



# SYSTEM IMPLANT MANUAL

Inspire II Implantable Pulse Generator Model 3024  
Stimulation Lead Model 4063  
Sensing Lead Model 4323

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**USA** Rx Only



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## Explanation of Symbols on Product or Package Labeling

Refer to the appropriate product for symbols that apply.



Open here



Do not reuse



Sterilized using ethylene-oxide gas



Use by



Serial number



Temperature limitation

**SENSE**

Lead that inserts into SENSE (sensing) port of IPG

**STIM**

Lead that inserts into STIM (stimulation) port of IPG



Caution, consult accompanying documents



Consult instructions for use



Date of manufacture



Manufacturer



Reference number



The Inspire therapy system is MR unsafe

The following is a trademark of Inspire Medical Systems, Inc.: Inspire®

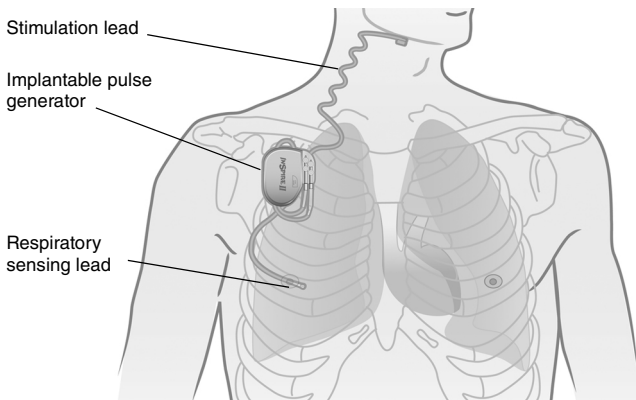
## Indications for Use

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 than 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).

## Therapy Overview

The implanted components of the Inspire therapy system consist of the Inspire II implantable pulse generator (IPG) Model 3024, the stimulation lead model 4063, and the respiratory sensing lead model 4323 (Figure 1).



**Figure 1.** Inspire system implanted components

When therapy is on, the Inspire system detects the patient's respiratory effort and maintains airway patency with mild stimulation of the hypoglossal nerve.

Therapy settings are stored in the IPG and configured by the physician using an external programmer.

The patient uses their Inspire sleep remote to turn therapy on before they go to sleep and to turn therapy off when they wake up. The sleep remote also provides the ability to pause therapy and adjust stimulation amplitude within physician defined limits.

## **Overview of the Manual**

This manual provides physicians with implant procedure and follow-up care information for the Inspire system. The manual includes instructions for handling, storing, and implanting the leads and IPG. Critical therapy information is provided for you to discuss with your patient, as well as instructions for follow-up care. General resterilization instructions for the IPG are also provided; the leads cannot be resterilized. Information on explanting the IPG and leads is included. This manual also explains how to register your patient's medical devices.

## **Sterile Package Contents**

The leads and IPG are provided in separate sterile packages.

### **Inspire II Implantable Pulse Generator (Model 3024)**

- One IPG
- One hex wrench
- Product literature (system implant manual, patient manual, patient registration form, and patient ID card)



## Implanted Component Descriptions

The implanted components of the Inspire system consist of an IPG, a respiratory sensing lead, and a stimulation lead. All implanted Inspire system components are intended for single-use only.

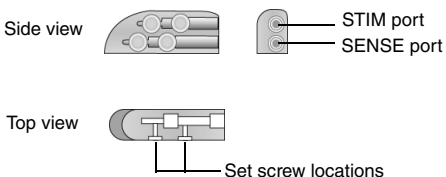
### IPG

The IPG (Figure 2) contains the battery and electronics that deliver Inspire therapy and store the therapy settings.



**Figure 2.** IPG

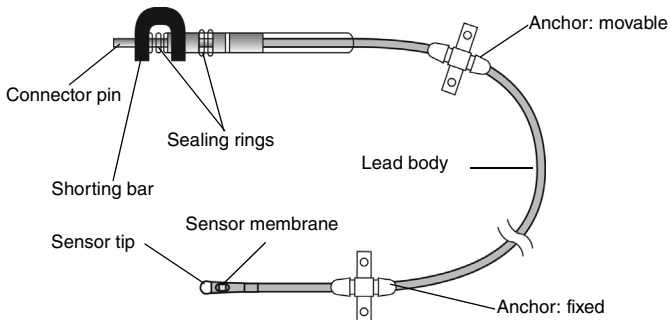
The IPG has two 3.2 mm low-profile connector ports (Figure 3), which are compatible with the connectors on the stimulation lead and the respiratory sensing lead. After inserting the lead connectors into the IPG connector ports, the lead connectors are secured using the set screws next to the connector ports.



**Figure 3.** IPG connector ports

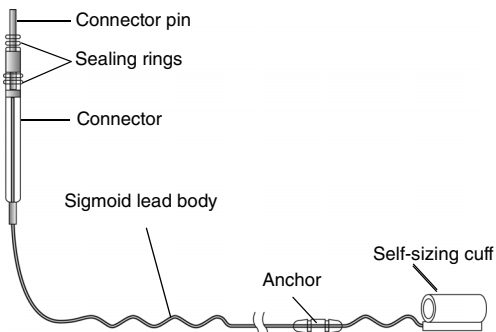
## Leads

The respiratory sensing lead (Figure 4) detects respiratory effort. The lead has a pressure-sensitive membrane that converts the mechanical energy of respiration into an electrical signal.



**Figure 4.** Respiratory sensing lead

The stimulation lead (Figure 5) delivers stimulation to the hypoglossal nerve. The lead has a flexible, self-sizing stimulation cuff. The stimulating electrodes are on the inner surface of the cuff.



**Figure 5.** Stimulation lead

## Contraindications

Contraindications for the use of Inspire UAS therapy include the following:

- Central + mixed apneas > 25% of the total apnea–hypopnea index (AHI)
- Any anatomical finding that would compromise the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate
- Any condition or procedure that has compromised neurological control of the upper airway
- Patients who are unable or do not have the necessary assistance to operate the sleep remote
- Patients who are pregnant or plan to become pregnant
- Patients who will require magnetic resonance imaging (MRI)
- Patients with an implantable device that may be susceptible to unintended interaction with the Inspire system. Consult the device manufacturer to assess the possibility of interaction.

## Adverse Effects

Possible adverse effects include, but are not limited to, the following patient related conditions:

- Damage to blood vessels in the vicinity of implant
- Excessive bleeding
- Nerve trauma or damage
- Allergic and/or rejection response to the implanted materials
- Infection
- Local irritation, seroma, hematoma, erosion, or swelling
- Persistent pain, numbness, or inflammation at the implant site
- Discomfort from the stimulation
- Tongue movement restrictions, irritation resulting from tongue abrasions on preexisting sharp or broken teeth
- Tongue soreness or weakness
- Problems with swallowing or speaking
- Undesirable change in stimulation over time, possibly related to tissue changes around the electrode(s), shifts in electrode position, loose electrical connections, or lead fractures
- Fibrosis to the extent that it makes it difficult to remove the system without damaging surrounding structures
- Dry mouth
- Other acute symptoms (i.e., headaches, coughing, choking, dysphasia, and speech related events)
- Insomnia

# Warnings and Precautions

## Warnings

- **Training** — Physicians must be trained in the proper use and surgical procedure before implantation or operation of the device.
- **Pediatrics** — The majority of cases of obstructive sleep apnea in younger pediatric patients (e.g., less than 18 years of age) result from anatomical obstruction (e.g., adenotonsillar hypertrophy) that would not be appropriately managed with neurostimulation therapy.
- **Components** — The use of components not provided by Inspire Medical Systems may result in damaged components, improper operation, or increased risks to the patient.
- **Diathermy** — Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy can also damage the neurostimulation system components, resulting in loss of therapy and requiring additional surgery for system explantation and replacement. Advise your patient to inform all their health care professionals that they should not be exposed to diathermy treatment.

