2025

Inspire Patient Experience Report

Market Surveillance & Quality Update

Overview

Every Obstructive Sleep Apnea (OSA) patient journey is unique, but one truth is universal; it's excruciating to live with and ultimately manage. Continuous Positive Airway Pressure (CPAP) therapy remains the standard of care, and while it is effective for many, it doesn't work for everyone. When CPAP is ineffective or poorly tolerated, patients may feel they've run out of options.

Inspire® therapy offers a potential alternative. This surgically implanted system is customized for each patient by a sleep medicine professional and is easily controlled with a small handheld remote. Today, more than 100,000 patients rely on Inspire therapy to find meaningful relief from OSA.

Since 2007, successful patient outcomes and care experiences are guiding tenets for Inspire Medical Systems. Dr. Glen Nelson, Inspire Medical Systems' first Board Chairman, established the motto, "If we put the patient first, we will never lose our way." This spirit guides and motivates us to publish an annual Patient Experience Report (PER). This report transparently shares therapy outcomes through a patient lens and aims to educate the reader on the experiences of others.

Highlights from the more than 300 peer-reviewed publications on Inspire therapy are available at *professionals.inspiresleep.com/publications*.

COMMITMENT TO QUALITY:

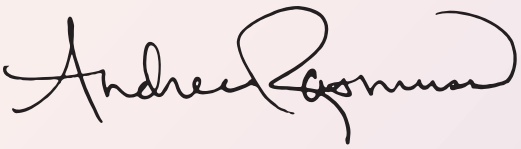
At Inspire Medical Systems, our dedication to achieving successful patient outcomes is paramount in everything we do. Our Quality Policy reflects our unwavering promise to uphold that commitment every single day.

Inspire Quality Policy:

- Relentlessly pursue safe, effective, and reliable treatment of obstructive sleep apnea.
- Strive to consistently improve the quality of life of our patients and exceed customer expectations.
- Maintain rigorous processes that ensure compliance with applicable global laws and regulations.

There are two primary data sources for the Inspire Patient Experience Report.

1. Post-market surveillance data 2. ADHERE, real-world global registry



Andrea Rasmussen
Vice President, Quality
Inspire Medical Systems, Inc.

DR. GLEN D. NELSON
Inspire Chairman of the Board
2006–2017

> "Put the patient first and you will never lose your way."

CONTACT INFORMATION

Feedback plays a vital role in our effort to continuously improve our products and services. To contact our patient and physician support team, please visit inspiresleep.com/contact for support or call 1-844-672-4386 (US) or +49 0800 00 09 78 99 (EU).

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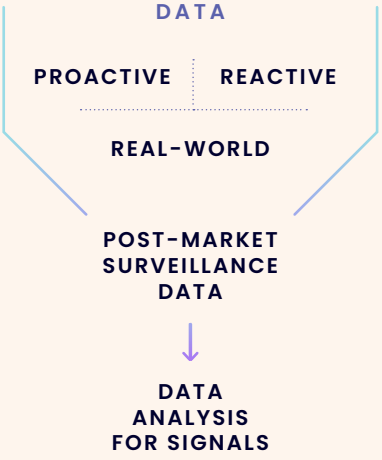
Post-Market Surveillance System Overview

Post-market surveillance is a systematic process used to collect and analyze experience gained from medical devices that have been commercially approved and placed on the market. Post-market experience data is collected from patients, healthcare professionals, product registries, regulators and Inspire employees.

Surveillance System

Inspire Medical Systems uses both proactive and reactive data to monitor the performance of our products. Data is collected from Inspire Medical Systems customers around the world. Data analysis from these sources may lead to corrective action, regulatory reporting, improvements to our products, and training.

Post-market surveillance data is collected from customer and patient-initiated complaints, product returns and Inspire employee reports. Underreporting of events is recognized throughout the medical device industry. Inspire Medical Systems is continuously improving the accuracy of the data through rigorous and regular employee training and customer awareness.



