inspire®
UPPER AIRWAY STIMULATION

PATIENT MANUAL

Inspire II Implantable Pulse Generator Model 3024

Rx Only

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Table of Contents

Glossary

Amplitude — See Stimulation Strength.

Apnea — A temporary absence of breathing.

Apnea-Hypopnea Index (AHI) — An index that provides information regarding the severity of a person's sleep apnea.

Atrial fibrillation — A type of abnormal heartbeat.

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

Body Mass Index (BMI) — A number based on a person's weight and height that serves as an indicator for healthy or unhealthy body composition.

Caution — A statement describing actions 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 without effort to breathe.

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

Defibrillation/Cardioversion — The use of electricity to treat an abnormal heart rhythm.

Diathermy — A medical treatment applied to the outside of the body that delivers energy into the body. Depending on the power level used, diathermy devices may or may not produce heat within the body. This treatment is typically

used to relieve pain, stiffness and muscle spasms, reduce joint contractures (in other words, shortening of muscles or tendons), reduce swelling and pain after surgery, and promote wound healing.

Dysphasia — Impaired speech.

Electrocautery — A process that uses heat produced by electric energy to destroy tissue.

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 stimulator or sleep remote from working properly. For example, electromagnetic interference could prevent your stimulator from communicating with your sleep remote.

Hypoglossal Nerve — The nerve that controls tongue movement.

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

Lead — A thin, implanted wire with protective coating that connects to the stimulator. The Inspire system has a respiratory 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.

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

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 and off, 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 pulses to the nerve that controls tongue movement (see Hypoglossal Nerve).

Stimulation Strength — The stimulation level (amplitude) measured in volts.

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

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

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

Upper Airway — The breathing path from the mouth and nostrils to the larynx (voice box).

Ventricular fibrillation — An abnormal heartbeat that can be life-threatening.

Warning — A statement describing an action or situation that could seriously harm the patient.

1. Introduction

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

You had a surgical procedure to implant the Inspire stimulator and leads (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.

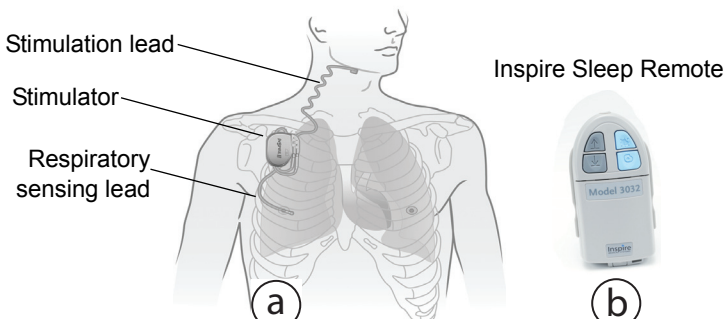

Figure 1. *Inspire system*

About This Manual

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

If you have questions that are not answered in this manual, or if any unusual situations or 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 20 and less than or equal to 65). 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 20 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).

Contraindications

Contraindications for the use of Inspire therapy include the following:

- Central and mixed apneas make up over 1/4 of the total apnea-hypopnea index (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
- Patients who require magnetic resonance imaging (MRI)
- 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

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, nausea, headaches, 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 months.

Once the therapy is turned on, there are additional risks such as 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 stimulator settings.

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. If you and your doctor decide to remove the system, another surgery will be required.

Ask your doctor for additional information regarding the risks of implant, use and removal of the Inspire system.

Benefits

Untreated obstructive sleep apnea (OSA) has a negative impact on sleep and the body's ability to recover during sleep. As a result, OSA patients may experience a high degree of daytime sleepiness, which affects mental performance.

Inspire therapy has been demonstrated to significantly reduce the severity of OSA. Proper treatment may lead to an increase in the ability to perform daily tasks and a decrease in the risk of accidents (eg, motor vehicle accidents). In addition, OSA has been linked to hypertension, stroke,

diabetes, heart failure, and early mortality. Treatment of OSA has been shown to reduce serious health side effects including these examples.

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 stimulator or leads, causing tissue damage, which may result in severe injury or death. Diathermy can also damage your stimulator or leads.

Magnetic Resonance Imaging (MRI). You should not be exposed to Magnetic Resonance Imaging (MRI). Exposure to MRI can damage your stimulator or leads, cause serious injury, or result in unintended stimulation. This is the case even if you have had the stimulator removed and only the leads remain implanted.