Injury to the patient or damage to the device can occur during diathermy treatment when:

- The neurostimulation system is turned on or off
- Diathermy is used anywhere on the body—not just at the location of the neurostimulation system
- Diathermy delivers heat or no heat
- Any component of the neurostimulation system (lead, extension, neurostimulator) remains in the body
- **Magnetic Resonance Imaging** — The use of magnetic resonance imaging (MRI) among IPG patients has been contraindicated by MRI manufacturers. Patients who have any component of the Inspire system implanted should not undergo MRI. MRI can cause tissue damage as well as damage to the Inspire system and components.
- **Sleep remote use** — When operating their Inspire sleep remote, patients should use special care near flammable or explosive atmospheres. An interaction between the flammable or explosive atmospheres and the battery in the sleep remote could occur. The consequences of using the battery-powered sleep remote near flammable or explosive atmospheres are unknown.
- **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.

## Precautions

### General

- **Pediatrics** — 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 (e.g., less than 12 years of age).
- **Expiration date** — Do not use any Inspire system product after its expiration date.
- **Component handling** — Precautions related to component handling during the implant procedure are located on page 18.
- **Storage temperature ranges**
  - Do not expose the IPG to temperatures above 52°C (125°F) or below -18°C (0°F).
  - Do not expose the leads to temperatures above 55°C (131°F) or below -10°C (14°F).

### Electromagnetic compatibility and medical procedures

For information on MRI and diathermy, see “Warnings” on page 12.

The IPG is designed to ensure immunity from most common sources of electromagnetic disturbance. In most cases, turning off the electromagnetic disturbance source, or moving away from the electromagnetic disturbance source will return the IPG to normal operation. Extremely strong sources of electromagnetic disturbance could interfere with normal IPG operation, causing the IPG to reset and requiring the IPG to be reconfigured. To reduce the possibility of electromagnetic interference (EMI), patients are recommended to use therapy only while asleep.

### Medical environment

Electrocautery, irradiation, lithotripsy, RF-ablation, X-ray, and fluoroscopy are typical electromagnetic disturbance sources in hospital and clinical environments. Medical treatments that use ultrasonics, defibrillation, or radiation can adversely affect the Inspire system.

- **Electrocautery** — Electrocautery may induce failure of the IPG. Alternatives to electrocautery should be used when available. Bipolar electrocautery should be used if alternatives are not available. If electrocautery must be used in the vicinity of the IPG, therapy should be turned off.
- **Radiation therapy** — The IPG should not be directly irradiated by therapeutic levels of ionizing radiation (such as produced by cobalt machines or linear accelerators used for cancer treatment) because of the risk of permanent damage to the IPG circuitry. If such therapy is required in the vicinity of the IPG, shield the device and confirm its function after treatment.
- **RF-ablation** — RF-ablation should not be used directly over the implant sites.
- **X-ray and fluoroscopy** — Exposure to diagnostic X-ray or fluoroscopic radiation should not affect the IPG or leads.
- **Therapeutic ultrasound** — Exposure to high ultrasonic frequencies may result in damage to the IPG or leads. It is not recommended to use high-output ultrasonic devices, such as an electrohydraulic lithotripter or bone growth stimulator on patients with an implanted IPG.

- **Ultrasonic scanning** — While there is no danger to the patient, ultrasonic scanning equipment could cause mechanical damage to an IPG or leads if used directly over the implant sites.
- **Defibrillation** — Defibrillation used anywhere on the patient's body can cause permanent damage to the IPG. Following defibrillation, the IPG should be interrogated to verify normal operation.

### **Home or work environment**

Based on laboratory tests of the IPG, the device should not be affected by the normal operation of electrical equipment, household appliances, electric machine shop tools, microwave ovens, internal combustion engines, low-powered radio, and microwave frequency transmitters. All such equipment should be kept in good repair and properly grounded to avoid the possibility of electrical shock or interference with the proper operation of the IPG.

Inspire therapy is intended for use during sleep only and should be turned off otherwise.

- **Equipment operation** — Patients should not operate potentially dangerous equipment, such as power tools, during stimulation.
- **Theft detectors** — In general, theft detectors have been known to cause inadvertent and potentially uncomfortable stimulation in neurological stimulation systems. Patients should use care to avoid theft detectors and be aware in the presence of such systems.
- **High-powered electric fields** — Consult Inspire Medical Systems when the patient will be in an area where contact with current carrying conductors is possible or near high-powered electromagnetic fields radiated by arc welding units, induction furnaces, induction stoves, resistance welders, radio or microwave frequency transmitters, etc.
- **Mobile and cellular phones** — Maintain a separation of at least 15 cm (6 in) between a phone and the IPG.

## Storage and Handling

Recommendations for storage and handling of the IPG and leads are provided in this section. Inspire Medical Systems sterilizes the IPG and leads with ethylene oxide (EtO) prior to shipment.

Information about precautions for handling components is located on page 18.

### IPG

Inspect the IPG and the lead sterile packages prior to opening. If the IPG package is damaged, the IPG may be damaged as well. Return a damaged package to Inspire Medical Systems; see the back cover of this manual for addresses.

**Table 1. IPG Storage and Handling**

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<b>Handling and Storage: Acceptable</b>	<b>Unacceptable</b>
Store and transport IPG within the following environmental temperature limits: -18°C (0°F) to +52°C (125°F). A full or partial electrical reset condition may occur at temperatures below -18°C (0°F).	Do not implant the IPG if it has been dropped on a hard surface from a height of 30 cm (12 in) or greater.

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**Resterilization**

Resterilization is not allowed.

- IPGs cannot be resterilized. If the sterile package seal is broken, or if the packages are otherwise damaged, do not use.
- Return the package to your local Inspire Medical Systems representative, see back cover for address.

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## Leads

If the lead sterile package seal is broken or the package is otherwise damaged, return the package to Inspire Medical Systems. Leads cannot be resterilized.

**Table 2. Lead Storage, Handling, and Resterilization**

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<b>Handling and Storage: Acceptable</b>	<b>Unacceptable</b>
<p>Store and transport leads within the following environmental temperature limits: -10°C (14°F) to +55°C (131°F).</p> <p>Only use sterile-gloved hands to handle the lead; rinse sterile surgical gloves in sterile water before handling the lead.</p> <p>Protect leads from materials that shed lint and dust.</p> <p>Exercise care and appropriate instrument selection when handling the stimulation lead cuff with a surgical instrument.</p>	<p>Do not implant a lead that was dropped.</p> <p>Avoid excessive traction or sharp instruments.</p> <p>Avoid severe bending, kinking, stretching, or handling with surgical instruments.</p> <p>Do not immerse a lead in mineral oil or silicone oil.</p> <p>Do not expose the respiratory sensing lead to static electricity.</p>
<hr/> <b>Resterilization</b>	
<p>Leads cannot be resterilized.</p> <ul style="list-style-type: none"><li>• If the sterile package seal is broken, or if the packages are otherwise damaged, do not use.</li><li>• Return the package to Inspire Medical Systems; see the back cover of this manual for addresses.</li></ul>	

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## Physician Training

Prior to implanting an Inspire system, surgeons will receive classroom instruction on Inspire implant techniques as well as cadaver training. Sleep physicians and sleep technicians will receive classroom instruction on how to titrate the device including hands on operation of the programmer.

