Inspire
Sleep Apnea Innovation

PATIENT MANUAL

Inspire IV Generator Model 3028

Rx Only

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Glossary

Amplitude — See Stimulation Strength.

Apnea — A temporary absence of breathing.

Apnea-Hypopnea Index (AHI) — The number of apneas and hypopneas a person experiences in a typical hour of sleep.

Bipolar cautery — A type of electrocautery that uses focused energy.

Body Mass Index (BMI) — An indicator of a person's body composition based on their height and weight.

Caution — A statement describing events that could result in minor or moderate injury to the patient, device damage, or improper functioning of a device.

Central Apnea — A temporary absence of breathing due to a lack of effort to breathe.

Contraindication — A condition or circumstance when a person should not have an Inspire system.

Defibrillation — The use of controlled electric shock to treat an abnormal heart rhythm.

Diathermy — A medical treatment applied to the outside of the body to heat areas of the body. This treatment may be used to relieve pain, stiffness of muscles, and promote wound healing.

Dysphagia — Difficulty or discomfort in swallowing.

Electrocautery — A process that uses heat produced by electric energy to reduce bleeding.

Electromagnetic Disturbance — Any electromagnetic event that may degrade the performance of a device.

Electromagnetic Interference (EMI) — The effect of an electromagnetic disturbance that prevents the generator or sleep remote from working properly. For example, electromagnetic interference could prevent your generator from communicating with your sleep remote.

Epworth Sleepiness Scale (ESS) — Questionnaire used to assess daytime sleepiness of an adult.

Functional Outcomes of Sleep Questionnaire (FOSQ) — Quality of life questionnaire used to assess daytime functioning in adults.

Generator — The implanted component of the Inspire system that contains the battery and electronics that control the stimulation.

Implantable Pulse Generator (IPG) — See Generator. Your doctor may refer to your generator as an IPG or implantable pulse generator.

Lead — An implanted wire with protective coating that connects to the generator. The Inspire system has a sensing lead and a stimulation lead.

Microwave Ablation — A type of tissue heating often used to treat tumors.

Mixed Apnea — A temporary absence of breathing with partial effort to breathe.

MR Conditional — The designation “MR Conditional” means you can undergo an MRI scan as long as certain criteria are met and the precautions provided by Inspire are followed.

MRI (magnetic resonance imaging) — A type of medical imaging that uses magnetic fields to create an internal view of the body.

Obstructive Sleep Apnea (OSA) — A common type of sleep apnea that is caused by the obstruction (blocking) of the upper airway.

Oxygen Desaturation Index (ODI) — The number of times per hour of sleep that the blood’s oxygen level drops.

Pause — A delay in therapy that allows the patient to temporarily stop stimulation without turning the therapy off. The pause time allows the patient to fall asleep before stimulation begins again.

Positive Airway Pressure (PAP) — A common treatment for obstructive sleep apnea. PAP devices provide air pressure to keep the airway open. Examples include CPAP and BPAP.

Precaution — See Caution.

Remote — See Sleep Remote.

Sleep Remote — Device the patient uses to turn therapy on, therapy off, pause therapy and to change stimulation strength within limits set by a doctor.

Sleep Study — An overnight evaluation of your sleep apnea. Therapy settings may be adjusted during a sleep study.

Start Delay — A delay between when the therapy is turned on and when the stimulation begins. Start Delay allows the patient to fall asleep before stimulation begins.

Stimulation — The delivery of electrical energy to the nerve that controls tongue movement.

Stimulation Strength — The amount of stimulation energy delivered to the nerve.

Therapy — Treatment of a disease or condition. The Inspire system uses stimulation to provide therapy.

Therapy Settings — The settings, stored in the generator, that define the therapy you receive.

Upper Airway — The breathing path from the nose and behind the tongue.

Warning — A statement describing an event that could seriously harm the patient.

1. Introduction

You have received an Inspire system to deliver Upper Airway Stimulation (UAS) therapy. UAS therapy is prescribed to treat sleep apnea.

The Inspire generator and leads are surgically placed in your body (Figure 1a). When your doctor has determined that you are ready to start therapy, you will receive an Inspire Sleep Remote™ (Figure 1b). You will use your sleep remote to turn your therapy on and off and adjust the strength of stimulation.

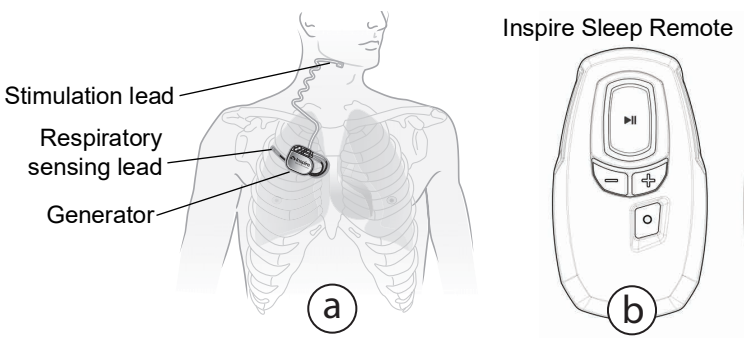


Figure 1. *Inspire system*

About This Manual

This manual contains important safety and therapy information that you need to know as you recover from your surgical procedure. The manual also describes the Inspire system and how Inspire therapy will work after your doctor turns your therapy on.