PROACTIVE DATA SOURCES

- Post-Market Clinical Studies
- Literature Searches
- Product Service Data
- Customer Surveys
- Social Media

REACTIVE DATA SOURCES

- Complaints
- Regulatory Safety Reports
- Non-conformance Reports
- Out-of-Tolerance Reports
- Audits

DATA SIGNALS DRIVE

- Corrective & Preventive Action
- Training
- Design Improvements
- Product Recalls

ADHERE Registry

Goal: Collect real-world outcomes data

- International multi-center, standard-of-care registry
- Eligibility – patients receiving Upper Airway Stimulation (UAS) for OSA

5,000 enrollments at 61 medical centers

US CENTERS

EU CENTERS
(Belgium, Germany, Netherlands, Switzerland)

Registry Data Collection

BASELINE	IMPLANT	POST-TITRATION (6MO.)	ANNUAL VISIT (12MO.)
Medical Records			
• Demographic	• Implant Time	• AHI	• AHI
• AHI	• Adverse Events	• ESS	• ESS
• OSA History		• Therapy Usage	• Therapy Usage
• ESS		• Clinical Global Impression	• Clinical Global Impression
		• Patient Experience	• Patient Experience

AHI = Apnea Hypopnea Index | ESS = Epworth Sleepiness Scale

Patient Satisfaction

Patient satisfaction is a result of clinical outcomes, patient experience, and quality of life. It is a measure of the timely, efficient, and patient-centered delivery of quality care. Patient satisfaction is thus a very important indicator to measure the success of Inspire therapy.

The ADHERE registry asks patients to answer four questions about their satisfaction with Inspire therapy.

How does Inspire therapy compare against your previous experience with CPAP?

91%[1] Say Inspire is better

I would recommend Inspire therapy to a friend or family member.

93%[1] Agree or strongly agree

Given the chance, I would choose to receive Inspire therapy again.

92%[1] Agree or strongly agree

Overall, how satisfied are you with Inspire therapy?

90%[1] Satisfied or very satisfied

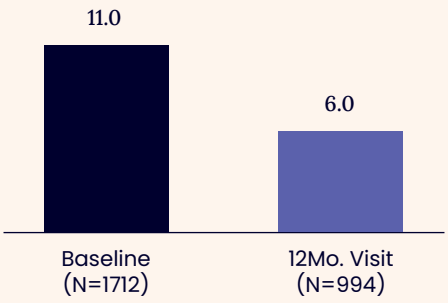
Quality of Life & Compliance

The Epworth Sleepiness Scale (ESS) is currently the most used subjective test of daytime sleepiness in clinical practice. It is a simple, self-administered, eight-item questionnaire that measures the risk of falling asleep in eight specific situations that are commonly met. A score of less than 10 is considered normal. The higher the score (from 10 to 24), the greater the reported subjective daytime sleepiness (Johns, 1991).

The ADHERE registry asks patients to complete an ESS survey at baseline and at 6 and 12-month follow-ups. ESS is the measure Inspire uses to quantify subjective benefit of therapy. Prior to Inspire therapy, patients were sleepy, and sleepiness is reduced to normal levels after treatment.

Compliance with therapy is a key factor required to gain the health benefits associated with treating obstructive sleep apnea. Longer CPAP usage has been shown to improve survival, cardiovascular events, blood pressure, excessive daytime sleepiness, cognitive function, and quality of life. However, average compliance to CPAP is often reported at less than 5 hours[2-3]. The ADHERE registry tracks average nightly compliance of Inspire therapy patients.

