inspire®
UPPER AIRWAY STIMULATION

PATIENT MANUAL

Inspire II Implantable Pulse Generator Model 3024

Rx Only

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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.

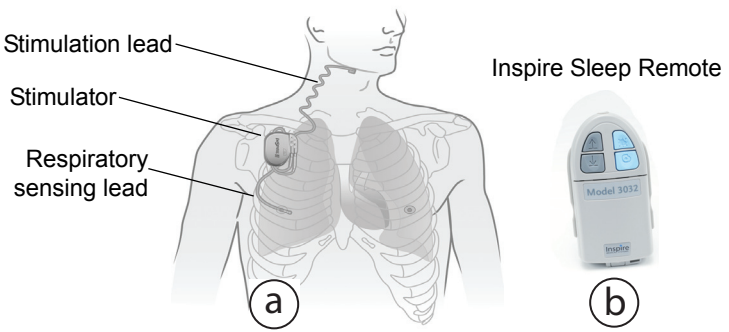

Figure 1. *Inspire system*

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 15 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 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).

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

- 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

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.