## System Implant

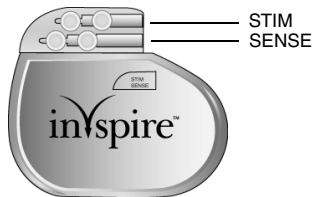
This section describes a general implant procedure for the Inspire system.

### Implantable Components

The Inspire system includes the following implantable components:

- Inspire II implantable pulse generator (Model 3024)
- Inspire respiratory sensing lead (Model 4323)
- Inspire stimulation lead (Model 4063)

The IPG has two lead connector ports (Figure 6). The connector port for the respiratory sensing lead is marked **SENSE**. The connector port for the stimulation lead is marked **STIM**.



**Figure 6.** IPG and connector ports

## Procedure Overview

The implant procedure begins with preoperative planning. It is recommended that the stimulation lead be the first Inspire component to be implanted. Secondly, a subcutaneous pocket is created for the IPG. The connector end of the leads will be tunneled to this pocket. After the stimulation lead is implanted, the respiratory sensing lead is implanted. After tunneling the connector end of the leads to the IPG pocket, the leads are connected to the IPG and the IPG is secured in the subcutaneous pocket.

## Patient Preparation

- Ensure the tongue is visible during the surgical procedure in order to observe the response to intraoperative test stimulation.
- The recommended body side for system implantation is the right side.
- Extend the patient's right arm away from his or her side to allow access to the thorax for respiratory sensor implantation.
- The patient's head and neck should be positioned to provide optimal access to the hypoglossal nerve.
  - Antimicrobial incise drape may be used.
  - Use only short acting paralytic agent to preserve tongue response.
- A nerve monitoring system is recommended to locate the hypoglossal nerve and confirm nerve recruitment.
- Surgical incisions are recommended to be made on natural skin creases to minimize visible scarring.
- The patient should be given antibiotics preoperatively as well as postoperatively.

## Surgical Materials

An Inspire system implant requires typical surgical equipment used during neck surgeries. The following is a list of additional materials typically used during the system implant procedure:

- Sterile sleeve, bag or equivalent (to bring the telemetry cable into the sterile field)
- Right angled forceps or hemostat (for cuff electrode placement)
- A nerve monitoring and stimulation system (to locate the hypoglossal nerve and confirm nerve recruitment)

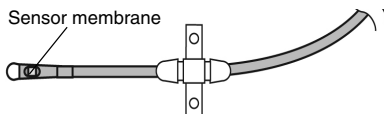
## Precautions for Handling Components

- The implanted components of this system should be carefully handled to avoid damage by excessive traction or sharp instruments. Any component showing signs of damage should not be used.



**Caution:** No instrument of any type should touch the sensor membrane. The sensor membrane covers the sensor, the flat square recessed surface near the tip of the respiratory sensing lead. Touching the sensor membrane will result in damage to the sensor.

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**Figure 7. Sensor membrane**

- IPG drop — If the IPG is dropped more than 30 cm (12 in) onto a hard surface, it should not be used.
  - Setscrew cautions — Counterclockwise rotation of a set screw beyond one or two revolutions while retracting it from the connector port may disengage the setscrew from the connector block. Do not use any hex wrench other than the one packaged with the IPG.
  - Leads should be handled with great care at all times. Any severe bending, kinking, stretching, or handling with surgical instruments may cause permanent damage to the lead body or the cuff. Do not implant a lead that was dropped.
  - Lead insulators attract small particles, such as lint and dust; therefore, to minimize contamination, protect the lead from materials shedding these substances. Handle the lead with sterile surgical gloves that have been rinsed in sterile water.
  - Do not immerse leads in mineral oil or silicone oil.
- **Static electricity** — The respiratory sensing lead is sensitive to static electricity. Therefore, the shorting bar should be left in place and removed just prior to implant.



**Cautions:**

- The black, U-shaped shorting bar must not be removed except during tunneling and immediately prior to connecting the lead to the IPG.
  - After tunneling, if the lead is not immediately connected to the IPG, the black, U-shaped shorting bar must be reattached.
-

## Stimulation Lead Implant

The stimulation lead is designed with a cuff that is placed around the hypoglossal nerve after the nerve is exposed.

The following is an overview of the recommended process for implanting the stimulation lead:

- Expose the hypoglossal nerve (see “Exposing the hypoglossal nerve” below).
- Place the cuff around the nerve and irrigate the cuff and nerve with sterile saline.
- Test the electrode placement using the IPG or an external nerve stimulator.
- Secure the stimulation lead anchor to the digastric muscle with permanent sutures.
- Form the IPG pocket and tunnel the lead connector to the pocket.

### Exposing the hypoglossal nerve

1. Make a 4–6 cm (1.6–2.5 in) incision along a natural skin crease from 3–4 cm (1.2–1.6 in) below the right edge of mandible.
2. Retract the submandibular gland cephalad.
3. Identify the digastric muscle, and carefully dissect in the submandibular triangle to identify the hypoglossal nerve.
4. Once the nerve is identified, it may be stimulated at a low setting (for example 0.5 mA) using an external nerve stimulator to confirm nerve function. Do not over stimulate the nerve with the external device.
5. Expose 1–2 cm (0.4–0.8 in) length of the hypoglossal nerve.

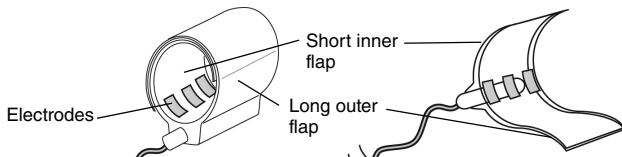


#### Cautions:

- Do not apply tension to the nerve and supporting tissue while exposing the nerve and placing the cuff.
  - Preserve the small nutrient blood vessels along the nerve fibers.
  - Maintain hemostasis. Fluid residuals increase the chances of hematoma formation and infection.
- 

### Placing the stimulation lead

To place the stimulation lead cuff, the cuff's short inner and long outer flaps (Figure 8) are wrapped around the hypoglossal nerve.



**Figure 8.** Stimulation lead cuff flaps

Refer to Figure 9 while completing cuff placement steps 1 through 4.

1. Using a right-angled forceps positioned under the nerve, grab the long outer flap.



**Caution:** Do not force the cuff into position. Be sure that a sufficient opening has been cleared. Forcing the cuff into position may result in nerve damage.

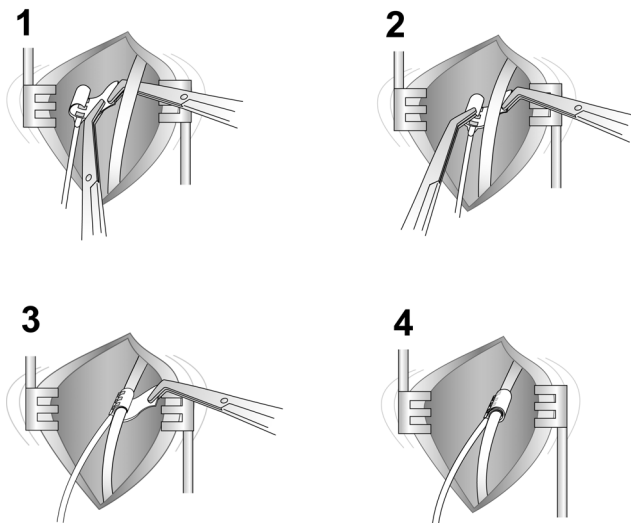
2. Hold the short inner flap open.
3. Pull the short inner flap over the nerve, then lay the long outer flap over the inner flap.