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 that come in contact with your stimulator or leads can cause damage to the component, tissue damage, or uncomfortable stimulation.

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 stimulator is working as intended.

Defibrillation / cardioversion. When you are in ventricular or atrial fibrillation, the first consideration is your survival. Use caution if defibrillation or cardioversion is necessary. External defibrillation or cardioversion can damage your Inspire system and can result in injury. After external defibrillation, your doctor should confirm that the Inspire system is working as intended.

System and Therapy

Training. Physicians must be trained in the proper use and surgical procedure before implantation or operation of the device.

Pediatric use. The majority of cases of obstructive sleep apnea in younger pediatric patients (eg, less than 18 years of age) result from anatomical obstruction (eg, adenotonsillar hypertrophy) which would not be appropriately managed with neurostimulation therapy**.**

Body Mass Index (BMI). BMI greater than 32 was not studied as part of the pivotal trial. Based on data from the feasibility study it may be associated with decreased likelihood of response to treatment. Use of Inspire UAS in

higher BMI patients is not recommended due to unknown effectiveness and safety.

Stimulator damage. Avoid excessive outside force on the stimulator. If the stimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

Interaction between Inspire stimulator and implanted cardiac devices. Use caution when considering the presence of both an Inspire stimulator and an implanted cardiac device. When a stimulator and an implanted cardiac device (eg, pacemaker, defibrillator) are required, the doctors involved with both devices (eg, neurologist, neurosurgeon, cardiologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery. To minimize or prevent device damage or interactions, your doctors should place the devices on the opposite side of the body from one another.

- Defibrillation therapy from an implanted defibrillator can damage the stimulator.
- 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 stimulator, particularly if used in close proximity to the device:

- Dental drills and ultrasonic 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 potentially create unwanted stimulation from your stimulator. Avoid them if possible.

- Antennas of citizen band (CB) or ham radios
- 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 (safe if outside the fenced area)
- Linear power amplifiers
- Large stereo speakers
- Magnets or other equipment that generate strong magnetic fields
- Microwave communication transmitters (safe if outside the fenced area)
- Perfusion systems (for example, hospital equipment used for maintaining blood flow)
- Power lines or power generators
- Resistance welders
- Television and radio transmitting towers (safe if outside the fenced area)

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 you suspect that 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 ask for a manual search. If security personnel use a handheld security wand, ask them not to hold the security wand near the stimulator longer than needed.
2. If you must pass through the theft detector or security screening device, make sure your therapy is off. When walking through the device, keep as far from it as possible.

   Note: Some theft detectors might not be visible.
3. Proceed through the security device. Do not linger near or lean on the security device.

System and Therapy

Pediatric use. The safety of implantation and the parameters for safe and effective stimulation of the hypoglossal nerve have not been evaluated in clinical studies for patients less than 22 years of age. There may be increased risk of nerve injury and stimulation-related adverse events in this population, particularly in younger children (eg, less than 12 years of age).

Using a programmer from another medical device. Do not try to use the programmer from another medical device with your Inspire system. A programmer from another

medical device will not make the desired (or any) adjustment to your Inspire system.

Patient Activities

Component manipulation (twiddler's syndrome). Do not manipulate (move) or rub your stimulator or leads through your skin; this is sometimes called “twiddler's syndrome.” Manipulation can cause damage to the components, lead dislodgement, skin damage, or unintended stimulation.

Scuba diving or hyperbaric chambers. Do not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) can damage your stimulator 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 stimulator; however, you should consider the movements involved in any planned activity and take precaution to not put undue stress on your stimulator 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.

Other Medical Procedures

If you need or desire a procedure like MRI or diathermy, consult your doctor about alternative procedures. For example, your doctor may suggest that you use X-ray, a CT (computerized tomography) 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 stimulator.
- *Computer disk drives:* Keep the stimulator away from disk drives.
- *Induction range:* Keep the stimulator away from the burners while the burners are turned on. Induction ranges, unlike conventional electric stoves, produce magnetic fields to generate heat.

- *Power tools:* Keep the motor away from the stimulator and leads.
- *Sewing machines or salon hair dryer:* Keep the stimulator away from the motors.

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

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

Stimulation Therapy for Apnea Reduction Clinical Study

Results from the Stimulation Therapy for Apnea Reduction (STAR) clinical study are below. If you have any questions about the clinical study information, contact your doctor.

