Clinical Paper Summary Guide

Inspire®

Contents

Efficacy

Efficacy: Inspire vs Alternatives

Safety

STAR 1-year & STAR 5-year

Objective

Determine efficacy of Inspire therapy by measuring Apnea-Hypopnea Index (AHI), ODI (Oxygen Desaturation Index), FOSQ (Functional Outcomes of Sleep Questionnaire), ESS (Epworth Sleepiness Scale) before & after implant. Results published at 1, 3, and 5 years.

Methods (design)

- Prospective (N=126).
- Multi-center.
- One week withdrawal substudy 1 year after implant.
- Five year follow-up.

Inclusion Criteria

AHI 20-50, <25% central + mixed apneas, AP Collapse, ≥22 years of age, BMI inclusion criteria was ≤32, included in detailed results.

STAR 5-year

Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes

Full Manuscript

(Paywall)

STAR 1-year Pivotal Trial

Upper-Airway Stimulation for Obstructive Sleep Apnea

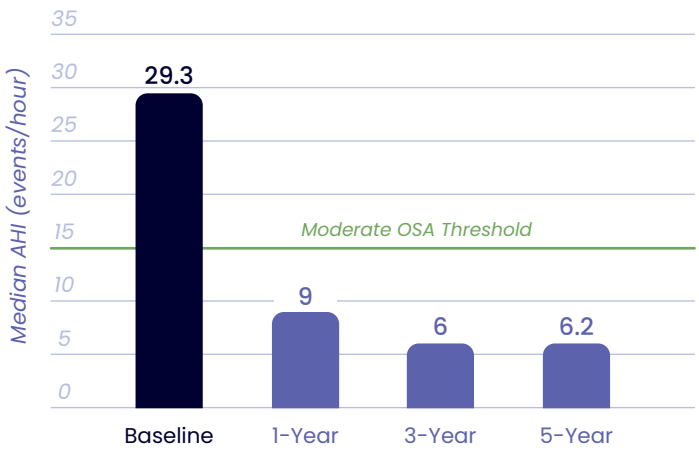
Full Manuscript

(Open Access)

Conclusion

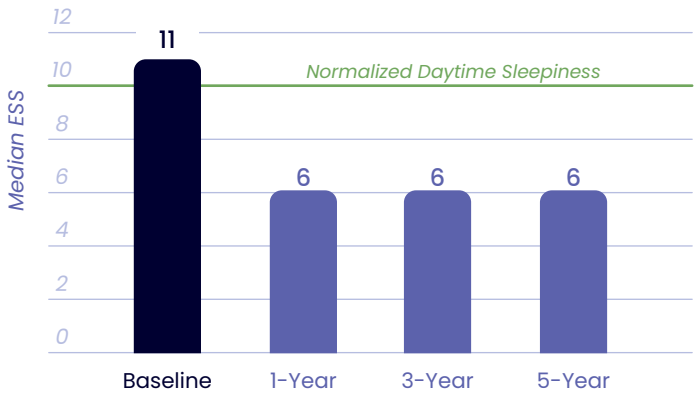
- IDE trial that led to FDA approval of Inspire therapy.
- Improvement in objective and subjective measures. Median AHI decreased from 29.3 to 6.2 (78% reduction) and Median ESS decreased from 11 to 6 after 5 year follow up.
- Two participants had a serious device-related adverse event requiring repositioning and fixation of the neurostimulator to resolve discomfort.

Apnea-Hypopnea Index (AHI)



Woodson et al., OTO-HNS 2018

Epworth Sleepiness Scale (ESS)