You will receive a separate manual describing how to use the sleep remote.

If you have questions that are not answered in this manual, or if any problems occur, contact your doctor.

2. Safety Information

Indications for Use

Inspire Upper Airway Stimulation (UAS) is used to treat a subset of patients with moderate to severe Obstructive Sleep Apnea (OSA) (Apnea-hypopnea Index [AHI] of greater or equal to 15 and less than or equal to 100). Inspire UAS is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate Positive Airway Pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level. PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage) and PAP intolerance is defined as:

1. Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or

2. Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it).

Inspire UAS is also indicated for OSA patients ages 18 to 21 years with moderate to severe OSA (15≤AHI≤100), and pediatric patients ages 13 to 18 years with Down syndrome and severe sleep apnea (10≤AHI≤50) who:

- Do not have complete concentric collapse at the soft palate level,
- Are contrainidicated for, or not effectively treated by, adenotonsillectomy,
- Have been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance, or
- Have followed standard of care in considering all other alternative/adjunct therapies.

Contraindications

Contraindications for the use of Inspire therapy include the following:

- Central and mixed apneas make up over 1/4 of the total AHI
- Patients with an implantable device that could experience unintended interaction with the Inspire system. Consult the device manufacturer to assess the possibility of interaction.
- Patients who are, or who plan to become pregnant (this has not been studied and potential hazards are unknown)
- Patients who require an MRI other than what is described in the Inspire MR Conditional labeling

- Patients who are unable or do not have the necessary assistance to operate the sleep remote
- Any condition or procedure that has compromised neurological control of the upper airway (consult your doctor)
- Any anatomical finding that would compromise the performance of upper airway stimulation

Risks and Benefits

Overview

Inspire UAS therapy has helped patients manage their sleep apnea and improve their quality of life. Proper treatment of OSA may increase performance on daily tasks and decrease the risk of accidents (for example, car accidents). OSA has been linked to hypertension, stroke, diabetes, heart failure, and early death. Treatment of OSA has been shown to reduce serious health side effects like these.

Inspire therapy may not work for everyone. Additional steps may be needed to treat sleep apnea. If it is decided to remove the implanted system, another surgery will be required. This involves additional risks which have not been studied.

Ask a doctor if you would like more information.

Risks from Clinical Study

Risks of the Inspire UAS system include those of any implanted device. Risks related to the surgical procedure

include pain, swelling, tongue weakness, and infection. Once therapy is turned on, there are additional risks such as discomfort from stimulation, tongue abrasion, mouth dryness, and difficulty speaking or swallowing.

All of the possible outcomes are not known, but the risks related to the Inspire system can be assessed by looking at the data from the STAR clinical study.

The implant surgery risks observed during the clinical study are included in the table below. This study included 126 patients who were implanted with the Inspire UAS system. After 60 months, 168 out of 177 (95%) of surgery-related events had been fully resolved with primarily medication or no intervention.

Table 1. Non-Serious Events Related to Surgery

Hazard Related to Surgery	Subjects with Event
Incision pain	38 of 126 subjects
Discomfort after surgery	34 of 126 subjects
Temporary tongue weakness	23 of 126 subjects
Sore throat from intubation during implant	15 of 126 subjects
Other symptoms after surgery (nausea, vomiting, abdominal pain, body pain, anxiety, ineffective airway clearance, loss of some taste, allergy to antibiotics, inability to void)	14 of 126 subjects
Headache	8 of 126 subjects
Mild infection	1 of 126 subjects

The risks from the use of Inspire therapy observed during the clinical study are included in the table below. After 60 months, 269 of the 335 (80%) therapy-related events were fully resolved with medication, changes to therapy settings, dental work to fix a jagged tooth, the use of a lower tooth guard during sleep to prevent tongue abrasions, or no intervention.

Table 2. Non-Serious Events Related to Inspire Therapy

Hazard Related to Therapy	Subjects with Event
Discomfort due to electrical stimulation	76 of 126 subjects
Tongue abrasion	34 of 126 subjects
Other symptoms (headaches, coughing, choking, and speech-related events)	31 of 126 subjects
Mouth dryness	19 of 126 subjects
Functionality issues with implanted system resulting in untreated sleep apnea, undesired stimulation, or a device replacement surgery	21 of 126 subjects
Usability or functionality issues with sleep remote resulting in untreated sleep apnea or undesired stimulation	33 of 126 subjects
Pain due to physical presence of implanted device	14 of 126 subjects
Mild infection	1 of 126 subjects

Two subjects had their devices removed, which required a surgical procedure. One chose to have the stimulator removed, and the leads were capped and left in the patient.

The other had the entire system removed as a precaution due to a nearby infection. Both surgeries were successfully completed without complication. There were 5 deaths over the course of the study all of which were unrelated to Inspire therapy.