MEDIAN ESS[1]



USAGE

5.7

Hours of nightly use @ 12-months (n=913[1])

UAS usage of 5.7 hours/night at 12-months exceeds average CPAP usage levels from major clinical studies.[2-3]

1 Data on File
2 Apnea Positive Pressure Long-term Efficacy 1: Study—Kushida et al, SLEEP, Vol. 35, No. 12, 2012
3 The HOME-PAP Study —Rosen et al, SLEEP, Vol. 35, No. 6, 2012

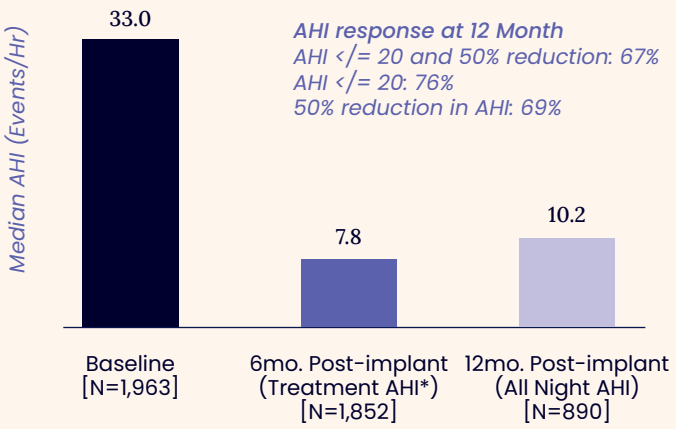
OSA Burden Reduction

The apnea-hypopnea index (AHI) is well established as the best studied metric of OSA severity. The AASM has identified the following severity grades based on the number of obstructive breathing events per hour:

- **Mild:** 5 to 15 events per hour
- **Moderate:** 15 to 30 events per hour
- **Severe:** greater than 30 events per hour

The ADHERE registry includes a follow-up PSG or HSAT at six months and twelve months post-implant.

APNEA HYPOPNEA INDEX (AHI[1])



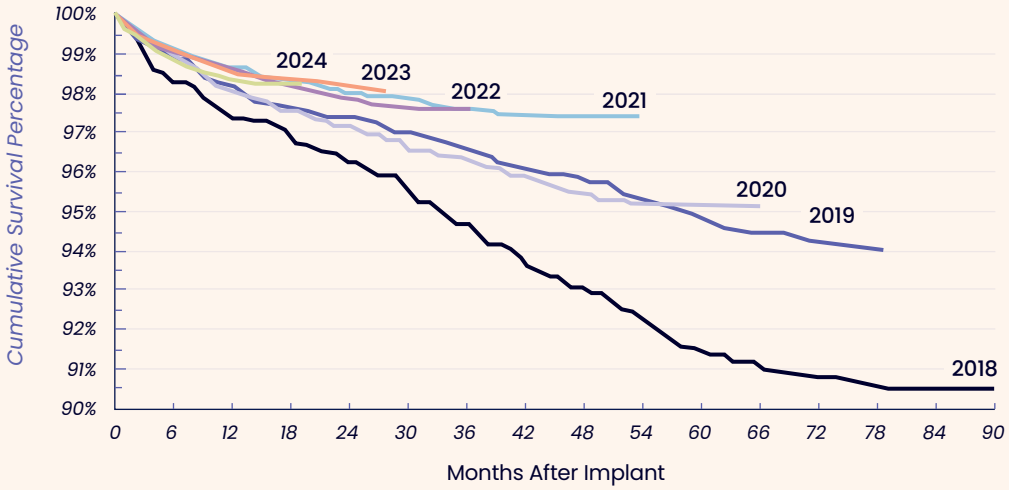
Surgical Revision & Device Explant Results

Inspire monitors and collects post-market surveillance data on surgical revisions and device explants. Our continued improvements in product performance and patient outcomes are both measurable and meaningful. Year-over-year progress is driven by:

- Ongoing enhancements to surgical technique through continuous training
- Strengthened Inspire Medical Systems field support training
- Reduced elective explant rates driven by more refined patient selection
- Continued optimization of post-implant patient care pathways
- Regulatory approval of expanded labeling

POST-MARKET REVISION RATES

Figure 1: Inspire Global System Survivability to Revision by Implant Year[4]



2024 PRIMARY REASONS FOR REVISION:

- **Device Movement** (device migration, erosion, tethering, dislodgement)
- **Device Deficiency** (related to the respiratory sensing lead [primary] or IPG)
- **Post-surgical Healing** (hematoma, incision dehiscence, resuture, seroma)

Top 3 reasons account for 69% of total revisions.

