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# *Inspire Medical Systems, Inc.*

## *Upper Airway Stimulation*

*Implantable neurostimulation  
to treat Obstructive Sleep Apnea*



Tim Herbert, President & CEO  
December 7, 2011

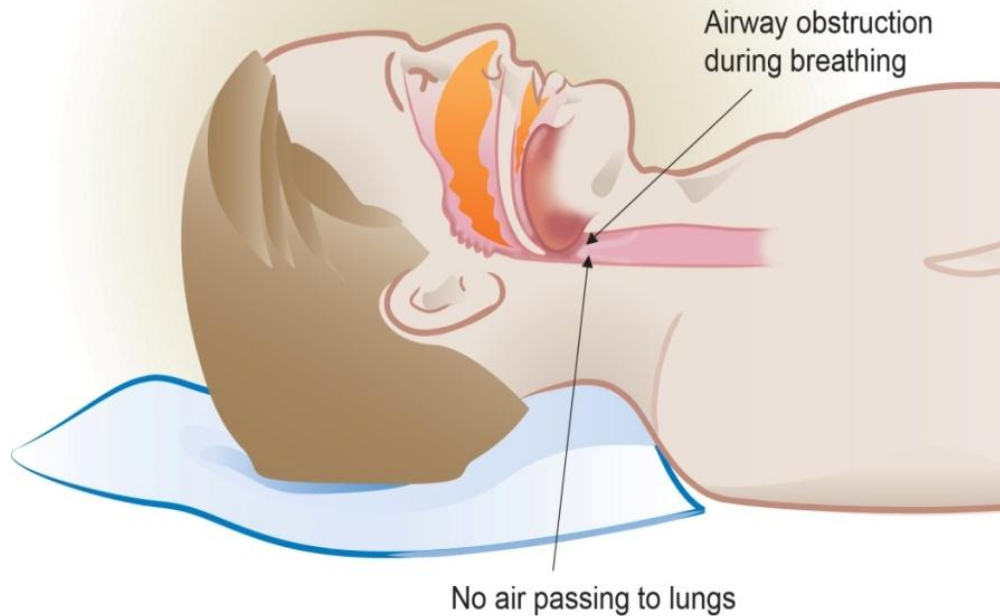
# Inspire Therapy History



- Inspire Medical Systems spun-out of Medtronic in May 2007
- Strong and developed Intellectual Property
  - 33 issued patents
  - 10 patent applications for new innovative approaches
- 23 global employees with combined medical device experience exceeding 350 years
- Robust, commercial-grade implantable technology
- Revenue generating – CE Mark with units sold in Europe
- Seasoned investors and board of Directors
  - Dr. Glen Nelson – chairman
  - Kleiner Perkins Caufield & Byers
  - US Venture Partners
  - Synergy Life Science Partners
  - Medtronic

# Obstructive Sleep Apnea (OSA)

## Typical Sleep Apnea Patient



- **Tissues in throat collapse and create blockage in the airway.**
- **Blockage in the airway prevents airflow to the lungs.**
- **Repeated oxygen desaturations occur throughout the night.**
- **Patients struggle to achieve deep, restorative sleep .**