**Cautions:**

- Be sure that the cuff flaps are properly placed.
- Do not suture the cuff around the nerve. The cuff is designed to expand and contract with the nerve. Suturing the cuff in place may result in nerve damage.

4. Make sure both flaps encircle the nerve.
5. Irrigate the cuff and nerve with sterile saline to facilitate adequate electrical contact between the electrodes and the nerve.



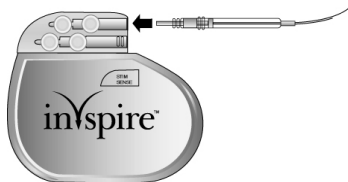
**Figure 9.** *Placing the cuff around the hypoglossal nerve*

## Test Stimulation

Use intraoperative test stimulation to help confirm proper lead position. Steps 1–6 describe test stimulation with the IPG; step 7 describes an alternative method using a stimulator other than the IPG.

1. Confirm that IPG therapy is off.
2. Insert the stimulation lead connector into the IPG connector port marked **STIM** (Figure 10).

**Note:** Refer to page 31 for instructions on connecting the stimulation lead to the IPG.



**Figure 10.** Insert the stimulation lead into the connector port marked **STIM**

3. Program the IPG using the physician programmer (see the programming manual for instructions). It is recommended to start at 0.5 volts and increase stimulation in 0.2 volt increments. Conduct intraoperative test stimulation while observing the tongue and neck area for signs of patient muscle response to stimulation.
4. Verify that the stimulation gives the appropriate response. Reposition the lead as necessary. During and after repositioning of the lead, apply sterile saline to the cuff to facilitate electrical contact of the cuff electrodes with the nerve. Continue to reposition the cuff if a stimulation response does not occur.
5. Confirm that IPG therapy is off when finished with intraoperative test stimulation.
6. Carefully disconnect the stimulation lead connector from the IPG.



### **Cautions:**

- Use care not to dislodge the lead.
  - Use care to not loosen the IPG set screws too far, which can result in the set screws unseating from the connector.
- 

7. Alternate method:
  - a. Use an approved external stimulator to conduct intraoperative test stimulation as an alternative to using the IPG.
  - b. The external stimulator will require sterile wires to interface with the connector of the stimulation lead.
  - c. Repeat the stimulation process described in steps 3 and 4 above to ensure proper placement of the cuff.

## Securing the Stimulation Lead

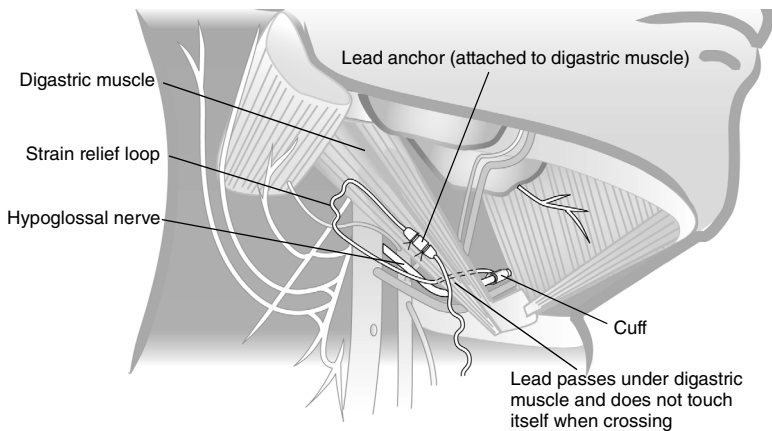
The stimulation lead is anchored to the tissues surrounding the hypoglossal nerve. The suggested method for anchoring the lead body is to anchor it to the digastric muscle using permanent sutures (Figure 11).

1. Position the cuff and stimulation lead:
  - Maintain the cuff and stimulation lead body parallel to the nerve to avoid placing torque or tension on the nerve.
  - It is recommended that the spine of the cuff is positioned inferior to the nerve.
2. Secure the stimulation lead with adequate strain relief by creating a lead loop in between the stimulation lead cuff and the anchoring site (e.g., digastric muscle).
3. Using both anchor recesses, tie permanent sutures to the anchor, then secure the anchor to the digastric muscle using the sutures.
4. It is recommended that the physician not close the neck incision until all system components are implanted and tested. Consider gently packing the neck incision with 4x4 gauze soaked in a saline/antibiotic solution. Remove such packing with care prior to closing the incision so as not to dislodge or disrupt the cuff placement.



### **Cautions:**

- Make sure that the anchor points are located in tissue that moves with the hypoglossal nerve.
  - Do not loop the lead such that the lead body crosses and touches itself. Crossing the lead bodies can result in fibrosis at the intersection point and reduce strain relief in the lead body.
  - Place sutures only around the anchor region of the lead.
  - Surgical instruments should not be used to handle the lead body directly. The lead is easily kinked and the insulation is easily damaged. Care should be used when handling the lead. Surgical instruments may be used for handling the lead anchor.
-



**Figure 11.** Anchoring the stimulation lead



## Making the IPG Pocket

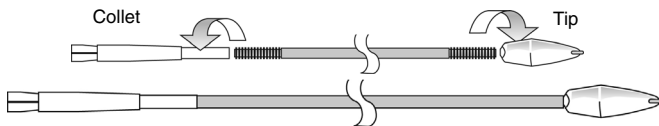
When selecting the location for the IPG pocket, consider patient lifestyle factors, such as the use of firearms, carrying backpacks, and other work or recreation related activities. The following instructions reflect the typical IPG pocket location.

1. Make a 5–6 cm (1.9–2.4 in) incision mid-line 2–3 cm (0.8–1.2 in) below the right clavicle, taking precautions to ensure that the patient's typical arm movements with activities of daily living will not cause the IPG to ride up onto the clavicle.
2. Make a subcutaneous pocket of sufficient size to contain the IPG and any excess lead wrap, which can typically be expected.

## Tunneling the Lead

These instructions apply to both the stimulation lead and the respiratory sensing lead. Use the tunneling tool to pass the lead connector from the point of lead implantation to the subcutaneous pocket, avoiding sharp angle bends of the lead body. An intermediate incision between the lead implant site and the IPG subcutaneous pocket is usually not necessary.

1. Locate the sterile tunneling tool (Figure 12) provided with the stimulation lead packaging.
  - Prior to assembly, the rod may be bent into a bow shape to aide tunneling. Generally, it is better to make multiple gentle bends than a single sharp bend.
  - The tool is assembled by threading the tip and the collet assembly to the stainless steel rod. Attach the tip first and the collet only after the tunnel is established.



**Figure 12.** Tunneling tool components

2. Simulate the final positioning by identifying where the lead connector will exit the eventual tunnel.
3. Tunnel the tunneling tool from the lead incision to the IPG pocket before attaching the collet. Advance the tunneling tool subcutaneously until the tip is exposed in the IPG pocket.