Study Results

The Inspire system delivers Inspire Upper Airway Stimulation (UAS) therapy to treat obstructive sleep apnea (OSA).

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. The study included adult

patients who were not effectively treated using continuous positive airway pressure (CPAP) therapy, and who had moderate to severe OSA.

Methods

The Inspire system includes an implanted stimulator, stimulation lead, and respiratory sensing lead. The Inspire system also includes an Inspire Sleep Remote™ that allows the patient to turn stimulation on and off and adjust stimulation.

For the STAR clinical study, the Inspire system was implanted in 126 patients. The data for the safety and effectiveness evaluation was collected for 12 months after the Inspire system was implanted.

Efficacy Results

The primary measures of OSA severity are the apnea hypopnea index (AHI) and the oxygen desaturation index (ODI). The STAR clinical study determined the percentage of patients who achieved at least a 50% reduction in AHI and had their AHI reduced to less than 20.

The study also determined the percentage of patients who had at least a 25% reduction in ODI. These patients were called ‘responders’, and the goal of the study was to show a 50% responder rate (63 out of 126).

Twelve months after the Inspire system was implanted, the AHI responder rate was 83 out of 126 (66%), and the ODI responder rate was 94 out of 126 (75%).

During the 13th month of therapy, 46 responders were divided up into 2 groups at random. One group kept their therapy turned on, and they continued to have significant reductions in their OSA severity. The other group turned their therapy off for one week, and their OSA severity increased to levels close to the levels measured before using Inspire therapy. When their therapy was turned on again, their OSA severity returned to the levels measured before turning the therapy off.

Study subjects were also given questionnaires to measure the impact of their OSA on their quality of life. These questionnaires were the Functional Outcomes of Sleep Questionnaire (FOSQ) and the Epworth Sleepiness Scale (ESS) questionnaire. The average scores for the entire patient population showed a significant improvement in ESS and FOSQ scores.

Safety Results

For the safety evaluation, the STAR subjects were followed for 18 months. After 18 months, there were no unanticipated events and only 2 events which required surgical intervention.The surgical intervention involved the repositioning of the stimulator and stimulation lead due to discomfort at the stimulator implant site.

Many of the procedure-related adverse events are of the kind to be expected with a surgical procedure. The procedure related events (and the probability of

experiencing those events within the first 18 months) included:

- Incision pain (35 out of 126 [28%])
- Post-operative discomfort (31 out of 126 [25%])
- Temporary tongue weakness (23 out of 126 [18%])
- Sore throat from intubation during implant (15 out of 126 [12%])
- Headache (8 out of 126 [6%])
- Other post op symptoms, such as nausea, (14 out of 126 [11%])
- Mild infection (1 out of 126 [1%])

After 18 months, 159 out of 171 (93%) of procedure-related events were fully resolved with either no intervention or medication.

The device related adverse events (and the probability of experiencing those events within the first 18 months) included:

- Discomfort due to electrical stimulation (59 out of 126 [47%])
- Tongue abrasion (30 out of 126 [24%])
- Mouth dryness (14 out of 126 [11%])
- Mechanical pain associated with presence of device (10 out of 126 [8%])
- Complaints regarding temporary usability or functionality issues with an implanted device (14 out of 126 [11%])

- Complaints regarding temporary usability or functionality issues with an external device (13 out of 126 [10%])
- Other acute symptoms, such as headaches, coughing, choking, dysphasia and speech related events (21 out of 126 [17%])
- Mild infection (1 out of 126 [1%])

After 18 months, 162 of the 217 (75%) device-related events were fully resolved primarily with medication, device reprogramming, dental work to fix a jagged tooth, or with the aid of a lower tooth guard used during sleep to prevent tongue abrasions, or no intervention.

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 3 deaths over the course of the study all of which were unrelated to Inspire therapy. There were 32 serious adverse events (SAE) 2 of which were related to Inspire therapy.

Conclusion

The STAR clinical study supported FDA approval 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, contact your doctor.