**People with moderate to severe OSA experience 15 or more events per hour**

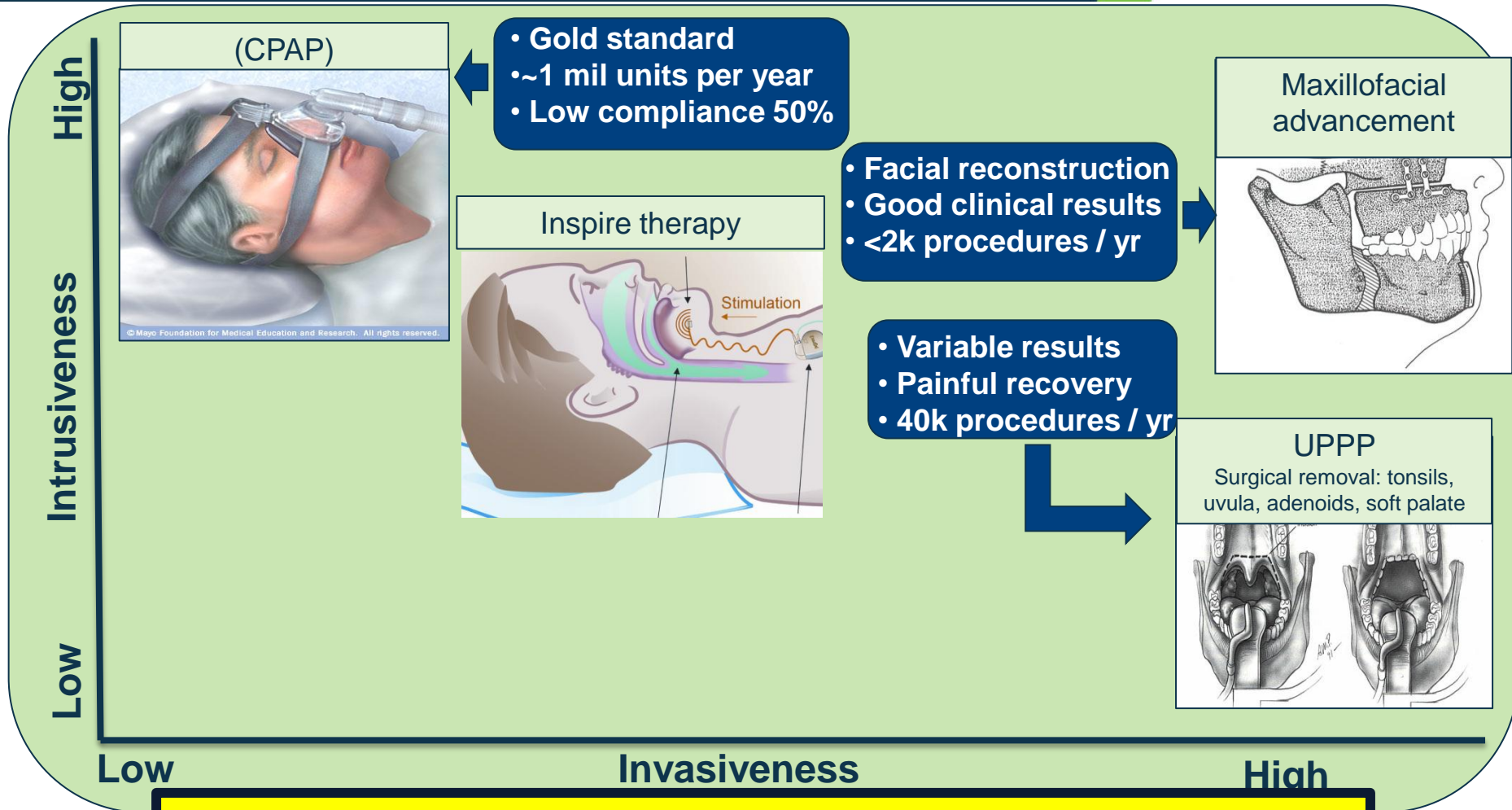
# Consequences of untreated OSA

*Sufferers of OSA experience many physical, mental, and lifestyle challenges*



Condition	Increased Risk
Motor Vehicle Accidents	2.0 – 6.7
Occupational Accidents	2.2
Coronary Artery Disease	1.2 – 5.4
Stroke	1.6 – 3.1
Hypertension	2.9
Congestive Heart Failure	2.4
Type 2 Diabetes	1.5
Death	1.5 – 5.2