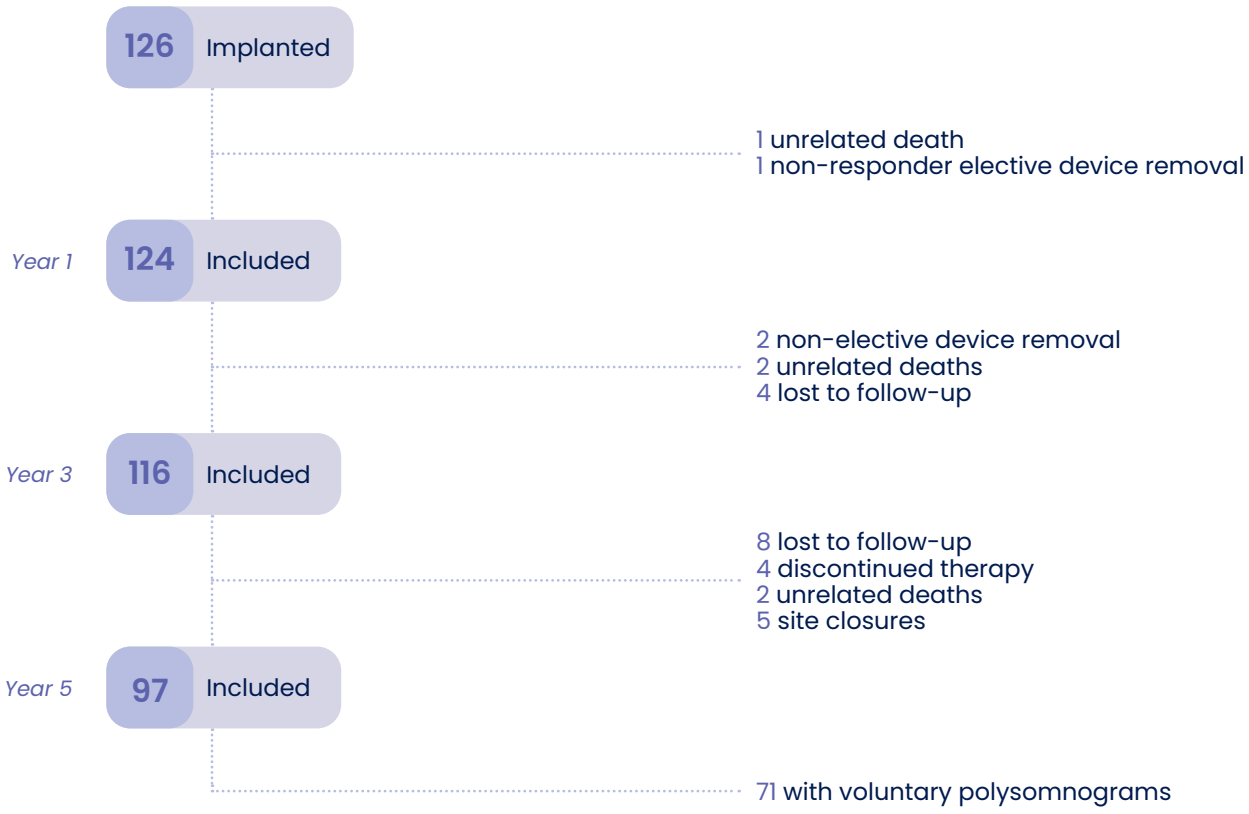
Woodson et al., OTO-HNS 2018

Detailed Results

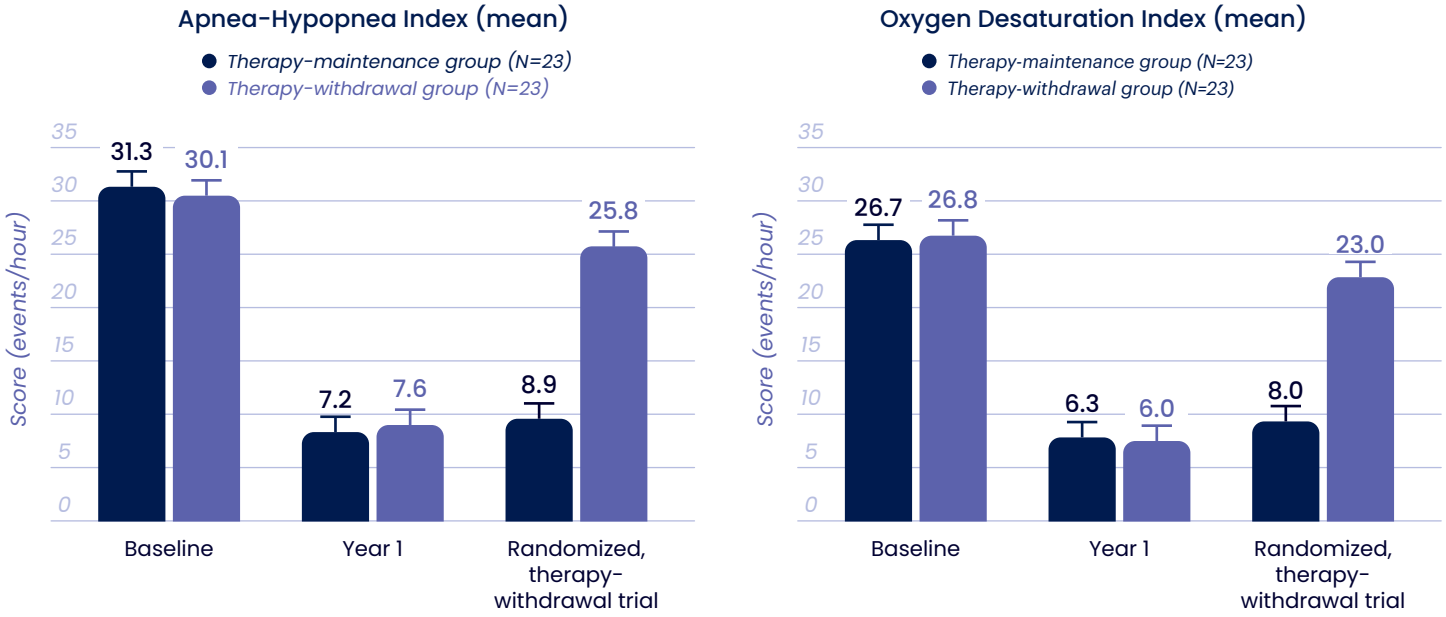
Consistent Results - 5 Years Post-Implant

