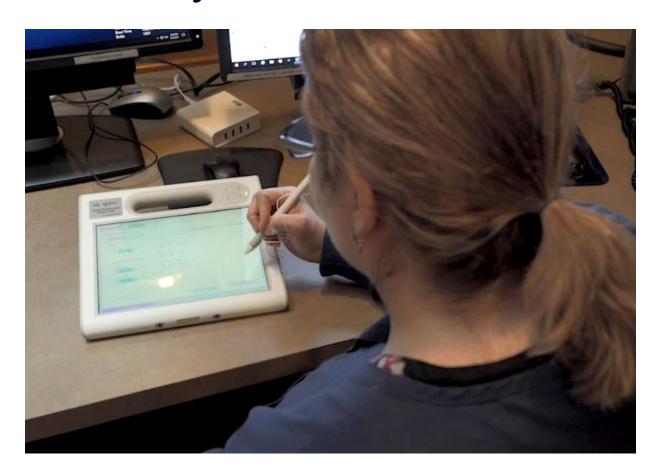
Check in phone call 1-2 weeks after activation helps with acclimation and adherence



Sleep Study to Confirm Amplitude Level

Sleep Technician Sets Up Telemetry Wand and Makes Adjustments From Control Room





Schedule follow up office visit with patient to review results and adjust settings as needed

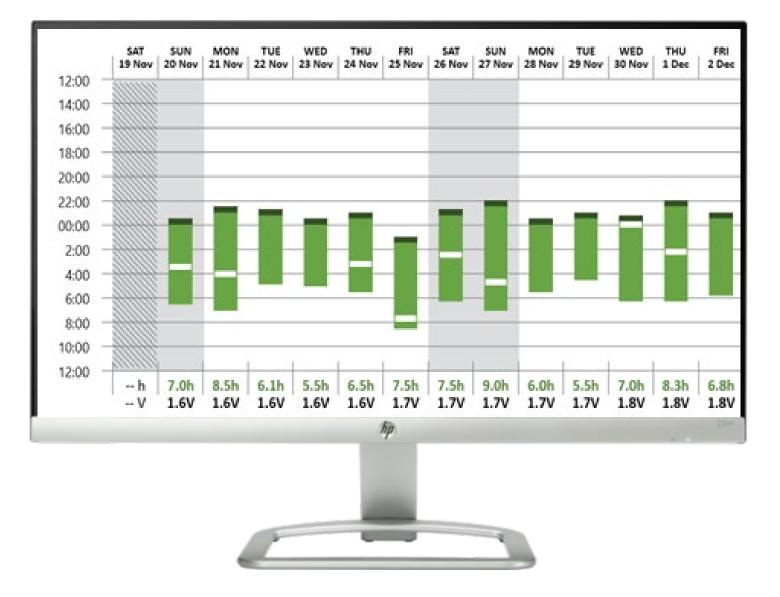


Long-term Follow-up

Patient care may require 2-4 office visits per year.