# Moderate to severe OSA treatments



***Upper Airway Stimulation addresses an unmet need:  
Less invasive, durable results, high patient compliance***

# How significant is the OSA?

**16 million**  
people have  
moderate to  
severe OSA  
in the U.S.

50% of  
the OSA  
population  
may be  
treated  
with  
CPAP

1/3 of  
patients  
are  
very  
good  
Inspire  
targets

**2+ mil**  
in US  
may  
benefit

>750,000 CPAP  
units sold in the US  
on an annual basis

Patients are <50%  
compliant to CPAP  
after 1 year of use

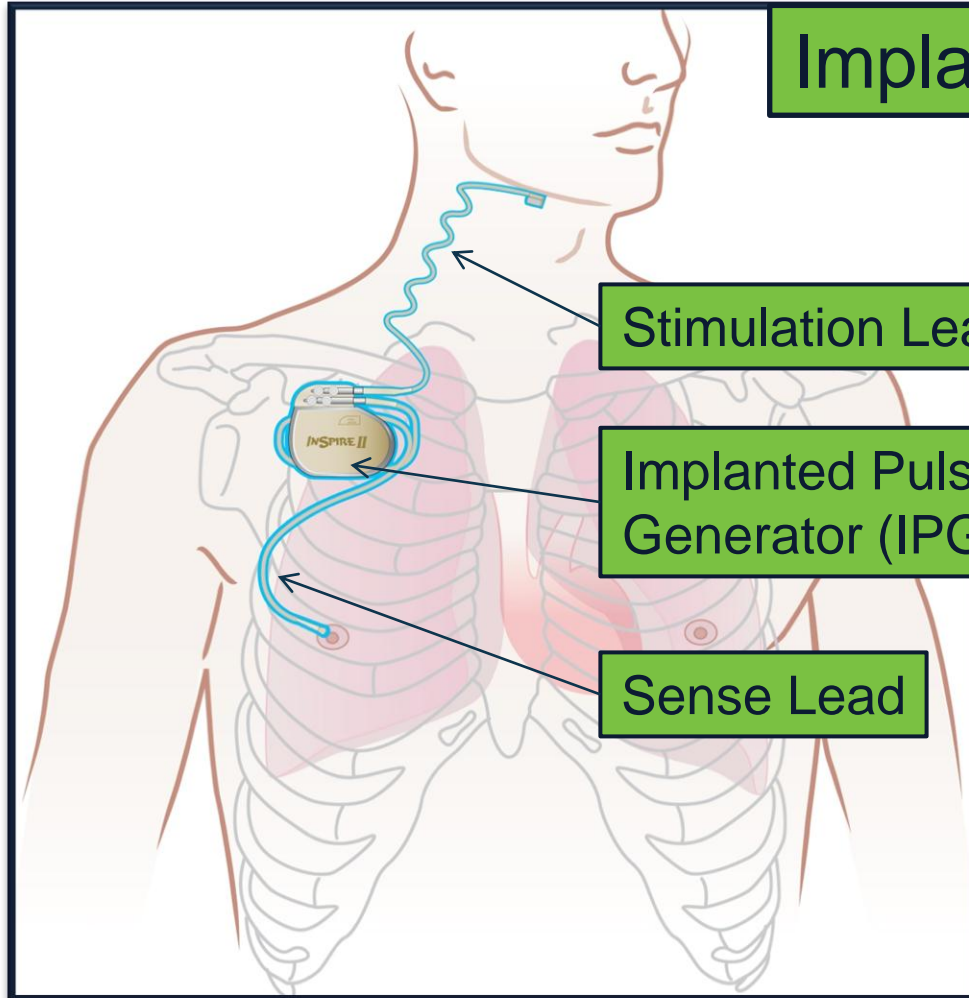
No pharmaceutical  
solution for OSA

Surgical solutions  
are either:

- 50% successful
- Poor patient selection

A 5% market penetration equates to a billion dollar market

# Second Generation Inspire System



## Implanted Components

Stimulation Lead

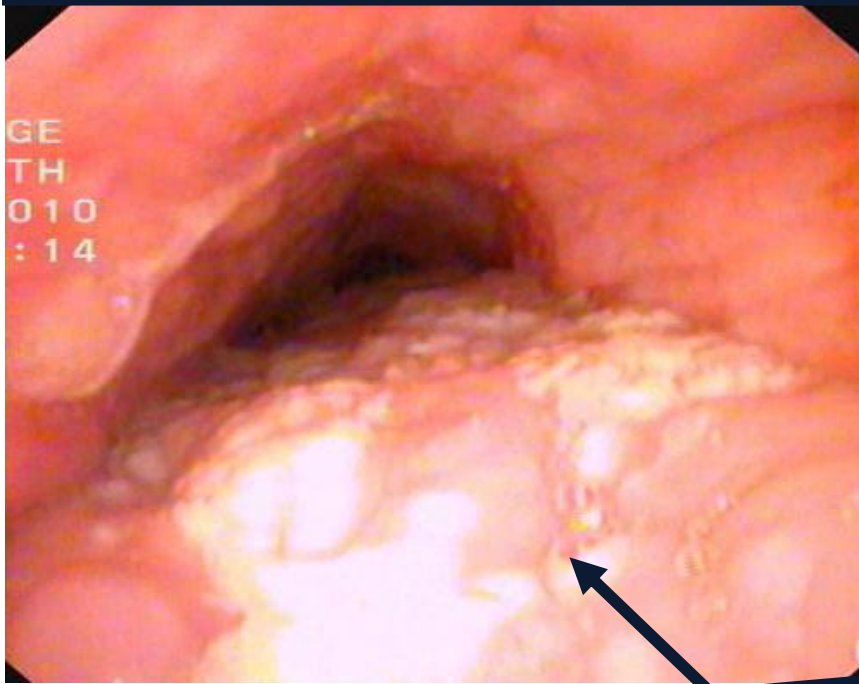
Implanted Pulse Generator (IPG)