A device revision is a surgical event where a patient requires that an implanted system component be replaced or a surgical intervention is necessary to remedy an adverse event or patient complaint.

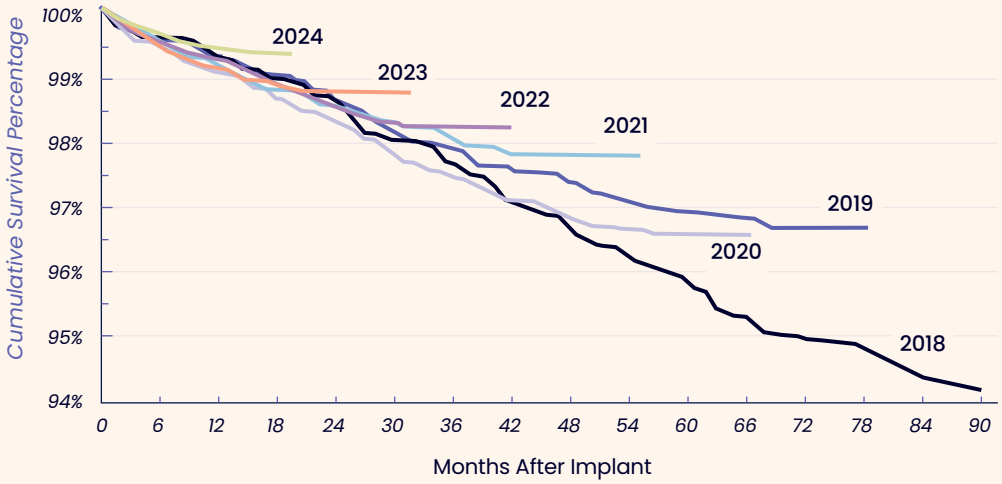
**Treatment AHI is defined as the AHI measurement after stimulation has been activated and optimal therapy achieved. The treatment AHI may be assessed during an HST or a PSG while using the optimal therapeutic setting.*

1. Data on File

4. Huntley, et al. Real-World Evaluation of Upper Airway Stimulation System Survival Using Post-Market Surveillance Data. [Poster abstract]. SLEEP 2023 Conference.

POST-MARKET EXPLANT RATES

Figure 2: Inspire Global System Survivability to Explant by Implant Year



2024 PRIMARY REASONS FOR EXPLANT:

- Elective Explant
- Infection
- MRI Compatibility

Top 3 reasons account for 93% of total revisions.

A device explant is a surgical event where a patient requires the removal of the entire implanted system or removal of an implanted system component.

Figures 1 and 2 illustrate the proportion of implanted patients who remain free from revision or explant-related events at specific time points post implant. These probabilities are calculated using the Kaplan-Meier statistical method, which estimates the likelihood that a patient will not require a surgical revision or device explant during a given period of time. For example, a 97% probability indicates that a patient had a 3% risk of undergoing a surgical revision or device explant procedure since their initial implant.

These statistical curves reflect estimates based on internal quality reporting systems. As our experience accumulates, the robustness and accuracy of these estimates continues to improve.

In 2024, Inspire's post-market surveillance system (illustrated earlier) identified the Respiratory Sensing Lead as the top reason for device deficiency revisions, which prompted corrective actions.

1 **Respiratory Sensing Lead – Damage:** During routine office visits, physicians review each patient's diagnostic data. In a small number of patients, a revision surgery is required as the lead insulation is damaged and is detectable during check-up. Many of the revisions are related to the Inspire Model 4323 Respiratory Sensing Lead which is no longer manufactured. The Inspire Model 4340 Respiratory Sensing Lead, released to the US market in 2019, is more robust and designed specifically to mitigate this risk[5].

In 2024, surgical revisions related to sensing lead damage or other sensor defects have been reduced to 10.3% of all surgical revisions performed in the year.