### Cautions:

- Follow the tunneling path established in step 2. Deep tunneling is not desirable. Pass the lead superficially to avoid damage to deep structures.
  - To avoid damage to the lead or body tissue, do not use excessive force or surgical instruments when using the tunneling tool.
  - For the stimulation lead, tunneling the lead under the clavicle bone is not recommended. A lead tunneled under the clavicle bone creates an increased risk of damage to veins and/or arteries.
  - To avoid damage to the collet, do not attach it to the tunneling tool until the tunnel is established from the lead implant site to the IPG pocket.
-



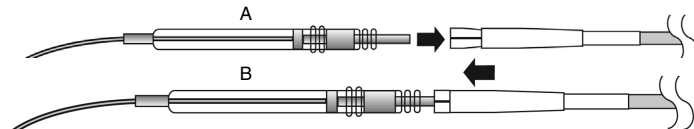
**Caution:** For the respiratory sensing lead, to avoid electrical damage to the sensor, avoid using cautery during the tunneling procedure and prior to connecting the lead to the IPG. The black, U-shaped shorting bar must be attached to the lead if cautery is performed and the lead is not connected to the IPG.

- For the respiratory sensing lead, remove the shorting bar from the connector; for the stimulation lead, proceed to step 5.



**Caution:** Avoid touching the lead connector within 2 cm (0.8 in) from the end after the shorting bar is removed and until the lead is connected to the IPG.

- Insert the lead connector into the tunneling tool collet as follows:
  - Slide the collet sleeve down toward the tunneling tool tip to allow the lead connector to be inserted into the collet.
  - Insert the pin of the lead connector into the collet of the tunneling tool (Figure 13 A)
  - Slide the sleeve over the collet to lock the connector pin in place (Figure 13 B).
  - It is not necessary to exert excessive force to secure the sleeve over the collet.



**Figure 13.** Inserting lead connector into tunneling tool collet

- Gently pull the lead out through the exit site in the IPG pocket.



**Caution:** Be sure the lead is routed so as to avoid sharp bends or kinks in the lead body.

- Remove the lead from the tunneling tool by sliding back the sleeve from the collet.

## Respiratory Sensing Lead Implant

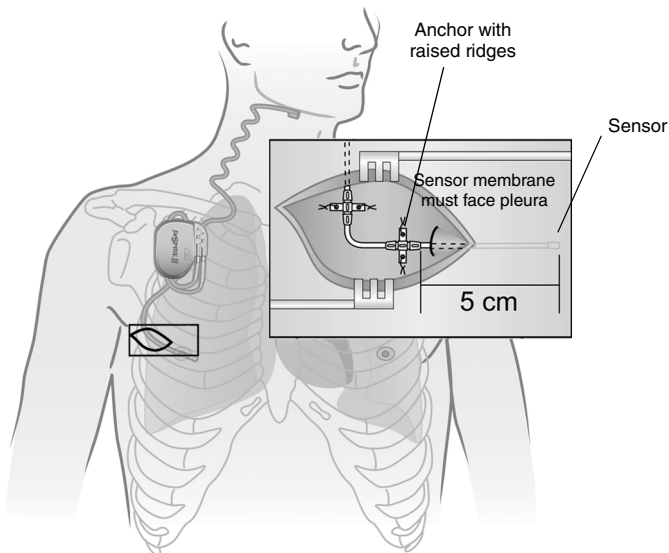


### Cautions:

- Use care when handling the lead. The pressure sensor is susceptible to damage due to electrostatic discharge. Leave the black U-shaped clip on the connector in place except during tunneling and connection to the IPG.
- Do not touch the recessed sensing membrane of the sensor with surgical tools as this will damage the sensor.

The respiratory sensing lead is placed in the extrapleural space (Figure 14).

The potential complications of bleeding and tension pneumothorax can be avoided by positioning the incision as outlined in the following steps:



**Figure 14.** Respiratory sensing lead extrapleural placement

1. Make a 4–6 cm (1.6–2.4 in) incision starting near the midaxillary line, parallel to the ribs, and toward midline on the right side of the chest.

**Note:** The respiratory sensing lead will be tunneled approximately 3–5 cm (1–2 in) in length between the intercostal muscle layers, and therefore the incision should be approximately 3–5 cm (1–2 in) from the desired sensor location. The desired sensor location is in line with the nipple.

**Note:** A neurovascular bundle is located inferior to each rib. Therefore, implantation of the sensor should be as close as possible to the superior rib surface.

2. Place the sensor between ribs 2–6, with a preference for the 4th or 5th intercostal space.
3. Use sharp and blunt dissection to expose the intercostal muscle layers.
  - Dissection is required to reach and identify the internal intercostal muscle.
  - The sensor will be inserted between the internal intercostal muscle and the external intercostal muscle layers.

4. Insert the tip of the respiratory sensing lead between the internal and external intercostal muscle layers at a shallow angle along the superior edge of the inferior rib forming the intercostal space.

**Note:** Enter the intercostal space toward the medial side of the incision in order to provide lateral space for lead anchoring within the incision.

5. Insert approximately 3–5 cm (1–2 in) of the length of the distal lead between the internal and external intercostal muscle layers.
  - The sensor membrane (flat surface) is required to face toward the pleura.
  - Raised ridges on the distal anchor are to face up, which confirms that the sensor membrane is facing toward the thoracic cavity.
6. Secure the respiratory sensing lead with permanent sutures using the two winglet features and two grooves of each of the two anchors on the respiratory sensing lead (i.e., eight total sutures to secure both anchors).
  - Ensure that the sensor membrane orientation is maintained during suturing of the anchors.

**Note:** The distal anchor is adhered to the lead body, and the second anchor may be slid along the lead body to the desired position. If the second anchor does not slide, use saline to moisten the lead body, which may improve the ability to slide the anchor. Position the sliding anchor to direct the lead toward the IPG pocket. Leave a small amount of excess lead length between the two sutures to allow the sutures to move with the body without placing tension on the lead. The excess lead should form an omega shape between the two lead anchors.

7. Suture the anchor in place to the subcutaneous tissues.
8. Check that the lead body exiting the intercostal muscles transitions smoothly before tunneling to the IPG pocket, forming the recommended omega-shaped strain relief between the two anchors.



**Caution:** Do not loop the lead such that the lead body crosses and touches itself. Crossing the lead bodies can result in fibrosis at the intersection point and reduce strain relief in the lead body.

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9. Tunnel the connector end of the respiratory sensing lead to the IPG pocket using the tunneling tool. Refer to “Tunneling the Lead” on page 25 for instructions.

## Connecting the Leads and IPG

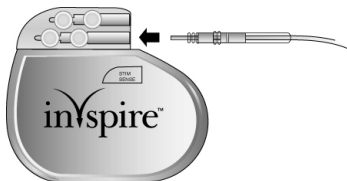


**Caution:** Saline or bodily fluids in the IPG connector may reduce battery longevity.

- Do not allow saline or bodily fluids to enter the IPG connector ports.
- Confirm that lead connectors are dry prior to inserting them into the IPG ports.
- Use care when inserting the hex wrench to avoid damage to the seals.
- Confirm that setscrew seals fully close after securing the lead in place.

Connect the respiratory sensing lead to the IPG

1. Wipe off any body fluids from the respiratory sensing lead connector.
2. Grasping the lead approximately 3 cm (1.2 in) from the connector end, insert the lead connector into the IPG connector port marked **SENSE** (Figure 15).
  - Make sure the lead connector is fully inserted into the IPG connector port by verifying that the lead connector pin reaches the back of the IPG connector port cavity.