Serious Adverse Events

During the five-year clinical study there were nine serious adverse events related to Inspire therapy in eight (6%) of the patients. All of the events involved a surgical procedure to reposition or replace the Inspire system, or at least one component of the Inspire system. One procedure was done to reposition the stimulation lead in order to improve therapy effectiveness. Four more procedures were conducted to reposition components to address patient discomfort. In addition, four patients required surgery to replace the system or a component of the system to improve or restore therapy. These surgeries were completed without any complications.

There were five deaths over the course of the study, all of which were unrelated to Inspire therapy.

Safety and Adverse Events Reported During ADHERE Registry

There was no difference in the rate of serious or non-serious adverse events in both subgroup of patients as observed in STAR trial. There was one report of Rhabdomyolysis in the 35<BMI≤40 group, which is an adverse event that had not been seen previously in the STAR trial.

Safety and Adverse Events Reported During Pediatric Down Syndrome Clinical Study

Of the 42 patients implanted with the Inspire UAS system in the Pediatric Down syndrome Clinical Study, all patients underwent implant without intraoperative complications, and no patients subsequently had the device removed.

Table 3. Complications after Upper Airway Stimulation in Adolescent Patients with Down Syndrome and Obstructive Sleep Apnea

Event	Subjects with Event	Percent of Subjects (n=42)
Nonserious adverse events		
Tongue or oral pain or discomfort	5	11.9%
Rash at surgical site	4	9.5%
Acute insomnia	2	4.8%
Cellulitis at surgical site	2	4.8%
Cheek swelling	1	2.4%
Perioperative urinary retention	1	2.4%
Oral ulcers	1	2.4%
Postobstructive central hypoventilation	1	2.4%
Serious adverse events		
Readmission	5	11.9%[a]
Reoperation	2	4.8%
Pressure ulcer	1	2.4%

[a] Four related to surgery and one unrelated to surgery

The most common post-implant complication was tongue or oral discomfort or pain, which occurred in 5 patients (11.9%) and was temporary. One patient had worsening of central apnea based on the 1-month activation polysomnogram, suggestive of post obstructive central hypoventilation.

Four patients (9.5%) had device- or surgery-related readmissions. The readmissions were the result of device extrusion due to the patient picking at the submental incision (resolved after replacement of the extruded device), surgical site infection at the chest incision exacerbated by patient picking (resolved with antibiotics), poorly controlled postoperative pain, and discomfort from sensing the stimulation in the jaw and chest (resolved without intervention). One readmission was not related to either the device or surgery.

One additional serious adverse event occurred when a patient had a pressure ulcer from extended positioning during the surgery (resolved without intervention).

The reoperation rate was 4.8% (n=2), representing one patient with extruded device and one patient who required revision due to incomplete insertion of the sensing lead. There were no adverse events that led to permanent injury, life-threatening illness, or death.

Benefits from Clinical Study

Inspire therapy significantly reduced the severity of OSA during the 5-year clinical study. The clinical study used two measures of sleep apnea severity: Apnea Hypopnea Index

(AHI) and Oxygen Desaturation Index (ODI). Apnea Hypopnea Index (AHI) is the number of times a person's airway is blocked during an hour of sleep. A patient's AHI was considered treated if it was reduced by half or more and was less than 20. Oxygen Desaturation Index (ODI) is the number of times blood oxygen drops during an hour of sleep. A patient's ODI was considered treated if it was reduced by one fourth or more. The goal of the Stimulation Therapy for Apnea Reduction (STAR) study was to show that at least half of the 126 patients in the study met these AHI and ODI goals after 12 months of therapy.

Twelve months after the Inspire system was implanted, 83 out of 126 patients met the AHI goal (66%) and 94 out of 126 patients achieved the ODI goal (75%). Inspire therapy improved the patients' ability to breathe during sleep. The average improvement in the patients' AHI and ODI continued throughout the 5-year study.

Untreated OSA has a negative impact on sleep and the body's ability to recover during sleep. It can cause daytime sleepiness, reduce mental performance, and reduce quality of life.The STAR study used the Epworth Sleepiness Scale (ESS) and Functional Outcomes of Sleep Questionnaire (FOSQ) scores to evaluate sleepiness and its effect on daily activities of patients. Patients' average ESS and FOSQ scores improved significantly, demonstrating that Inspire therapy improves the overall quality of a patient's life throughout the 5-year study.

Summary of STAR Clinical Study

The Stimulation Therapy for Apnea Reduction (STAR) clinical study evaluated the safety and effectiveness of Inspire therapy in 126 patients for 12 months after the Inspire system was implanted and continued to evaluate a majority of the patients (77%) for a total of five years. The study included adult patients who were not effectively treated using continuous positive airway pressure (CPAP) therapy, and who had moderate to severe OSA.

The STAR clinical study demonstrated the safety and effectiveness of Inspire therapy for the treatment of moderate to severe OSA in adult patients who are not effectively treated by CPAP. For additional information regarding Inspire therapy or the STAR clinical study, contact your doctor.