2 **Respiratory Sensing Lead – Tip Failure:** This results in a revision surgery for a small number of patients because the sensing lead tip separates from the primary lead body. Three specific action items were formally implemented to mitigate this risk in 2021:

- Best practice surgical training on the handling and insertion of the lead
- An improved surgical technique for implanting the sensing lead; specifically, moving from a 3-incision procedure to a 2-incision procedure
- Acknowledgment of possible sensing lead interactions with patient anatomy

Implementation of these mitigations decreased the reported occurrence rate of this issue in patients post mitigation from approximately 1.1% (1 in 90 procedures) to 0.07% (1 in 1,400 procedures).

In the post-mitigation implant population (patients implanted from 2022–2025), surgical revisions due to sensing lead tip failures remain extremely rare, occurring at a rate of only 0.01%. Based on current trends, we expect this rate will remain below 0.1%.

5. In 2025, Inspire released the Model 3150 Inspire V IPG to the U.S. market, eliminating the respiratory sensing lead and thereby removing the risk of sensing lead–related revisions in this patient population.

Field Corrective Actions & Product Recalls

In 2024, Inspire's post-market surveillance system detected two distinct product nonconformities that resulted in field corrective actions to ensure continued patient safety, product reliability and regulatory compliance.

1 MODEL 3028 INSPIRE IV IMPLANTABLE PULSE GENERATOR (IPG)

Inspire identified a single production lot of Model 3028 Inspire IV IPGs that had an increased rate for a specific manufacturing defect (epoxy degradation) in the IPG connector block. If this defect is present, it can lead to:

- Stimulation below normal therapeutic levels and/or early depletion of the battery (resulting in loss of therapy)
- Inappropriate or inconsistent stimulation effect
- Painful stimulation or perceived shocking sensation

A revision surgery is not required to replace the IPG unless the defect is present.

Consequently, a field corrective action was initiated for all 32 IPGs in this production lot. All implanting surgeons and patients who implanted or received IPGs from this production lot were notified to ensure that patients are monitored on a routine basis to identify device performance issues related to this manufacturing defect.

2 MODEL 4063 STIMULATION LEAD & MODEL 4340 RESPIRATORY SENSING LEAD

Inspire issued a voluntary recall for a subset of Model 4063 and Model 4340 leads with a chance for mismatch between the shelf box serial number label and the serial number of the lead provided in the box. When present, this labeling error may lead to an incorrect registration of the lead serial number required for device tracking. There were 405 Model 4340 lead and 100 Model 4063 leads with the potential for this labeling error. There was no patient safety issue or device performance problem.

Healthcare providers were provided instructions to inspect the labeling of leads to confirm the serial number on the lead matched the serial number on the box label, and to confirm the serial number used for device tracking registration was correct.

Complications — ADHERE Registry

The ADHERE Registry, which includes 5,000 patients, collects information related to serious complications with the Inspire implant or system. Complications are classified as either serious or non-serious. A serious complication (adverse event) is an event that is one or more of the following: requires hospitalization and/or surgical intervention; leads to a persistent or significant disability or incapacity; is life-threatening.

Serious complications, reported to date, are detailed in the table below according to the period in which they occurred (intraoperative or postoperative). The intraoperative period includes the operative and immediately postoperative period (<10 days post-implant). The postoperative period refers to the remainder of the follow-up period.

SERIOUS COMPLICATIONS

As of 2025, 0.4% and 2.6% of patients in the ADHERE Registry have experienced serious intraoperative and postoperative complications, respectively.

Serious Intraoperative Complications[1]	% of Patients
Hematoma	0.1%
Arrhythmia	0.1%
Bleeding	<0.1%
Anesthesia-related Issues	<0.1%
Failed Implant	<0.1%
Pneumothorax	<0.1%
Other	<0.1%
Total	**0.4%**

Serious Postoperative Complications[1]	% of Patients
Infection	0.1%
Explant (entire system)	0.4%
Revision (2 or more components)	0.4%
Revision (IPG only)	0.4%
Revision (Sensing lead only)	0.8%
Revision (Stimulation lead only)	0.6%
Other	0.2%
Total	**2.6%**

NON-SERIOUS ISSUES

In addition to the serious adverse events noted above, non-serious issues are also collected in the ADHERE Registry. Most frequent non-serious issues (with incidence rate > 2.0%) are detailed in the table below. The most common non-serious complication is stimulation-related discomfort, which is typically addressed with adjustments to the therapy programming.

