Inspire
Sleep Apnea Innovation

RESPIRATORY SENSING LEAD

4340

Technical Manual

!USA ℞ ONLY

Explanation of symbols on product or package labeling

	Caution, consult accompanying documents
eIFU indicator	Consult electronic instructions for use
!USA	For USA audiences only
℞ ONLY	Caution: Federal Law (USA) restricts this device to sale on or by the order of a physician
	Do not reuse
STERILE EO	Sterilized using ethylene oxide
MR	The Inspire therapy system is Magnetic resonance (MR) conditional
	Do not use if the package is damaged
	Open Here
	Manufacturer
	Date of manufacturing
	Use by
SN	Serial number
REF	Reference number
	Temperature limitation
SENSE	Lead that inserts into SENSE (sensing) port of implantable pulse generator (IPG)

The following is a trademark of Inspire Medical Systems, Inc.: Inspire®.
This product and/or the use of this product in a method may be covered by one or more patents or patent applications, available at www.inspiresleep.com/patents.

Device Description

The Inspire® Respiratory Sensing Lead (Model 4340) is designed to detect respiratory effort. The lead features a pressure sensitive membrane that converts the mechanical energy of respiration into an electrical signal. The lead incorporates a standard connector for coupling to the implantable pulse generator (IPG).

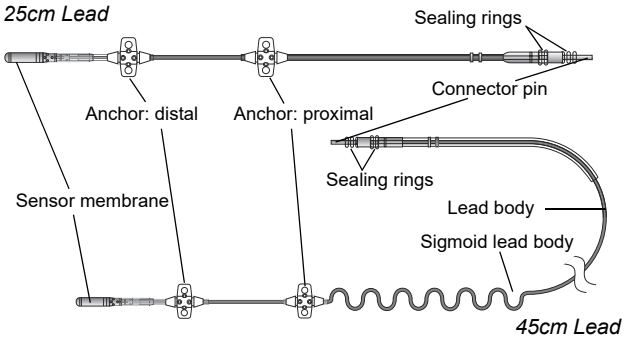

Figure 1. *Respiratory sensing leads, 25cm (Top) and 45cm (Bottom)*

Instructions for Use

Refer to the *Inspire System Implant Manual* for information on indications, contraindications, clinical warnings/precautions, clinical summary, and instructions for use. Contact Inspire Medical Systems at the address on the back cover of this document for a copy of the *Inspire System Implant Manual*.

Contents of Package

The lead and accessories are supplied sterile. The package contains:

- One respiratory sensing lead
- Product literature

Specifications

Parameter	Respiratory Sensing Lead
Length	45 cm (18 in), 25cm (9.8in.)
Sensor diameter	3.6 mm (.14 in)
Dynamic pressure sensing range	0 – 100 mm Hg +/- .5 mm (0 – 136 cm H_2O +/- .68 cm H_2O)
Materials in contact with human tissue	Silicone elastomer Silicone adhesive Silicone rubber Barium sulfate Blue colorant

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 2 years or less.

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

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

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

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

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

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

A. Terms and Conditions

1. The product labeling must indicate a limited warranty exists.
2. For implantable products, this limited warranty applies only for a product replacement in the original patient.
3. All registration materials must be completed and returned to Inspire Medical Systems within 30 days of first use.
4. The product must be replaced with an Inspire Medical Systems product.
5. If the product is implantable, it must be implanted before the product expires and implanted with other Inspire Medical Systems products.
6. The product must be returned to Inspire Medical Systems, 5500 Wayzata Blvd, Suite 1600, Golden Valley, MN 55416 within 30 days that the product first fails to function within normal tolerances. The product may be returned at no cost to you. Contact your Inspire Medical Systems representative for information on how to return the product.
7. Inspire Medical Systems will inspect the returned product and determine whether a limited warranty credit is due.
8. All products returned to Inspire Medical Systems become its property.

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

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

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

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

B. Limited Warranty Period

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

- **Within the United States:**
  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 Inspire Sleep Remote is first used.
- **Outside the United States:**
  1. Three (3) years from date an IPG or lead is implanted in the patient.
  2. Two (2) years from the date a physician programmer or Inspire Sleep Remote is first used.

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