**Figure 15.** Insert the respiratory sensing lead connector into IPG connector port marked **SENSE**

3. Use the white-handled hex wrench to tighten the 2 setscrews adjacent to the **SENSE** port (Figure 16) until resistance is felt, then tighten each screw 1/4 turn more. Do not over tighten.
  - Tighten the setscrew furthest from the lead port first.
  - Prior to tightening the setscrew nearest to the lead port, gently tug the lead to confirm that the first setscrew has secured the lead in place.
  - After tightening both setscrews, confirm that the seals covering the setscrews are fully closed.

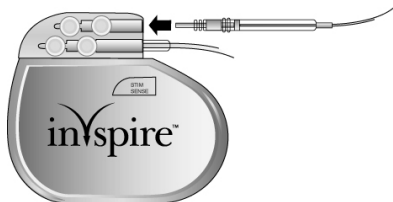


**Figure 16.** Tighten the two lower setscrews

4. Test the sensor function as follows:
  - a. Place the telemetry cable into a sterile sleeve and hold the telemetry head centered over the IPG.
  - b. Verify sensor function by observing a sensor waveform on the using the programmer.
  - c. Once function has been verified, turn the therapy off.

### Connect the stimulation lead to the IPG

1. Wipe off any body fluids from the stimulation lead connector.
2. Grasping the lead approximately 3 cm (1.2 in) from the connector end, insert the lead connector into the IPG connector port marked **STIM** (Figure 17).
  - Make sure the lead connector is fully inserted into the IPG connector port by verifying that the lead connector pin reaches the back of the connector port cavity.



**Figure 17.** Insert stimulation lead connector into IPG connector port

3. Use a white-handled hex wrench to tighten the 2 setscrews adjacent to the **STIM** port (Figure 18) until resistance is felt, then tighten each screw 1/4 turn more. Do not over tighten.
  - Tighten the setscrew furthest from the lead port first.
  - Prior to tightening the setscrew nearest to the lead port, gently tug the lead to confirm that the first setscrew has secured the lead in place.
  - After tightening both setscrews, confirm that the seals covering the setscrews are fully closed.

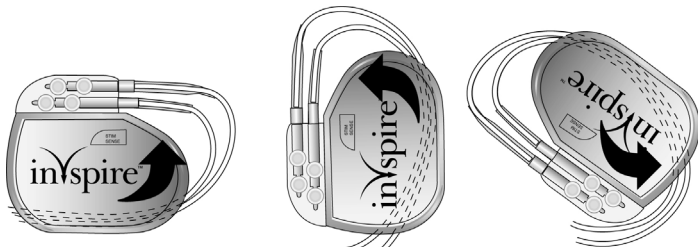


**Figure 18.** Tighten the two upper setscrews

## Implanting the IPG

When implanting the IPG, consider patient lifestyle factors, such as the use of firearms, carrying backpacks, and other work or recreation related activities.

1. Wrap the excess lead body behind the IPG (Figure 19) and position the IPG and wrapped excess lead body in the pocket. Implant the IPG with the logo facing up toward the skin.

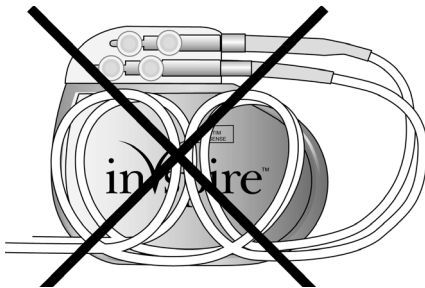


**Figure 19.** Wrap excess lead length



**Caution:** When placing the IPG and leads into the subcutaneous pocket:

- Do **not** coil the leads. Coiling the leads (Figure 20) can twist the lead bodies and may result in lead dislodgement.
- Do **not** grip the leads or IPG with surgical instruments.
- Ensure that the IPG logo is facing up toward the skin.



**Figure 20.** Do not coil excess lead length

2. Test the system using the physician programmer.
  - a. Place the telemetry cable into a sterile sleeve and hold the telemetry head centered over the IPG.
  - b. To check stimulation function, evaluate both the stimulation response and the sensor waveforms. Refer to the physician programming manual for instructions.



3. Following the system function check, verify that the therapy is off and the stimulation amplitude is programmed to 0 volts. It is recommended to keep the therapy off for the first month after the implant surgery to allow for healing and encapsulation of the stimulation lead.

## **Completing the Implant Procedure**

After testing, complete the implant procedure:

1. Secure the IPG by placing permanent sutures through one of the two suture holes and attaching to the fascia (not to muscle).
2. Irrigate all incision sites with a generous amount of bacitracin and saline solution or equivalent before closing.
3. Close the surgical incisions.
4. At the discretion of the physician, antibiotics may also be administered postoperatively.

## **Postoperative Follow-up**

Follow up with normal postoperative care. A 7–14 day check of surgical incision healing is recommended.

To allow for healing after surgery, the system should not be activated for about 1 month following implant. Refer to the Inspire programmer manual for additional information.

Regular patient follow-up should be scheduled to monitor the condition of the IPG battery and to confirm that the therapy values are appropriate.

## Physician Instructions to Patient

Give the patient information concerning the Inspire system. This should include information on the IPG, the sleep remote, the stimulation lead, and the respiratory sensing lead.

Patients should be instructed as follows:

- It is normal to feel some discomfort from the incisions and to have some pain at the implant sites for 2–6 weeks.
- It is best to avoid bending or twisting for several weeks after the implant procedure, as such movements could impair the healing process. This time period allows the leads and IPG to fix themselves more securely in place.
- Avoid physical activities that could damage the implant site or implanted device.
- Inform personal physicians, consulting physicians, or dentists that they have an implanted stimulation system.
- Carry their Inspire Medical Systems ID card at all times.

The "Precautions" section on page 13, which includes information about cellular phones and electromagnetic interference in the home or work environment, should also be conveyed to the patient.

## Patient Registration

Upon completion of the registration form by the clinician, this form serves as a permanent record of facts related to the implanted device. A copy of this form should be returned to Inspire Medical Systems. Refer to the back cover of this manual for mailing address.

## Therapy Activation

Inspire therapy should be activated approximately 4 weeks after the implant procedure to allow for healing.

## Therapy Titration

At least one sleep study will be needed approximately 4–8 weeks after therapy activation to titrate stimulation settings. Additional titration sleep studies may be needed to improve therapy effectiveness and patient comfort.

# Surgical Revision and Explant

## Lead Repositioning

- If the stimulation or respiratory sensing lead becomes displaced, any repositioning should be attempted as soon as possible, before scar tissue builds up.
- If the lead must be repositioned (or removed) proceed with caution to avoid damage to surrounding tissue.
- Extreme forces used during removal can damage leads or result in dismantling of the leads.
- If removal is unavoidable, return the removed lead, or portion thereof, to Inspire Medical Systems.