ADHERE Registry

ADHERE is an ongoing, international, multicenter, observational registry designed to capture outcomes of 5,000 patients implanted with the Inspire™ Upper Airway Stimulation (UAS) System. A retrospective analysis was conducted on a subset of these patients to evaluate the safety and effectiveness of Inspire UAS in obstructive sleep apnea patients (OSA) patients with baseline AHI scores greater than 65 and less than or equal to 100, and with BMI levels above 32 and less than or equal to 40. The retrospective analysis of the AHI subgroups included 1,483 patients and BMI subgroups included 1,218 patients.

Patients in the AHI and BMI subgroups had a final follow up visit with at least one of the following values recorded at that final visit: AHI, ESS, Therapy Usage, CGI (Clinical Global Impression), and/or Patient Satisfaction data.

The results for these patients were compared to those of patients meeting the STAR pivotal trial's patient selection criteria, i.e., those with AHI scores of 65 or less, and with BMI levels less than or equal to 32. The results of the ADHERE data analysis demonstrated that Inspire UAS provides higher AHI and BMI patients with a favorable safety profile, AHI reduction, and quality of life improvements similar to those experienced by the STAR trial patients.

Warnings

Medical Procedures

Diathermy. Do not allow a healthcare provider to use any kind of diathermy at any location on your body. Energy from diathermy can be transferred through your generator or leads, causing tissue damage, which may result in severe injury. Diathermy can also damage your generator or leads.

Magnetic Resonance Imaging (MRI). You are only eligible for certain types of MRI scans. If the precautions provided by Inspire are not followed, exposure to MRI may cause serious injury. This warning applies if any component of the Inspire system remains implanted. For the MRI guidelines, refer to manuals.inspiresleep.com.

Radio-Frequency or Microwave Ablation. You should not be exposed to radio-frequency or microwave ablation. The electrical current can cause heating, especially at a lead electrode site, resulting in tissue damage.

Electrocautery. Avoid the use of electrocautery. Electrocautery tools used near or in contact with your generator or leads can cause tissue damage, uncomfortable stimulation, or damage to the implanted devices.

If electrocautery is necessary, these guidelines must be followed:

- Confirm that therapy is off before using electrocautery.
- Bipolar cautery should be used.
- After electrocautery, your doctor should confirm that the generator is working as intended.

System and Therapy

Training. Physicians must be trained before using or performing any surgical procedure with the Inspire system.

Pediatric Use. The majority of cases of obstructive sleep apnea in younger pediatric patients result from anatomical obstruction which would not be appropriately managed with Inspire therapy**.**

However, some pediatric patients whose sleep apnea is not appropriately managed by surgical removal of the anatomical obstruction may be treated by Inspire therapy. Parents and/or other caregivers of pediatric patients using

Inspire therapy should review this manual with the patient and be prepared to assist them in using Inspire therapy.

Body Mass Index (BMI). Based on the data from the ADHERE Registry, Inspire therapy shows similar safety and effectiveness profile in patients with BMI less than or equal to 40. Inspire does not have data on safety and effectivenesss of the therapy in patients with BMI greater than 40.

Pediatric patients with Down syndrome and a BMI index over the 95th percentile on the Centers for Disease Control and Prevention neurotypical growth curves have not been studied.

Device Damage. Avoid excessive outside force on the generator and leads. Damage to the implanted devices could lead to loss of therapy and tissue damage.

Interaction Between Inspire Generator and Implanted Cardiac Devices. Use caution when considering having both an Inspire system and a cardiac device implanted in the body. The doctors involved with both devices should discuss the possible interactions between the devices before surgery. To minimize device interactions, your doctor should place the devices at least six inches away from one another.

- The electrical pulses from the Inspire system could affect the ability of the cardiac device to sense and respond to heart function as intended. This could result in serious injury.

Precautions

Medical Procedures

Consult your doctor regarding the following medical procedures. These procedures may cause permanent damage to the generator or leads, particularly if used in close proximity:

- Ultrasound probes
- Electrolysis
- Bone growth stimulators
- Laser procedures
- Psychotherapeutic procedures (for example, electroshock therapy)
- Radiation therapy
- High-output ultrasonics / lithotripsy (If lithotripsy must be used, consult your doctor.)

Electromagnetic Interference

The following equipment or environments could generate enough electromagnetic disturbance to create unwanted stimulation or to interfere with the functioning of the implanted system. Avoid them if possible.

- Antennas of citizen band (CB) or ham radios
- Dental drills
- Electric arc welding equipment
- Electric induction heaters

- Electric steel furnaces
- Equipment used for decreasing or eliminating magnetic fields
- High-power amateur transmitters
- High-voltage areas, power lines, or power generators
- Linear power amplifiers
- Large stereo speakers
- Equipment that generates strong magnetic fields
- Microwave communication transmitters
- Perfusion systems (for example, hospital equipment used for maintaining blood flow)
- Resistance welders
- Television and radio transmitting towers

It is possible that equipment not listed above could also generate similar levels of electromagnetic disturbance. If you suspect that equipment is causing unwanted stimulation or interfering with the implanted Inspire system, do the following:

1. Move away from the equipment or object.
2. If possible, turn off the equipment or object.

Inform the equipment owner or operator about the interference. If the above actions do not resolve the effects of the interference, or your therapy is not the same after exposure to electromagnetic interference, contact your doctor.