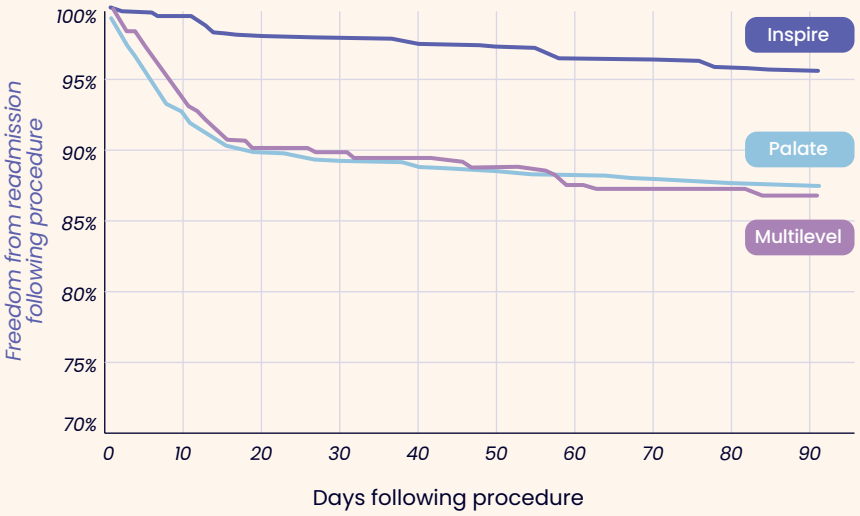
Most Common Non-Serious Issues[1]	% of Patients
Stimulation-related Discomfort	7.8%
Insomnia/Arousal	5.0%
Tongue Abrasion	3.2%

1. Data on file

Comparison to Anatomy — Altering OSA Surgery Third Party Data

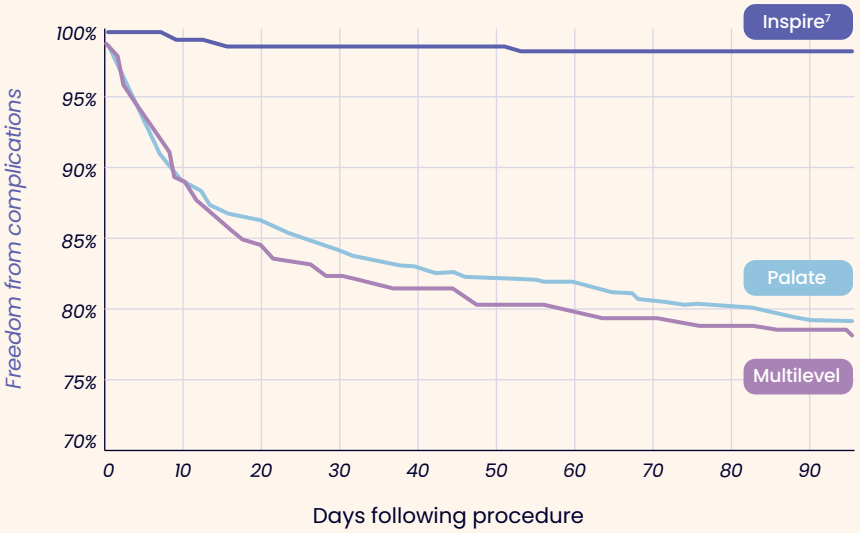
There are other CPAP alternatives available for moderate to severe OSA patients, including anatomy-altering surgeries. *Nord, et. al.* evaluated readmissions and complications following Inspire Upper Airway Stimulation (UAS) compared to palatal or multilevel sleep surgery. Both hospital readmission and complications following the procedure were significantly lower in the UAS group compared to anatomy altering surgeries. This information is included in the Inspire Patient Experience Report to provide a reference point for the complication rates seen with the Inspire procedure.