## System or IPG Explant

- Extreme forces used during removal can damage the lead or result in dismantling of the lead.
- A lead that has been cut off should have the remaining lead end sealed.
- If the leads are left in place, the proximal connector ends of the leads should be capped to minimize tissue irritation and induced currents.
- Lead removal may not be possible due to the risk of damaging surrounding structures. The decision to remove the leads or leave them in place is made between the physician and the patient on a case by case basis. The implications of both options should be discussed, for example:
  - Removing the leads will extend the duration of the surgical procedure, require two additional incisions, and require the dissection of fibrotic tissue that may have formed around the leads.
  - Leaving the leads in place means the patient will still be susceptible to electromagnetic interference, which may prevent the patient from receiving an MRI. Furthermore, patients must be made aware that they need to notify medical personnel that they still have implanted leads even if the IPG has been removed and the lead ends have been capped.
- Return all explanted components to Inspire Medical Systems for disposal.

## Explant Disposition

When replacing an IPG, (due to battery depletion or explanting the IPG at the death of a patient who is to be cremated) return the IPG to Inspire Medical Systems for analysis and disposal. See the back cover of this manual for mailing address.

# Clinical Summary

## Stimulation Therapy for Apnea Reduction (STAR) Clinical Trial

The Inspire Upper Airway Stimulation (UAS) system was evaluated in a multicenter trial at study centers in the United States and Europe for the indication of moderate to severe obstructive sleep apnea (OSA) in patients who were not effectively treated by continuous positive airway pressure (CPAP).

### Patients Studied

The study enrolled 929 OSA patients. These patients were evaluated against patient selection criteria that included moderate to severe OSA, a BMI (body mass index) less than or equal to 32, and the absence of a complete concentric collapse at the level of the soft palate. Following the evaluation period, 126 patients met all selection criteria and proceeded to implant. All 126 implant procedures were successful, and 124 of the 126 implanted patients provided evaluable data through at least 12 months. The STAR trial was an intent to treat study. Therefore, the 2 patients who did not provide evaluable data through 12 and 18 months post-implant are assumed to be non-responders and were included in the evaluation as such. The patient demographics for the STAR trial are included in Table 3. The patients' baseline AHI showed a mean of 32.0 and a median of 29.3, and the baseline ODI showed a mean of 28.9 and a median of 25.4.

**Table 3. STAR Trial Subject Demographics**

Continuous Measures	Mean N = 126	Median
Age, year	54.5	55
Body Mass Index, kg/m <sup>2</sup>	28.4	29.2
Neck Size, cm	41.2	41.9
Systolic BP, mmHg	128.7	128
Diastolic BP, mmHg	81.5	80.5
Male	105 (83%)	Total N = 126
Race		
Caucasian	122 (97%)	
African American	0 (0%)	
Hispanic	1 (1%)	
Asian	1 (1%)	
Others*	2 (2%)	* 1-Surinam, 1-Turkey

## Study Design and Methods

The STAR trial was a multicenter, prospective trial with a 12-month single arm study and a randomized controlled therapy withdrawal study at 13 months. Following implant of the Inspire system, patients were followed at 1, 2, 3, 6, 9, 12, 13, 15, 18 months, and every 6 months thereafter. The patients' baseline AHI and ODI (oxygen desaturation index) values were the mean results from their screening (pre-implant) and 1-month (post-implant but prior to therapy activation) sleep studies. Baseline results were compared to the 12-month results to determine the percentage of patients who experienced a clinically meaningful reduction in the severity of their OSA in terms of their AHI and ODI scores. For this study, a clinically meaningful reduction in AHI and ODI was defined as (1) a 50% reduction in the AHI compared to the pre-implant screening and 1-month visit (post-implant but prior to therapy activation) and an AHI < 20 events per hour, and (2) a 25% or greater reduction in ODI at the 12-month visit compared to baseline.

Upon completion of the overnight sleep study at the 12-month visit, a randomized controlled therapy withdrawal study was conducted. The first 46 responders were randomized 1:1 to either the therapy maintenance (ON) group or the therapy withdrawal (OFF) group, resulting in 23 subjects in each group. Patients randomized to the therapy withdrawal group had Inspire therapy turned OFF for at least five days. Patients randomized to the therapy maintenance group continued their use of the Inspire system. All randomized patients participated in a sleep study at the 13-month visit. The therapy withdrawal group had the sleep study performed with Inspire therapy OFF, and the therapy maintenance group had the sleep study performed with the Inspire therapy ON. The mean change of AHI for each arm was compared to determine the extent of treatment effect from Inspire therapy.

The percentage of sleep time a patient had an oxygen saturation (SaO<sub>2</sub>) level below 90% was recorded during the sleep studies, and two validated quality of life questionnaires were administered at follow-ups through 18 months. The quality of life questionnaire was the Epworth Sleepiness Scale (ESS), which rates a patient's daytime sleepiness, and the Functional Outcomes of Sleep Questionnaire (FOSQ), which assesses the effect of a patient's daytime sleepiness on activities of ordinary living. The hypotheses for the secondary efficacy endpoints, which included the randomized withdrawal study, FOSQ, ESS, and SaO<sub>2</sub>, were tested according to a hierarchical strategy in order to preserve an overall Type I error rate of 5%.

## Study Results

### Titration

All subjects underwent polysomnography (PSG) for titration of therapy settings at 2 and 6 months. Additional titration PSG studies were performed as needed. Through 18 months, patients had an average of 3.3 (range 2–6) titration studies.

### Safety

Of the 126 patients implanted with the Inspire UAS system in the STAR trial, 124 were followed through 18 months. There were no unanticipated events and only 2 events required surgical intervention. Both events consisted of an IPG migrating out of position and were resolved with a surgical procedure performed under local anesthesia to reposition the IPG.

Many of the procedure-related adverse events reported are expected with a surgical procedure. The procedure-related events are described in Table 4.

**Table 4. Procedure-Related Adverse Events  
(and the probability of experiencing them in the first 18 months)**

Event	Number of Subjects with Event	Percent of Subjects (n=126)
Incision pain	35	28%
Post-operative discomfort	31	25%
Temporary tongue weakness	23	18%
Sore throat from intubation during implant	15	12%
Other post-operative symptoms (such as gastrointestinal (nausea, vomiting, abdominal pain, constipation), body pain (back, knee, wrist, hand), allergy to antibiotics, anxiety, ineffective airway clearance, loss of some taste, inability to void)	14	11%
Headache	8	6%
Mild infection	1	1%

The device-related adverse events are described in Table 5.

**Table 5. Device-Related Adverse Events  
(and the probability of experiencing them in the first 18 months)**

<b>Event</b>	<b>Number of Subjects with Event</b>	<b>Percent of Subjects (n=126)</b>
Discomfort due to electrical stimulation	59	47%
Tongue abrasion	30	24%
Other acute symptoms (i.e., headaches, coughing, choking, dysphasia, and speech-related events)	23	17%
Mouth dryness	14	11%
Complaints related to temporary usability or functionality issues with an implanted device	13	11%
Complaints related to temporary usability or functionality issues with an external device	13	10%
Mechanical pain associated with presence of device	10	8%
Mild infection	1	1%

At the completion of the 18-month follow-up visits of all study patients, 75% of device-related events were fully resolved, primarily with either 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. Twenty-five percent (25%) of device-related events were unresolved at 18 months. Currently unresolved events include reports of discomfort due to stimulation, tongue abrasion and various stimulation related events including dry mouth, headaches, intermittent waking, isolated stimulation sensation events, audible buzzing, and intermittent fatigue. Despite these reported events, patients continued to report high (85%) compliance with the therapy at 18 months.

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 proximity to an infection. Both explants were successfully completed without damage to the surrounding structures. 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.