Theft Detector or Security Screening Devices

Use care when approaching theft detectors and security devices (such as those found in airports, libraries, department stores, and government buildings). When approaching these devices, do the following:

1. Show the security personnel your Inspire identification card and notify them that you have an implanted medical device.
2. Make sure your therapy is off.
3. Proceed through the security device. Do not linger near or lean on the security device.

   Note: Some theft detectors might not be visible.

System and Therapy

Defibrillation. After external defibrillation, confirm that the Inspire system is working as intended by turning therapy on. If therapy does not work as expected, contact your doctor.

Using a Remote From Another Medical Device. Do not try to use the remote from another medical device with your Inspire system. A remote from another medical device will not make the desired (or any) adjustment to your Inspire system.

Sleep Remote and MRI Scans. Do not bring your sleep remote into the MRI scanner (magnet) room. Bringing the remote into the MRI scanner room could cause damage to the remote and make it unable to function.

Patient Activities

Component Manipulation (Twiddler's Syndrome). Do not move or rub your generator or leads through your skin; this is sometimes called “twiddler's syndrome.” Manipulation of the implanted devices can cause damage, dislodgement, skin damage, or unintended stimulation.

Scuba Diving or Hyperbaric Chambers. Do not dive below 30 meters (100 feet) of water or enter hyperbaric chambers above 4.0 atmospheres absolute (ATA). Pressures below 30 meters (100 feet) of water (or above 4.0 ATA) can damage your generator or leads. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your doctor.

Skydiving, Skiing, or Hiking in the Mountains. High altitudes should not affect the generator, however, you should consider the movements involved in any planned activity and take precaution to not put undue stress on your generator or leads. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or break a lead, requiring additional surgery to repair or replace the lead.

Pediatric Use

- For pediatric and some adolescent patients, there is a potential to grow out of your OSA without intervention in some cases. Therefore, please give serious consideration and discuss with your doctor the decision to surgically implant this device.

- In younger patients undergoing this surgical implantation, please take into consideration the need for a lifetime of serial surgical reimplantation for battery replacements, which may potentially be associated with future surgical complications.
- Parents are advised to monitor pediatric patients and to discourage touching or scratching the skin around the implant area, to avoid complications such as excessive scarring or other injury.

MRI Examinations

Your Responsibilities Before the Appointment

Bring your patient identification (ID) card to every MRI appointment. The patient ID card will identify your implanted device and it contains the website where your MRI clinician can obtain instructions about your eligibility for an MRI scan.

Bring your sleep remote to every MRI appointment so the physician can confirm that your Inspire system is functioning normally before and after your MRI scan. However, do **not** take the remote into the MRI scanner (magnet) room.

Bring the manual for your sleep remote to every MRI appointment.

At the MRI Appointment

Present your patient ID card to the MRI clinician and inform the clinician that you have an implanted system. Be sure to inform the MRI clinician of any other implanted components.

To obtain the MRI guidelines, the MRI clinician can go to manuals.inspiresleep.com. You must meet eligibility requirements before getting an MRI scan.

Prior to an MRI scan, the therapy must be turned off. Instructions for turning therapy off can be found in the remote manual or at manuals.inspiresleep.com.

Other Medical Procedures

If you need or desire a procedure like diathermy or an MRI scan for which you are not eligible, consult your doctor about alternative procedures. For example, your doctor may suggest that you use X-ray, CT scan, or ultrasound in the place of an MRI procedure.

Mobile Devices and Common Household Electrical Items

Most of the electrical devices that you encounter in an ordinary day are unlikely to affect your Inspire system. However, electromagnetic interference can impact you and your Inspire system in certain situations. The following equipment is unlikely to affect your system if you follow these guidelines:

- *Mobile phones and other radio-frequency sources (tablet computers, AM/FM radios, cordless and conventional telephones):* Keep these items at least 15 cm (6 in) away from the generator.

- *Induction range:* Keep the generator away from the range while the burners are turned on. Induction ranges, unlike conventional electric stoves, use magnetic fields to generate heat.
- *Power tools:* Keep the motor away from the generator and leads.
- *Sewing machines or salon hair dryer:* Keep the generator away from the motors.

If you suspect that equipment is causing unwanted stimulation or is interfering with your Inspire system, do the following:

1. Move away from the equipment.
2. If possible, turn off the equipment.
3. If you have a question about your Inspire system after exposure to electromagnetic interference, contact your doctor.