Outcome Measure		Baseline	Year 1	Year 3	Year 5
AHI	n	126	124	98	71
	Median	29.3	9	6	6.2
ESS	n	126	123	113	92
	Median	11	6	6	6
ODI (4%)	n	126	124	98	71
	Median	25.4	7.4	4.8	4.6
FOSQ	n	126	123	113	92
	Median	14.6	18.2	18.8	18.7

Median is used because data was not normally distributed.



One week withdrawal sub-study one year after implant



Notes:

The first 46 therapy responders (Residual AHI ≤50% of baseline and residual AHI <20.) underwent a one year PSG, then were randomized 1:1 to a 1 week withdrawal or to a therapy maintenance arm, with an additional PSG after approximately 1 week.

Next Study:

Hypoglossal Nerve Stimulation Effects on Obstructive Sleep Apnea Over Time: A Systematic Review & Meta-analysis

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Hypoglossal Nerve Stimulation Effects on Obstructive Sleep Apnea Over Time: A Systematic Review & Meta-analysis

Objective

Determine the efficacy of hypoglossal nerve stimulation to treat obstructive sleep apnea.

Methods (design)

- Meta-analysis (an analysis of high quality published studies). Determines if results are consistent across reports, centers, and demographics.

Inclusion Criteria

Published clinical studies had to satisfy established meta-analysis guidelines (PRISMA). Identified 44 studies including 8670 patients.

Conclusion

- Report objective measure improvements as mean difference [95% confidence interval].
- HGNS significantly reduced AHI by 23 [21–25], ODI by 16 [15–17] up to 12 months postoperatively.
- Sher criteria success was 80% [75–85%] at 12 months.

Kim et al. 2023

Hypoglossal Nerve Stimulation Effects on Obstructive Sleep Apnea Over Time: A Systematic Review & Meta-analysis

Full Manuscript

(Paywall)

Next Study:
Efficacy & Usage or CPAP Compared to Inspire Therapy
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Efficacy & Usage of CPAP Compared to Inspire

Objective

Compare AHI, ESS, and usage to determine efficacy of PAP vs Inspire therapy.

Methods (design)

- Retrospective.
- Multi-center.
- Identified 63 Inspire therapy patients and 63 PAP therapy patients by propensity score matching on age, BMI, & AHI.
- Mean disease alleviation (MDA) is the multiple of effectiveness (reduction in AHI) and adherence (usage). This score allows comparison between therapies that accounts for patient compliance.

Inclusion Criteria

For Inspire Therapy Patients: non-adherent to PAP; For both PAP and Inspire Therapy Patients: diagnosed with moderate to severe OSA; BMI ≤35; ESS ≥11; using treatment for >1-year.

Conclusion

- Inspire therapy patients demonstrated AHI and ESS improvement of similar magnitudes to those observed in PAP patients.
- Inspire therapy use per night averaged an hour longer than PAP therapy use per night.
- Comparable effectiveness and longer user per night are notable in the Inspire therapy cohort since failure or rejection of PAP therapy is required for Inspire therapy eligibility. Inspire therapy candidates are—by definition—a difficult to treat subset of obstructive sleep apnea patients.
- Mean disease alleviation is slightly higher for Inspire therapy patients, due to comparable effectiveness with increased therapy adherence.