3. Inspire Upper Airway Stimulation Therapy

Your Inspire System

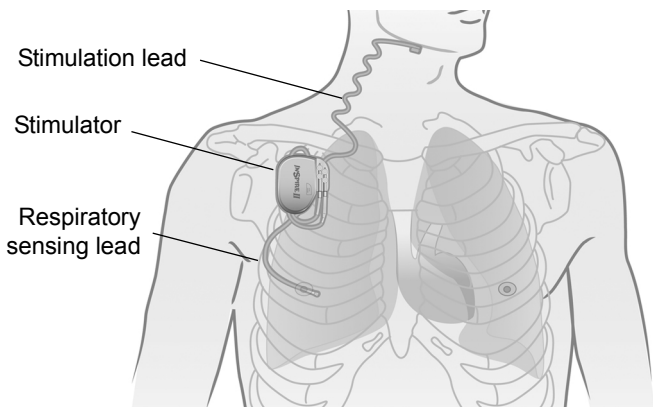

Figure 2. *Implanted components of the Inspire system*

The implanted components of the Inspire system (Figure 2) are a stimulator, a stimulation lead, and a respiratory sensing lead. For more detailed information about each component, refer to “Specifications” on page 27.

- **Stimulator —** 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 settings so your sleep apnea is treated effectively. At this point, you will receive your sleep remote (Figure 3), which will allow 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. You will turn your therapy off during the day.

When you are preparing to go to sleep, you will 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 delivers mild stimulation to the nerve that controls your tongue movement (the hypoglossal nerve) as it senses breathing. 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 an involuntary movement of the upper airway muscles and/or tongue. If the stimulation strength is too high, the upper airway may have a strong response that may be uncomfortable. 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 a brief 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 stimulator battery last?

Typical battery life is approximately 10 years. However, your stimulator battery life depends significantly on the number of hours you have therapy on and the therapy settings. The lower end for battery life is approximately 7 years.

How is the battery replaced?

To replace the stimulator battery, your doctor replaces the entire stimulator. 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.

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.

The Surgical Procedure

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

Understanding the Surgical Procedure

The surgical procedure lasts approximately 2 hours and requires general anesthesia.

To implant the components, the surgeon makes 3 small skin incisions (cuts) on the right side of your body: one on your chest, one near your rib cage, and one on your neck.

Taking into consideration your comfort during the activities of daily life and minimizing the visible effects of the surgery, the surgeon determines where to place the components.

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. 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 follow-up

visits, your doctor may need to adjust your therapy settings as your body heals and adjusts to your Inspire system.

During continued follow-up visits, your doctor will monitor your stimulator 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. Typical patients have about three sleep studies. 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, bouncing, or stretching. These types of activities could affect your healing process and cause you discomfort.

Travel Information

It is possible that airport security devices may affect the operation of your stimulator and detect the metal in your stimulator. Always tell security staff that you have an implanted stimulator and carry your Inspire Identification Card for verification. This also applies if you encounter similar security devices in other travel situations.

For detailed instructions about how to interact with security devices, refer to “Theft Detector or Security Screening Devices” on page 11.

Your Inspire Identification Card

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

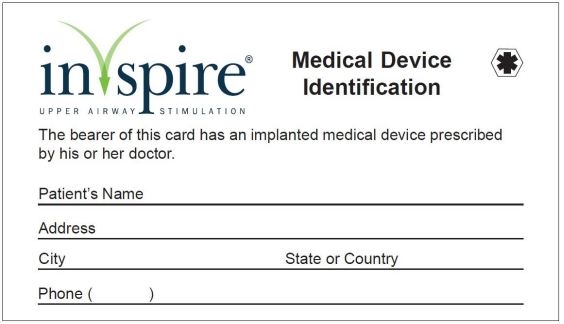

Figure 4. *Inspire Identification Card*

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. Also, 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.

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: 9700 63rd Ave N, Maple Grove, MN 55369

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

Website: www.inspiresleep.com

4. Specifications

Stimulator	
Height	52 mm (2 in)
Length	60 mm (2.4 in)
Thickness	10 mm (0.4 in)
Weight	49 g (2 oz)
Tissue-Contacting Material	Titanium, polyurethane, silicone rubber, parylene coating

Stimulation Lead	
Length	25, 35, 45 cm (10, 14, 18 in)
Lead Diameter	1.5 mm (0.06 in)
Tissue-Contacting Material	Platinum/Iridium, polyurethane, silicone elastomer, silicone adhesive, polyether urethane

Respiratory Sensing Lead	
Length	25, 35, 45 cm (10, 14, 18 in)
Lead Diameter	2.3 mm (0.1 in)
Tissue-Contacting Material	Silicone elastomer, silicone adhesive, silicone rubber

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 patients' 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, 9700 63rd Avenue North Maple Grove, MN 55369 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.

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