FCC Supplier's Declaration of Conformity

Supplier's Declaration of Conformity
47 CFR § 2.1077 Compliance Information

Unique Identifier: Inspire Generator Model 3028

Responsible Party - U.S. Contact Information

Inspire Medical Systems
5500 Wayzata Blvd, Suite 1600
Golden Valley, MN 55416
(844) OSA-HELP
(844-672-4357)

FCC Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

3. Inspire Upper Airway Stimulation Therapy

Your Inspire System

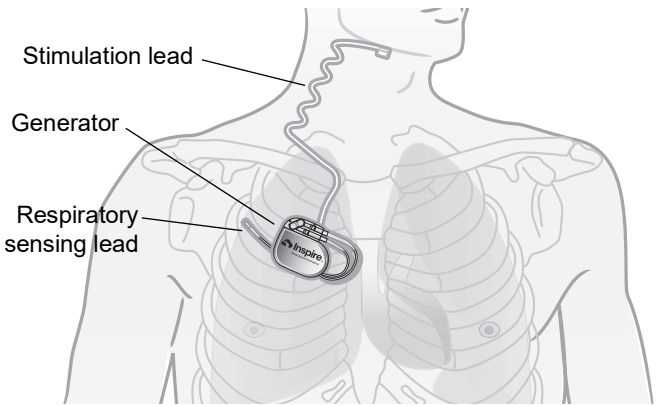


Figure 2. *Implanted components of the Inspire system*

The implanted components of the Inspire system (Figure 2) are a generator, a stimulation lead, and a respiratory sensing lead. For more detailed information about each component, refer to “Specifications” on page 35.

- **Generator —** Contains the battery and electronics that provide stimulation.
- **Respiratory Sensing Lead —** When therapy is on, this lead monitors your breathing.
- **Stimulation Lead —** When therapy is on, this lead delivers stimulation to activate the muscles in your upper airway.

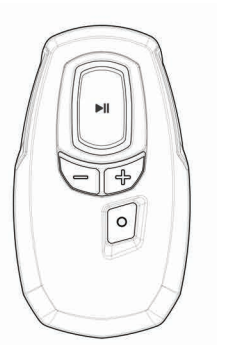


Figure 3. *Sleep remote*

After you have healed from the surgical procedure, your doctor will adjust your therapy settings so your sleep apnea is treated effectively. You will receive your sleep remote (Figure 3), which allows you to turn therapy on and off. You will also be able to adjust the stimulation strength within a range determined by your doctor.

Therapy Summary

Inspire therapy is only used when you are sleeping. Turn your therapy off during the day.

When you are preparing to go to sleep, use your sleep remote to turn your therapy on. You will feel a brief stimulation confirming that therapy has been turned on. After the confirmation, stimulation is delayed so you have time to fall asleep.

When the delay time has passed, the Inspire system keeps your airway open by delivering mild stimulation to the nerve that controls the tongue. The stimulation causes the upper airway muscles to stiffen, preventing airway blockages. The therapy does not wait for an apnea to occur before delivering stimulation.

Stimulation is delivered throughout the night to prevent apneas.

Frequently Asked Therapy Questions

What does stimulation feel like?

Most patients report that the stimulation is a mild sensation. Stimulation results in movement of the upper airway muscles and tongue. Stimulation strength can be adjusted so that therapy is comfortable and effective.

Will I feel anything when I turn therapy on?

Yes. When therapy is turned on you should feel stimulation for a few seconds. Then stimulation is delayed for a period of time while you fall asleep. After this start delay, stimulation resumes.

How long will my generator battery last?

Typical battery life is about 10 years. However, your generator battery life depends on how often therapy is used and your therapy settings. Most generator batteries will last at least 7 years.

How is the battery replaced?

To replace the generator battery, your doctor replaces the entire generator. A surgical procedure is required.

Is it normal for the stimulation sensation to change when I change position?

Yes, it is normal to notice minor changes in stimulation sensation when you change sleeping positions.

Will I need additional sleep studies?

You will need at least one sleep study so your doctor can adjust your therapy settings. Your doctor may need additional sleep studies to monitor and adjust your therapy settings.

Is it safe for me to have an MRI scan?

Your Inspire system was designed, tested, and approved to be used safely with MRI scanners under certain conditions.

The electromagnetic fields present during MRI scans have the potential to cause tissue damage. The design of the Inspire system allows for MRI under certain conditions that are known to be safe.

Prior to receiving an MRI scan, your doctor will verify that you meet the patient eligibility requirements.

During the MRI procedure, you are monitored continuously to ensure your safety.

Can I use my therapy while sleeping in an airplane?

Yes, you can use the therapy in an airplane.

The Surgical Procedure

The generator, respiratory sensing lead, and stimulation lead are implanted during a surgical procedure.

Understanding the Surgical Procedure

The surgical procedure lasts approximately 2 hours and you will be asleep during the procedure.

The surgeon makes 2 or 3 small skin incisions (cuts) on your body: one on your chest, one on your neck, and sometimes one near your rib cage.

The majority of patients are able to return home on the same day or the day following the surgery.

After the Surgical Procedure

To allow for healing, therapy is usually not turned on for several weeks after the surgical procedure.

During the 2 to 6 weeks after surgery, it is normal to feel some discomfort from the incisions and to have some pain at the implant sites. Follow your doctor's instructions for post-surgical care. If you are a parent or caregiver of a pediatric patient, make sure the child does not scratch their incision sites. Call your doctor if you notice signs of infection such as redness and swelling near an implant site.

Once you start to use Inspire therapy, your doctor will schedule regular follow-up visits. During the initial visits, your doctor may need to adjust your therapy settings as your body heals and adjusts to your Inspire system.