Sense Lead

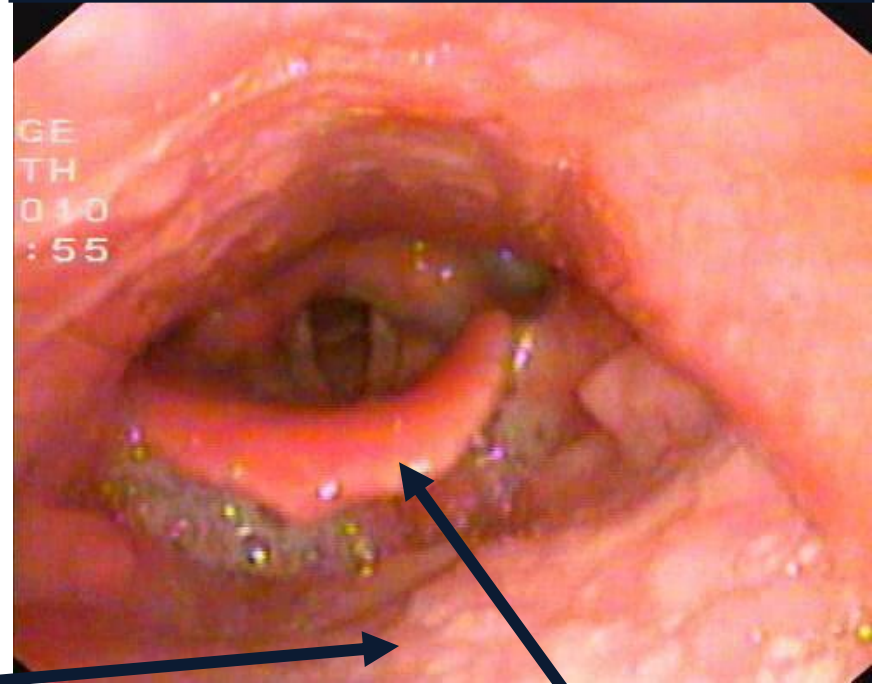
- 3 small skin incisions
- Direct visualization
- ~2 hour procedure
- Fast post-op recovery times
- No removal or altering anatomy
- Reversible

# Mechanism of Action: Advancement of tongue opens upper airway

Airway Obstructed  
STIMULATION OFF



Tongue Advanced  
STIMULATION ON



Tongue

Epiglottis

Stimulation is provided while the patient inhales which prevents a collapse in the airway

## Inspire 1 Proof of Principle Trial

- 8 patients
- Completed in 2001
- Demonstrated therapy concept

## Inspire 2 Feasibility Trial (Phase 2)

- 44 patients
- Completed in 2010
- Demonstrated safety
- Validated patient selection criteria

## Inspire STAR Pivotal Trial (Phase 3)

- 120 patients
  - Implants to be completed 1<sup>st</sup> Qtr 2012
- 12-month follow-up period
- Data will be submitted for FDA commercial-approval
- Target US-approval late-2013

# Feasibility Trial - AHI Response

Patients meeting Pivotal Selection Criteria (N=18)

