

FACT SHEET: INSPIRE® THERAPY

What is Inspire therapy?

- Inspire therapy is a promising new FDA-approved treatment for people with moderate to severe Obstructive Sleep Apnea (OSA) who are not receiving consistent benefits from continuous positive airway pressure (CPAP).
- Inspire therapy is a fully implanted system that delivers mild stimulation to keep a patient's airway open during sleep.
- Inspire therapy does not require a mask.
- Results from the STAR clinical trial, recently published in the *New England Journal of Medicine*, showed that Inspire therapy can significantly reduce sleep apnea events and significantly improve patient quality of life measures.

How does Inspire therapy work?

- Inspire therapy is a fully implanted system, controlled with a small handheld Inspire sleep remote.
- The implanted system consists of three fully implanted components: a small generator, a breathing sensor lead, and a stimulation lead.
- When activated, Inspire therapy senses breathing patterns and delivers mild stimulation to key airway muscles, which keeps the airway open during sleep.
- A patient simply turns the therapy on before bed and off upon waking using the handheld Inspire sleep remote.
- The Inspire system is typically implanted during an outpatient procedure.
- After implantation, physicians optimize therapy settings for a patient during a routine sleep study.
- A patient will then typically return once a year for a checkup.



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The STAR Trial

- The STAR trial was a clinical trial designed to evaluate the safety and effectiveness of Inspire therapy.
- The STAR trial enrolled patients that had the following characteristics:
 - Moderate to severe Obstructive Sleep Apnea
 - Unable to achieve consistent benefits from CPAP therapy
 - Body-mass index (BMI) of ≤ 32
 - Passed a comprehensive airway anatomy examination
- The STAR trial was conducted at 22 leading medical centers across the United States and Europe.
- The STAR trial results were published in the January 9, 2014 edition of the *New England Journal of Medicine*.
- The STAR trial showed that Inspire therapy can significantly reduce sleep apnea events and significantly improve patient quality of life measures:
 - 68% median reduction in apnea-hypopnea index (AHI)
 - 70% median reduction in blood oxygen desaturation index (ODI)
 - Significant improvement in daytime functioning as measured by Epworth Sleepiness Scale (ESS) and Functional Outcomes of Sleep Questionnaire (FOSQ)

Inspire Therapy Advantages

- Clinically proven to provide significant reductions in OSA and significant improvements in quality of life
- In contrast to conventional OSA surgeries, Inspire therapy preserves natural airway and facial anatomy
- Does not require a mask or oral appliance
- Simple and easy-to-use, putting patients in control of their OSA

Safety information for Inspire therapy is provided at www.InspireBetterSleep.com. Information at this site should not be used as a substitute for patients talking with their doctor. Patients are encouraged to review this safety information and talk with their doctor about diagnosis and treatment options.