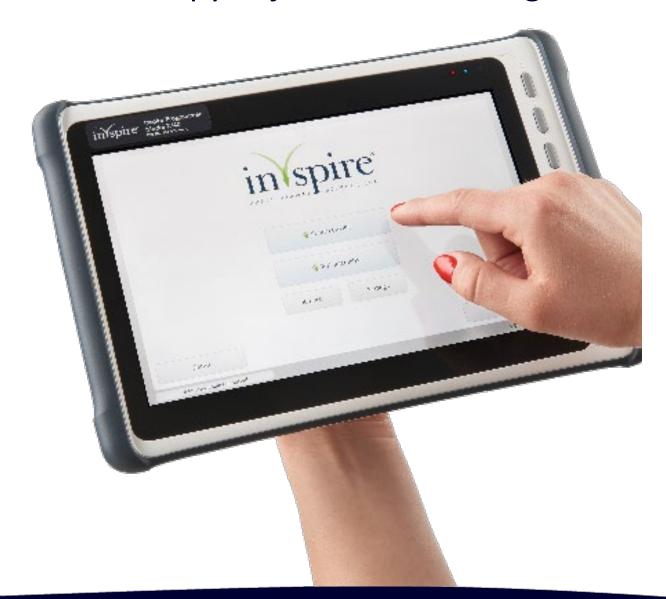
Inspire Cloud

Nightly adherence monitoring via USB upload



Inspire Programmer

Used for therapy adjustments and high-level diagnostics

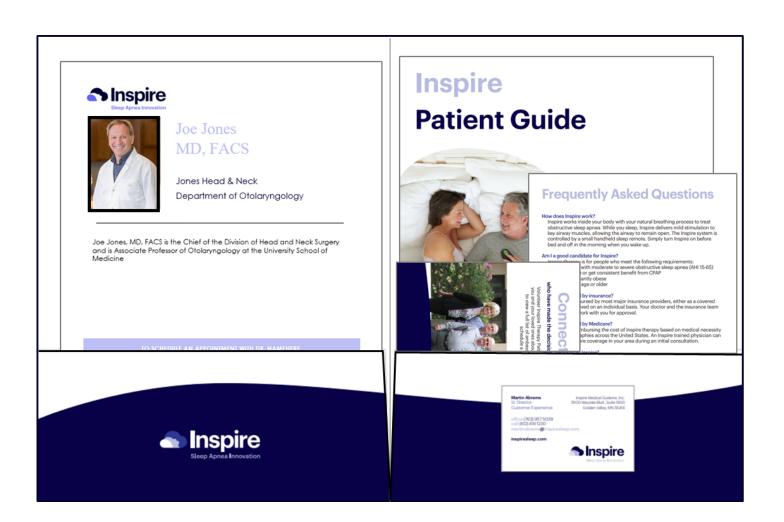




Inspire Therapy - Sleep Practice Options

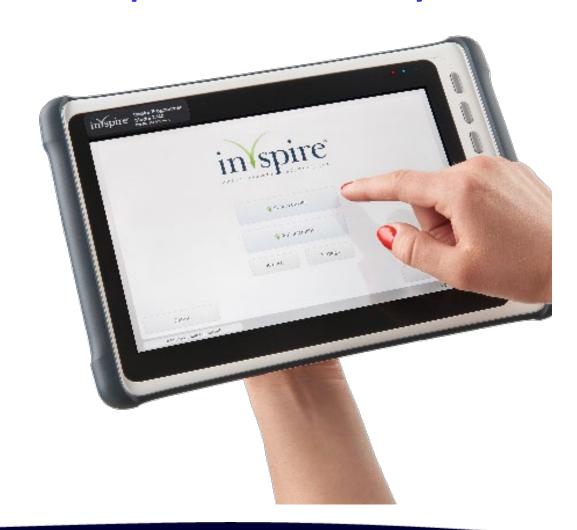
1. EVALUATION CENTER

- Educate at risk patients
- Refer to trained ENT for procedure



2. EVALUATION & FOLLOW UP CENTER

- Educate at risk patients
- Refer to trained ENT for procedure
- Manage Post Implant Care Pathway





Inspire Evaluation & Follow Up Center

Next Steps

- Meet with ENT (Collaborative care and scheduling discussion)
- Execute Business Associate Agreement
- Complete Staff Training Talking with patients about Inspire and collaborative scheduling
- Identify point person to lead patient identification & screening protocols
- Review billing & coding guide with office manager
- Purchase programmer time with patient flow
- Complete post implant care training (MD and staff) time with patient flow





2020 Inspire Coding and Payment: Sleep Study

Commonly Billed Codes - PSG

CPT Code	Code Description	2020 Hospital Payment Medicare National Avg.	2020 Physician Payment Medicare National Avg.
95810	Polysomnography; sleep staging with 4 or more additional parameters of sleep, attended by a technologist	\$908	\$501 (F) \$625 (NF)

2020 Inspire Coding and Payment: Follow-up

Commonly Billed Codes – Interrogation & Programming

CPT Code	Code Description	Physician Payment	Outpatient Hospital APC / Payment
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter by physician or other qualified health care professional; without programming (not at the time of implantation)	\$20 (F) \$20 (NF)	5734 \$109
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter by physician or other qualified health care professional; with simple programming (not at the time of implantation)	\$42 (F) \$43 (NF)	5741 \$36
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter by physician or other qualified health care professional; with complex programming (not at the time of implantation)	\$55 (F) \$56 (NF)	5742 \$113

Fine Print:

Code 95976 is defined for simple programming and code 95977 is defined for complex programming. Simple programming refers to changing three or fewer parameters. Complex programming refers to changing four or more parameters.



Important Information Related to Coding and Billing

Inspire provides this information for your convenience only. It is not intended as a recommendation regarding clinical practice. It is the responsibility of the provider to determine coverage and to submit appropriate codes, modifiers, and charges for the services rendered. Consult with your billing advisors or payers for advice on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service. Additional information can also be accessed through CMS, and information, including Medicare Manuals are available on the Internet. You should also contact your Medicare Administrative Contractor to clarify your questions or concerns regarding billing and coding.

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Important Safety Information

Inspire therapy is indicated for moderate to severe Obstructive Sleep Apnea in adult patients with an apnea-hypopnea index (AHI) between 15 and 65. It should be used after you have tried positive airway pressure treatments and they have not worked, or you could not tolerate them.

Your doctor will need to evaluate your condition to determine if Inspire therapy is right for you. For example, Inspire therapy is not intended for patients with a complete concentric collapse at the level of the soft palate, or those in whom central and mixed apneas make up 25% or more of their apnea-hypopnea index. Patients who require MRI should discuss Inspire therapy with their doctor. In addition, Inspire therapy has not been clinically tested in patients with a body mass index greater than 32.

As with any surgically implanted device, there are risks associated with the Inspire system. First, there are risks related to the surgical procedure itself such as pain, swelling, temporary tongue weakness, and infection. These types of events are generally expected with any kind of surgery, and almost all of them are resolved on their own or with medication within a period of weeks or months. In rare cases tongue paresis and atrophy were observed. Once the therapy is turned on, some patients may experience discomfort from stimulation, tongue abrasion, mouth dryness, and discomfort from the presence of the device. The majority of these events are resolved either on their own, with medication, or by adjusting the therapy settings. You will not be able to have diathermy if you have the Inspire system implanted. Inspire therapy may not work for everyone. Your doctor may need to take additional steps to address your sleep apnea. There are additional risks associated with removing your system.

This therapy is not for everyone. Please contact your doctor to decide whether Inspire therapy is right for you. For further information, please call <u>1-844-OSA-HELP (1-844-672-4357)</u> or <u>click here</u> to view Inspire Product Manuals.

800-341-000, Rev C



New Evaluation & Follow-up Center Framework