Heiser 2022

Hypoglossal nerve stimulation versus PAP therapy for OSA

Full Manuscript

(Open Access)

Related Studies

Pascoe - JAMA Oto 2022 - Inspire therapy vs PAP

Full Manuscript

(Open Access)

Walia et al. - 2020 - Inspire therapy vs PAP

Full Manuscript

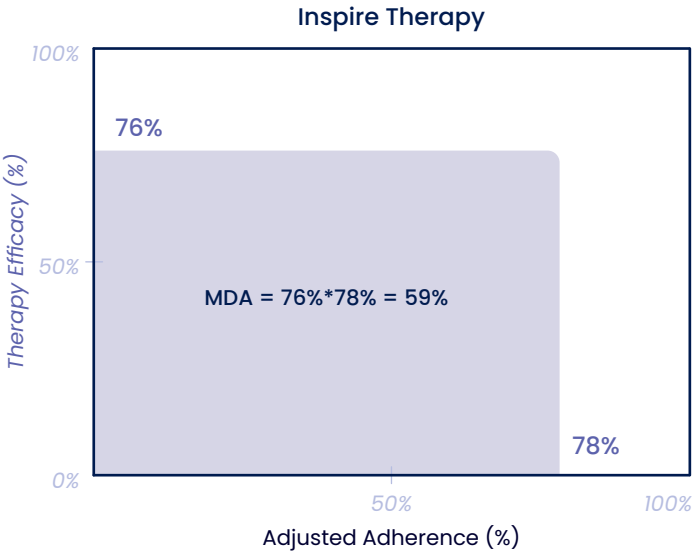
(Paywall)

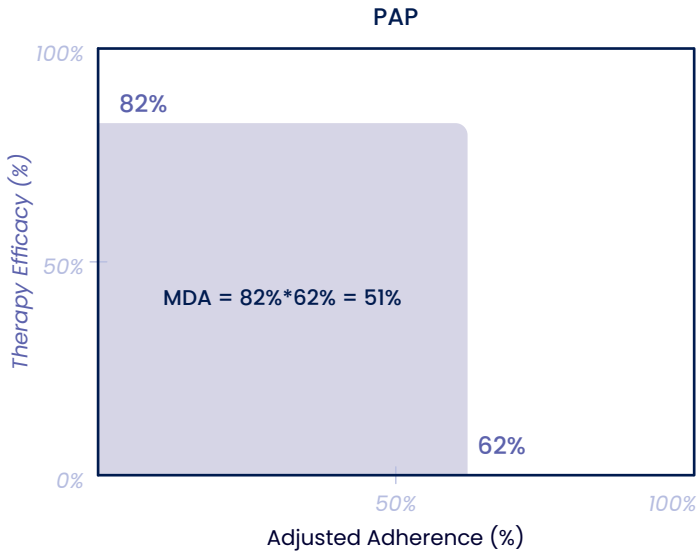
Detailed Results

Patients in this study were compared to other patients which were similar. For example similar: age, AHI, & BMI.

	HNS (N=63)		PAP (N=63)		P-Value	
	AHI	ESS	AHI	ESS	AHI	ESS
Baseline mean ± SD	33.9 ± 15.1	15.4 ± 3.5	36.8 ± 21.6	14.6 ± 3.9	0.146	0.050
12-mo FU mean ± SD	8.1 ± 6.3	7.5 ± 4.7	6.6 ± 8.0	10.8 ± 5.6	--	0.268
Reduction mean ± SD	23.0 ± 13.0	8.0 ± 5.1	30.9 ± 21.9	3.9 ± 6.8	--	0.042
(Baseline vs. 12-mo FU)	<0.001	<0.001	<0.001	0.056	0.075	--
Usage mean ± SD (hrs/night)	5.04 ± 2.58		4.03 ± 2.12		0.087	

Notes: Inspire therapy treats OSA in patients who are not effectively treated by PAP and may be underserved by other treatment options.





Mean Disease Alleviation (MDA) = Therapy efficacy x Adjusted adherence

Therapy Efficacy = AHI Reduction/Baseline AHI

Adjusted adherence = usage hrs per night / 6.5

6.5 hrs = average sleep time in western industrialized countries

Next Study:

Inspire efficacy vs traditional sleep surgery - ADHERE

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Inspire efficacy vs traditional sleep surgery-ADHERE

Objective

Compare traditional single and multilevel sleep surgery to Inspire (UAS).

Methods (design)

- Case control.
- Retrospective.
- International multi-center.