Your doctor will monitor your generator battery status and adjust your therapy settings so your therapy continues to be comfortable and effective. Make sure to tell your doctor if your therapy becomes uncomfortable or if you believe that it is not effective.

Whenever you visit your doctor, make sure to bring this manual with you.

Sleep Studies

You will have at least one sleep study. During the study, your Inspire system settings will be adjusted to best treat your sleep apnea. You may have additional sleep studies to

monitor and adjust your therapy. Your doctor will determine when sleep studies are needed.

Activities and Exercise

On the advice of your doctor, and as you begin to feel better after your surgery, you can gradually resume your normal lifestyle. Returning to your daily activities should make you feel better, not worse. It is important that you follow your doctor's advice. Ask your doctor about any strenuous activities, such as lifting heavy objects.

Caution: For several weeks after the implant procedure, avoid sudden, excessive, or repetitive bending, twisting, or stretching. These types of activities could affect your healing process and cause you discomfort.

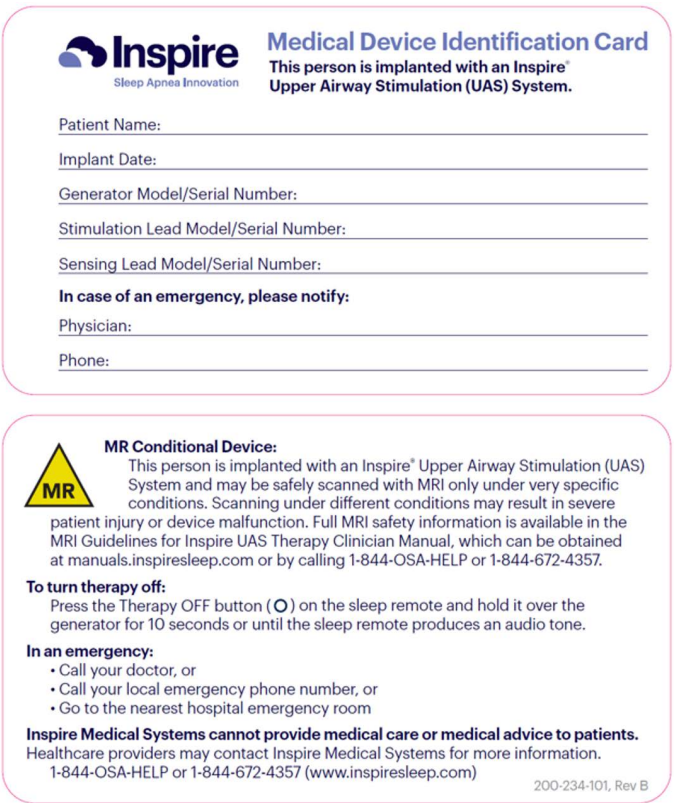
Security Screening and Travel Information

It is possible that airport security devices may affect the operation of your generator and detect the metal in your generator. Always tell security staff that you have an implanted generator and carry your Inspire Identification Card for verification.

For detailed instructions about how to interact with security devices, refer to “Theft Detector or Security Screening Devices” on page 18.

Your Inspire Identification Card

Your doctor gave you an identification card (Figure 4) which has important information about your Inspire system.



Inspire
Sleep Apnea Innovation

Medical Device Identification Card

This person is implanted with an Inspire® Upper Airway Stimulation (UAS) System.

Patient Name:

Implant Date:

Generator Model/Serial Number:

Stimulation Lead Model/Serial Number:

Sensing Lead Model/Serial Number:

In case of an emergency, please notify:

Physician:

Phone:

MR

MR Conditional Device:
This person is implanted with an Inspire® Upper Airway Stimulation (UAS) System and may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction. Full MRI safety information is available in the MRI Guidelines for Inspire UAS Therapy Clinician Manual, which can be obtained at manuals.inspiresleep.com or by calling 1-844-OSA-HELP or 1-844-672-4357.

To turn therapy off:
Press the Therapy OFF button (O) on the sleep remote and hold it over the generator for 10 seconds or until the sleep remote produces an audio tone.

In an emergency:
- Call your doctor, or
- Call your local emergency phone number, or
- Go to the nearest hospital emergency room

Inspire Medical Systems cannot provide medical care or medical advice to patients.
Healthcare providers may contact Inspire Medical Systems for more information.
1-844-OSA-HELP or 1-844-672-4357 (www.inspiresleep.com)

200-234-101, Rev B

Figure 4. *Inspire Identification Card*

Carry your identification card at all times. In the event of an accident, this card supplies information about your Inspire system and identifies your doctor. If you need to bypass devices with strong magnetic fields, such as a theft detector or an airport security device, you can present your identification card to the screening personnel.

Bring this card with you to all MRI appointments (see “MRI Examinations” on page 20).

If you lose your identification card or your contact information changes, contact your doctor.

