Issue Overview: Obstructive Sleep Apnea and Inspire® Upper Airway Stimulation (UAS) Therapy

Millions of people each year are significantly impaired by the consequences of Obstructive Sleep Apnea (OSA). Patients with OSA stop breathing frequently during sleep, often for a minute or longer. Daytime sleepiness, depression, weight gain, increases in automobile and industrial accidents, and diminished quality of life are all commonly observed in people with OSA as a result of fragmented sleep patterns. Furthermore, poorly managed OSA may lead to development of systemic hypertension, cardiovascular diseases (heart failure, heart rhythm disorders), stroke and diabetes.

CPAP, or Continuous Positive Airway Pressure, is the current standard of treatment for OSA and is successful when used correctly and regularly. However, CPAP requires patients to wear a ventilation mask during sleep hours and several studies have demonstrated that roughly half of all patients that start on CPAP therapy eventually become non-compliant. Other recommended treatments for OSA include weight loss, oral appliances and surgeries. Most surgical options involve removing tissue and/or permanently altering patient anatomy which can contribute to significant post-operative pain and long recovery times.

Inspire Upper Airway Stimulation (UAS) therapy is a new, FDA-approved treatment for a subset of people with moderate to severe OSA who are unable to use CPAP and meet other patient selection criteria.

Here's how it works: Many people with OSA experience decreased muscle tone in their airway during sleep. When this occurs, the tongue and other soft tissues can relax, obstruct the airway and cause apnea events. Inspire therapy is an implanted device that works with the body's physiology to prevent airway obstruction during sleep. Inspire therapy consists of three components: a small pulse generator, a sensing 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. The patient controls the system—turning the therapy on before bed and off upon waking—using the handheld Inspire sleep remote. While Inspire therapy does require a surgical procedure, in contrast to other surgical options to treat sleep apnea, Inspire therapy does not require removing or permanently altering facial or airway anatomy. As such, the procedure is less invasive and may result in a shorter recovery time.

The results from the STAR (Stimulation Therapy for Apnea Reduction) trial, a pivotal clinical trial, were published in the *New England Journal of Medicine* in January 2014. The multi-center clinical study was designed to evaluate the safety and effectiveness of Inspire therapy in patients with moderate to severe OSA who are unable to use CPAP. Patients who participated in the STAR trial experienced a reduction in apnea events and improvements along several indices designed to measure quality of life, including:

- 68 percent median reduction in apnea hypopnea index (AHI)
- 70 percent median reduction in oxygen desaturation index (ODI)
- Significant improvement in daytime functioning as measured by Epworth Sleepiness Scale (ESS) and Functional Outcomes of Sleep Questionnaire (FOSQ)
- 85 percent of bed partners reported no snoring or soft snoring for partners using Inspire therapy

Inspire therapy was developed by Inspire Medical Systems (Minneapolis, Minn.)

Safety information for Inspire therapy is provided at www.inspiresleep.com. Inspire therapy is not for everyone. 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.