READMISSION FOLLOWING PROCEDURE[6]



- Palatal surgery had a higher risk of readmission or return to OR (12% vs 4%, p<0.0001), and a higher complication rate (21% vs 2%, p<0.0001) than Inspire therapy
- Multilevel surgery results had a similarly higher risk of readmission/return to OR (12% vs 4%, p<0.0001, complications: 22% vs 3%, p<0.0001)

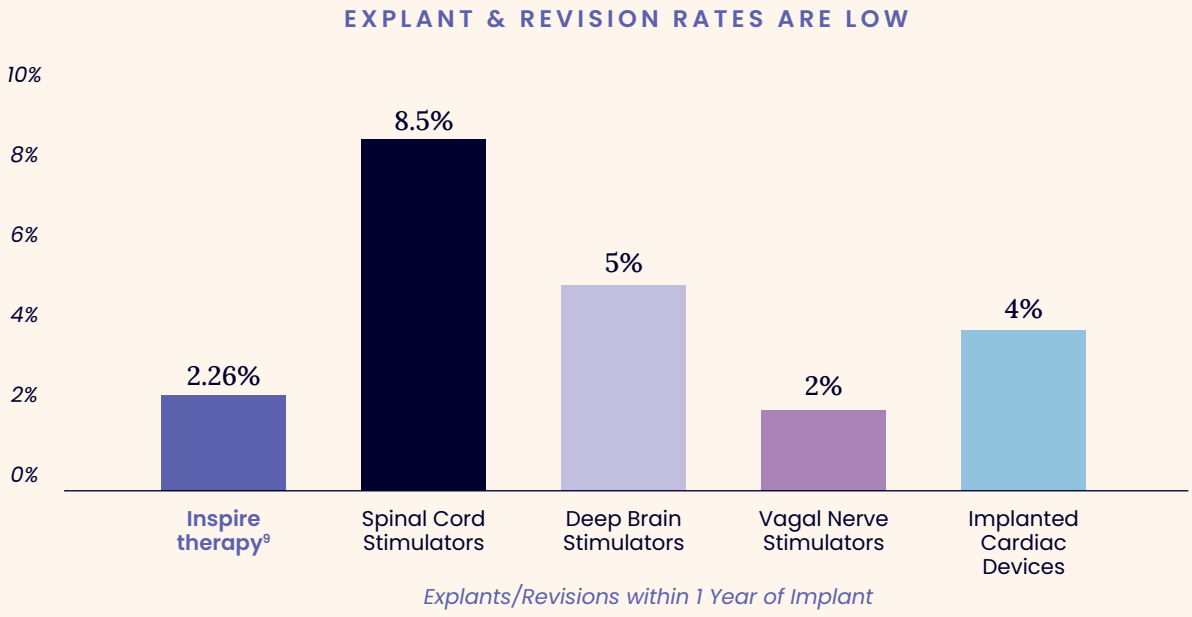
COMPLICATIONS FOLLOWING PROCEDURE



- The first 20 days following surgery were the most risky for readmission for both palate and multilevel surgeries, but the Inspire therapy group had relatively few complications, measured out to 90 days

6. Nord R, Fitzpatrick T, DeShazo JP, Reiter ER. Comparison of readmission and complication rates between traditional sleep surgery and hypoglossal nerve stimulation. Laryngoscope Investig Otolaryngol. 2022;7(5):1659-1666.
7. Based on Inspire implants from April, 2014–March, 2021.

A third-party review and analysis of Inspire therapy post-market data[8] has stated the real-world commercial performance of Inspire therapy is comparable to the observed clinical study data. The reported rates of explant and revision are very low and compare well against rates for other implanted stimulators.



8. Moroco, et al. J Clin Sleep Med. 2024;20(9):1497–1503
9. Based on Inspire implants from January, 2018–March, 2022.

BUS-00009, Version 1, April 2026

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