Manufacturer's Information

Your primary resource for all questions and requests is your doctor. As an additional resource, you may contact Inspire Medical Systems, Inc:

Address: 5500 Wayzata Blvd, Suite 1600
Golden Valley, MN 55416

Phone: 763-205-7970 or 1-844-672-4357 Toll Free

Website: www.inspiresleep.com

4. Specifications

Generator	
Height	46 mm (1.8 in)
Length	51 mm (2.0 in)
Thickness	8.4 mm (0.33 in)
Tissue-Contacting Material	Titanium, polyurethane, silicone

Stimulation Lead	
Tissue-Contacting Material*	Platinum/Iridium, polyurethane, silicone elastomer, silicone adhesive, polyether urethane, barium sulfate, titanium dioxide, silicone rubber

Respiratory Sensing Lead	
Tissue-Contacting Material*	Silicone elastomer, silicone adhesive, silicone rubber, barium sulfate, blue colorant, polyether urethane

* The leads are available with either silicone or polyurethane outer tubing. Speak to your physician if you have any questions or concerns about either material.

Inspire Medical Systems Limited Warranty

Summary

Inspire provides a limited warranty against defects. The warranty period for implanted products is 3 years. All other products have a warranty period of 1 year.

The warranty information below is intended for doctors (referred to as physicians in the warranty), but is included here for reference. Ask your doctor if you have any questions. The information below takes precedence over the information contained in this Summary.

Inspire Medical Systems' products consist of Implantable Pulse Generators (IPG), tools to connect the IPG to implantable leads, leads, Inspire Sleep Remotes, and physician programmers.

1. **EXCLUSION OF WARRANTIES, NO WARRANTIES FOR TOOLS.** The implied warranties of MERCHANTABILITY and fitness for a particular purpose and all other warranties, express or implied with regard to tools are EXCLUDED from any transaction and shall not apply. Inspire Medical Systems will not be liable for any damages, whether direct, consequential, or incidental caused by tool defects, failures, or malfunctions, whether such claims are based on warranty, contract, tort or otherwise. No person has any authority to bind Inspire Medical Systems to any representation or warranty with respect to tools. You may have other rights, which vary from state to state. If one or more of the provisions of this exclusion of warranties for tools shall be deemed void or unenforceable, the remaining provisions shall continue to have full force and effect.
2. **LIMITED WARRANTY FOR PRODUCTS OTHER THAN TOOLS.** This limited warranty is available if products other than tools fail to function within normal tolerances due to defects in materials or workmanship that manifest during the specified warranty period.

During the operational life of an IPG, battery energy is consumed to monitor the patient's breathing and provide therapy. On the basis of individual patient physiology, certain patients may require more frequent therapy, thus requiring replacement of the IPG in less than the warranty period shown below. This is considered normal for those patients and not a malfunction or defect in the IPG.

If the purchaser complies with the Terms and Conditions, Inspire Medical Systems will issue a limited warranty toward the purchase of a new Inspire Medical Systems IPG product. The limited warranty credit amount will be the full purchase price of either the original unit or the replacement unit, whichever is less.

- For patient products, for example, IPG, lead, Inspire Sleep Remote, Inspire Medical Systems will issue a credit to the hospital conducting replacement surgery on behalf of the original patient. Any cost reductions extended as a result of this warranty shall be fully and accurately reflected on the patient's bill and reported to that applicable payor using the appropriate methodology.
- For physician products, for example, physician programmer, Inspire Medical Systems will issue a credit to the original purchaser of the product.

A. Terms and Conditions

1. The product labeling must indicate a limited warranty exists.
2. For implantable products, this limited warranty applies only for a product replacement in the original patient.
3. All registration materials must be completed and returned to Inspire Medical Systems within 30 days of first use.
4. The product must be replaced with an Inspire Medical Systems product.
5. If the product is implantable, it must be implanted before the product expires and implanted with other Inspire Medical Systems products.

6. The product must be returned to Inspire Medical Systems, 5500 Wayzata Blvd, Suite 1600, Golden Valley, MN 55416 within 30 days that the product first fails to function within normal tolerances. The product may be returned at no cost to you. Contact your Inspire Medical Systems representative for information on how to return the product.
7. Inspire Medical Systems will inspect the returned product and determine whether a limited warranty credit is due.
8. All products returned to Inspire Medical Systems become its property.

This limited warranty represents the entire obligation of Inspire Medical Systems for products other than tools and is made IN LIEU OF any other warranties, whether express or implied, including MERCHANTABILITY or fitness for a particular purpose.

Inspire Medical Systems will not be liable for any damages, whether direct, consequential, or incidental caused by product defects, failures, or malfunctions, whether such claims are based on warranty, contract, tort or otherwise.

No person has any authority to bind Inspire Medical Systems to any warranty or representation except those specifically contained herein.

This limited warranty gives specific legal rights, and you may also have other rights, which vary from state to state. If one or more of the provisions of this limited warranty shall be deemed void or unenforceable, the remaining provisions shall continue to have full force and effect.

B. Limited Warranty Period

The applicable limited warranty period for each product is listed and calculated as follows:

1. Three (3) years from date an IPG or lead is implanted in the patient.
2. One (1) year from the date a physician or Inspire Sleep Remote is first used.

Inspire
Sleep Apnea Innovation

Manufacturer
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5500 Wayzata Blvd, Suite 1600
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