## Efficacy

The sleep studies, which were scored by an independent sleep scoring core lab, showed statistically significant and clinically relevant reductions in the patients' AHI and ODI scores. Table 6 reports the percentage of patients who experienced a clinically meaningful reduction in their OSA severity (i.e., responders). As this is an intent to treat study, these results are based on a total of 126 patients even though only 124 patients provided evaluable data through 12 and 18 months. The other 2 patients are assumed to be non-responders and are included in the evaluation as such.

**Table 6. Therapy Responders at 12 Months Post-Implant**

Responder	Responder Rate at 12-Month Follow-Up	Responder Rate at 18-Month Follow-Up
50% Reduction in AHI from baseline and AHI < 20	66% (83/126)	65% (80/124)
25% Reduction in ODI from baseline	75% (94/126)	80% (99/124)

The average reduction of AHI from baseline to 12 months was 68% and 70% for ODI. Baseline AHI showed a mean of 32.0. In comparison, the AHI at the 12-month PSG study showed a mean of 15.3. Baseline ODI showed a mean of 28.9. In comparison, ODI at the 12-month PSG study showed a mean of 13.9. The patients also had statistically significant improvements in terms of time with  $\text{SaO}_2 > 90\%$ , ESS and FOSQ scores at 12 months relative to baseline. The mean FOSQ score at baseline was 14.3, at the 12-month visit it was 17.2, and at the 18-month visit it was 17.3. The mean ESS score at baseline was 11.6, at the 12-month visit it was 7.0, and at the 18-month it visit was 7.0. The mean percentage of sleep time with  $\text{SaO}_2 < 90$  at baseline was 8.7%, at the 12-month visit it was 5.9%, and at the 18-month visit it was 5.6%. These results through 18 months show the durability of Inspire therapy's treatment effect.

The randomized controlled therapy withdrawal study provided further evidence that improvements were attributed directly to the Inspire therapy. AHI increased significantly in the therapy withdrawal (OFF) group compared to AHI scores in the therapy maintenance (ON) group. The results from the randomized control therapy withdrawal study showing the difference between the therapy OFF arm and the therapy ON arm are provided in Table 7.

**Table 7. Randomized Controlled Therapy Withdrawal Study Results in Month 13**

AHI	Mean AHI		Change (13M–12M) Mean	95% CL for Mean Change	p-value
	12-Month	13-Month			
Therapy ON	7.2	8.9	1.7	(-1.1, 4.5)	< 0.0001
Therapy OFF	7.6	25.8	18.2	(11.4, 24.9)	



The randomized controlled therapy withdrawal study confirmed that the significant OSA severity reduction at 12 months is attributable to the Upper Airway Stimulation therapeutic effect. An analysis of AHI responder status relative to baseline characteristics is provided in Table 8.

**Table 8. AHI Responder Analysis of Baseline Characteristics**

<b>Baseline Characteristics</b>	<b>Responders N = 83 Mean % (N)</b>	<b>Non-responders N = 43 Mean % (N)</b>	<b>Association of AHI Response to Baseline Characteristics p-value</b>
Age	55.9	51.8	0.03
Gender (% Male)	82%	86% (37)	0.56
BMI	28.3	28.6	0.50
Neck Size	41.0	41.6	0.32
Baseline AHI	30.7	34.6	0.08
Baseline ODI	27.1	32.3	0.02
Prior UPPP (%)	20.5% (17)	11.6% (5)	0.22
Baseline FOSQ	14.7	13.6	0.059
Baseline ESS	11.2	12.3	0.22

While the percentage of patients with prior UPPP surgery is noted to be twice as high in the responder group as compared to the non-responder group, the observation was not statistically significant (p-value of 0.22).

### **Conclusion**

Upper Airway Stimulation is a safe and effective treatment for patients with moderate to severe OSA who are not effectively treated by CPAP.

# IPG Specifications

## Factory Settings

*Table 9. Inspire II IPG (Model 3024) Factory Settings*

<b>Parameter</b>	<b>Value</b>
<b>General</b>	
Therapy On/Off	Off
Usage	0
Start Delay	30 mins
Pause Time	15 mins
Therapy Duration	8 hrs
<b>Stimulation</b>	
Amplitude	0 V
Rate	30 Hz
Pulse Width	90 $\mu$ s
Amplitude Ramp	Off
Electrode Configuration	Outer (+) Center (-) Case (off)
Patient Control	Off
<b>Sensing</b>	
Exhalation Sensitivity   Threshold	-1   0
Inhalation Sensitivity   Threshold	-1   0
Refractory Hard   Soft	63%   13%
Invert Signal	Off
Max Stim Time	3 secs

## Configurable Settings

The parameters in Table 10 can be changed using an Inspire programmer. See the physician programmer manual for more information.

**Table 10. Inspire II IPG (Model 3024)  
Configurable Settings**

Parameter	Values	Increment
Stimulation		
Start Delay	0–75 mins	5 mins
Pause Time	5–30 mins	5 mins
Therapy Duration	1–15 hrs	1 hr
Amplitude	0.0–5.0 V	0.1 V
Rate	20, 25, 30, 33, 40 Hz	
Pulse Width	60, 90, 120, 150, 180, 210 $\mu$ s	
Amplitude Ramp	0.0–0.5 sec	0.125 sec
Electrode Configuration	Outer (+) Center (-) Outer (-) Center (+) Case (+) Outer (-) Case (+) Center (-) Case (+) Outer (-) Center (-)	
Patient Amplitude Control	On, Off	
Sensing		
Exhalation Sensitivity	-4 to +3	1
Exhalation Threshold	-1, 0, +1	1
Inhalation Sensitivity	-7 to +1	1
Inhalation Threshold	0, +1	1
Hard Off Period	38, 50, 63, 75%	
Soft Off Period	13, 25%	
Invert Signal	On, Off	
Max Stim Time	2–4 secs	1.0 sec

## Battery Information

**Table 11. Inspire II IPG (Model 3024)  
Battery Information**

<b>Description</b>	<b>Value</b>
Chemistry	Lithium primary cell
Manufacturer	Inspire Medical Systems
Longevity <sup>a</sup>	10.6 years average (0.7 years standard deviation)

<sup>a</sup> Longevity data is based on STAR trial therapy settings at the 12-month endpoint. IPG longevity will vary based on usage and therapy settings. The minimum estimated longevity from the STAR trial is 7 years.

## Physical Description

**Table 12. Inspire II IPG (Model 3024)  
Physical Description**

<b>Description</b>	<b>Value</b>
Height	52 mm (2 in)
Length	60 mm (2.4 in)
Thickness	10 mm (0.4 in)
Volume	23 cm <sup>3</sup> (1.66 in <sup>3</sup> )
Mass	49 g (2 oz)
Radiopaque identification	NCR
Tissue contacting materials	Titanium, polyurethane, silicone rubber, parylene coating

### **Radiopaque identification**

The IPG's radiopaque identification, NCR (Figure 21), can be confirmed by using fluoroscopy on the IPG.



**Figure 21. Radiopaque identification**

# Inspire Medical Systems Limited Warranty

Inspire Medical Systems' products consist of Implantable Pulse Generators (IPG), tools to connect the IPG to implantable leads, leads, 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, e.g., IPG, lead, 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, e.g., 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.

This limited warranty represents the entire obligation of Inspire Medical Systems for IPGs 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 IPG 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 programmer or sleep remote is first used.









**Manufacturer**

Inspire Medical Systems, Inc.

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