Inclusion Criteria

Identified 233 patients that had received single or multilevel sleep surgery, who would have met Inspire Criteria as of 2020. Compared these patients to 465 Inspire patients from the ADHERE device registry.

Conclusion

- Inspire therapy had better AHI reduction and comparable ESS reduction.
- Inspire therapy is less invasive and does not change anatomy.

Detailed Results

	Procedure	Airway Surgery	Inspire (UAS)	P-Value
Age (Years)	Mean ± SD (n)	46.1 ± 11.8	59.5 ± 10.8	<.001
Gender	(% Male)	88%	83%	
Baseline AHI	Mean ± SD (n)	35.0 ± 13.1 (233)	35.5 ± 15.0 (465)	0.88
Final AHI (12 Mo)	Mean ± SD (n)	19.3 + -16.3 (196)	14.1 + -14.4 (465)	<.001
AHI Change	Mean ± SD (n)	-15.9 + -17.3 (196)	-21.4 + - 17.8 (465)	<.001
Baseline ESS	Mean ± SD (n)	11.3 ± 5.1 (233)	11.9 ± 5.5 (465)	0.22
Final ESS (12 Mo)	Mean ± SD (n)	5.9 + - 4.0 (129)	7.3 + -4.7 (415)	0.01
ESS Change	Mean ± SD (n)	-5.8 + - 5.2 (124)	-4.7 + -5.2 (388)	0.06

Huntley 2020

Comparison of Traditional Upper Airway Surgery and Upper Airway Stimulation for OSA

Full Manuscript

(Paywall)

Next Study: **Comparison of readmission & complication rates between traditional sleep surgery & hypoglossal nerve stimulation** >>>>>>>>>>>>

Comparison of readmission & complication rates between traditional sleep surgery & hypoglossal nerve stimulation

Objective

Compare readmission & complication rates between Inspire therapy and traditional sleep surgery 90-days postoperatively using electronic health records; controlling for differences in patient populations.

Methods (design)

- Insurance claims database review for adverse events within 90 days after the procedure.
- Multi-center.
- Propensity score matched patients based on age, sex, race, BMI and metabolic disorder diagnosis.
- Propensity score matching of Inspire vs. palate surgery identified 1,014 patients for each cohort.
- Propensity score matching of Inspire vs. multilevel surgery identified 374 patients for each cohort.

Nord 2022

Comparison of readmission and complication rates between traditional sleep surgery and hypoglossal nerve stimulation

Full Manuscript

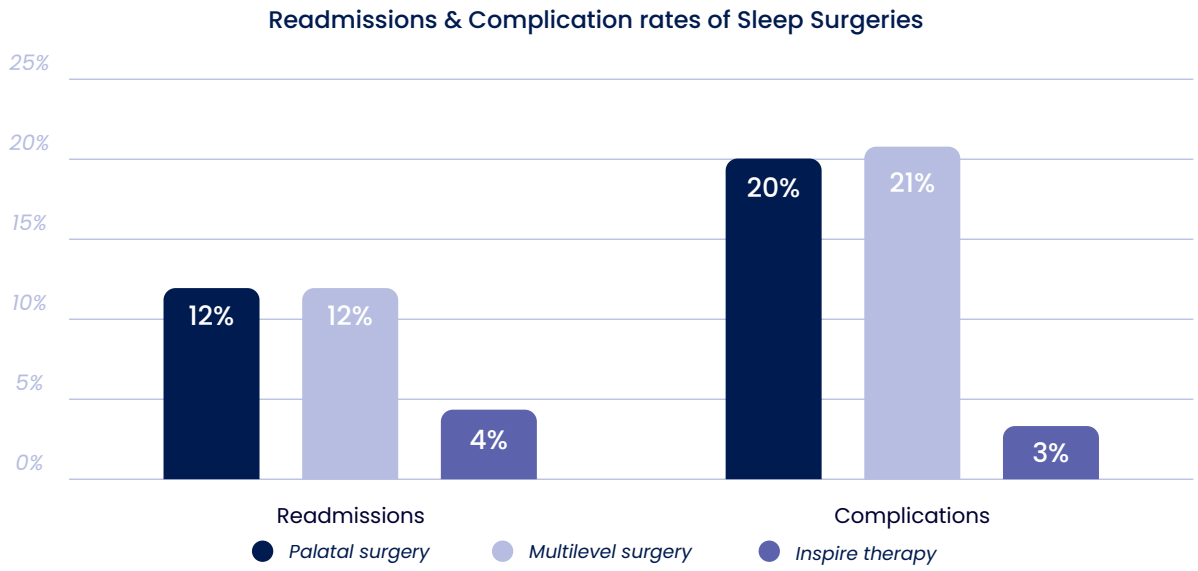
(Open Access)

Inclusion Criteria

Primary diagnosis of OSA; ≥22 yrs old; had Inspire therapy, palate, or multilevel surgery

Conclusion

- In the 90 days after the procedure, Inspire therapy has a lower risk of complication and readmission that traditional sleep surgery.