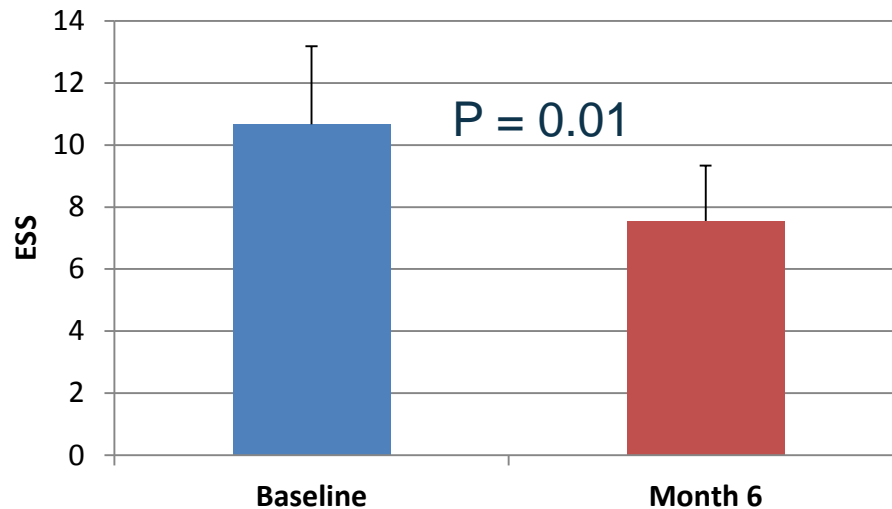


**Responder Rate: 78% (14/18)**

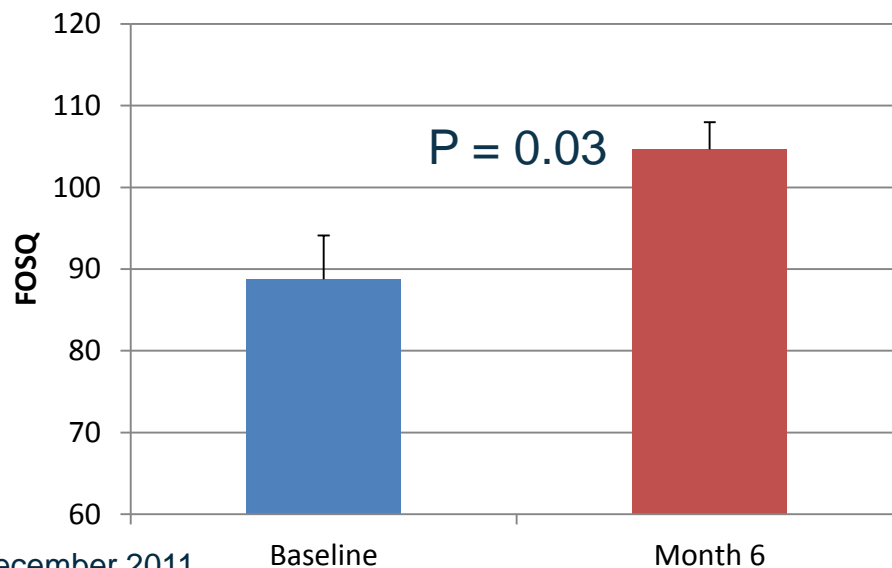
AHI = Apnea-Hypopnea Index

# Quality of Life Measure

Patients met Pivotal Selection Criteria (N=18)



- Epworth Sleepiness Scale (ESS) measures day-time sleepiness
- STAR Trial Objectives: significant improvement



- Functional Outcome of Sleep Questionnaire (FOSQ) measures day-time function
- STAR Trial Objectives: significant improvement

## 1. Safety

- Therapy safety profile is satisfactory beyond 24-months
- 100+ patients safely implanted with Inspire therapy

## 2. AHI Responder Rate

- Therapy responders have shown sustained benefit beyond 12-months
- Patient selection criteria has been prospectively validated

## 3. Quality of Life

- Quality of life measures showed statistically significant improvement and meet pivotal trial success criteria

1. Obstructive Sleep Apnea is a large disease state with unmet market needs
2. OSA has a strong first-line therapy (CPAP) to drive patient diagnosis – patients are only 50% compliant to CPAP
3. Physiologic collapse of the airway – no pharmaceutical solution
4. Established diagnostics to OBJECTIVELY evaluate Inspire therapy in clinical setting
5. Defined roadmap to demonstrate safety and efficacy and obtain US regulatory approval (approved in Europe)