Detailed Results

	Procedure	Cohort (n)	90 Days readmissions (% risk)	90 Days complications (% risk)
Inspire therapy vs. Palate	Inspire therapy	1014	35 (3.5%)	23 (2.3%)
	Palate	1014	118 (11.6%)	204 (20.1%)
Inspire therapy vs. Multilevel	Inspire therapy	374	15 (4%)	10 (3%)
	Multilevel	374	45 (12%)	79 (21%)

Next Study:

Device-related outcomes following hypoglossal nerve stimulator implantation

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Device-related outcomes following hypoglossal nerve stimulator implantation

Objective

Analysis of postmarket approval surveillance data along with corresponding sales volume to estimate revision and explant rates up to three years after implant. Postmarket surveillance data is collected by Inspire to meet regulatory requirements.

Methods (design)

- Explant and revision rates and risk were calculated using the event counts divided by sales volume over the same period. Indications were categorized for analysis.

Inclusion Criteria

Monthly units sold from January 1, 2018 through March 31, 2022, along with explant and revision counts for HGNS implanted within that same period. Postmarket surveillance data was analyzed through March 31, 2023 to include at least one year of surveillance.

Conclusion

- Out of 20,881 implants 151 (0.723%) were explanted within the first year; infection was responsible for over half of these. 322 revision procedures (1.542%) were required within a year of implant. These rates are very low and compare well against rates for other implanted stimulators.

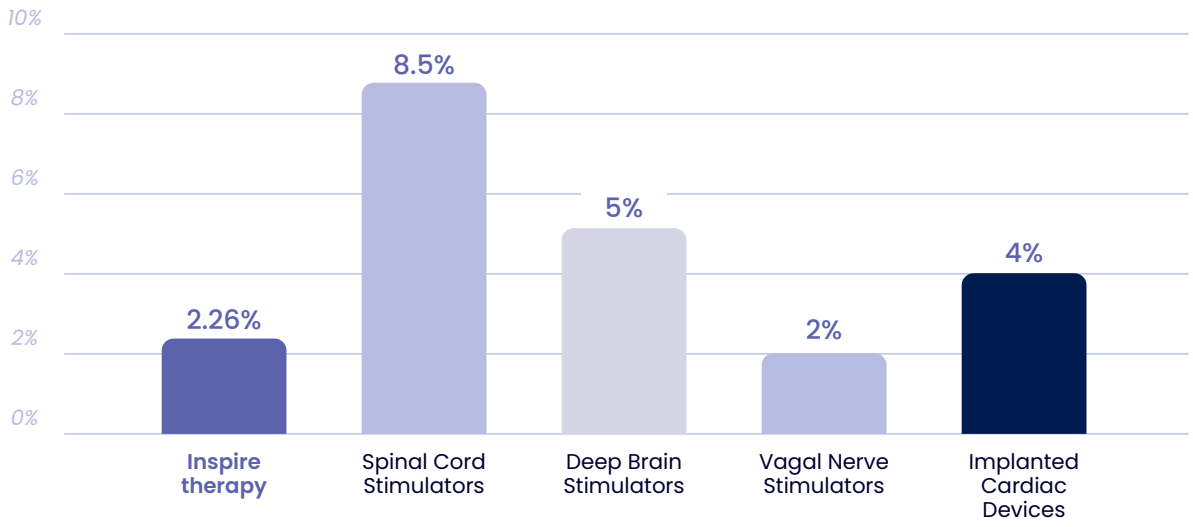
Moroco et al. - 2024

Device-related outcomes following hypoglossal nerve stimulator implantation

Full Manuscript

(Paywall)

Explant & Revision Rates are Low



Explants/Revisions within 1 Year of Implant

Moroco, et al.

Inspire is not for everyone. It is a surgically implanted system that is intended to treat obstructive sleep apnea in patients who are not effectively treated by, or able to tolerate CPAP. 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. In rare cases tongue paresis and atrophy may occur. 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/ or call 1-844-OSA-HELP

801-382-001 Rev. B