

### LABEL SPECIFICATION

# PRESS RELEASE 03/27/2014

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### **Press Release**

### For Immediate Release

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# Siesta Medical's Encore™ System Cleared for Hyoid Suspension in the Treatment of Obstructive Sleep Apnea

**Los Gatos, CA (March 27, 2014)** – Siesta Medical, Inc. (Private), a provider of innovative minimally invasive surgical implants and tools for obstructive sleep apnea, announced today FDA clearance for performing hyoid suspension with its Encore™ System.

Hyoid Suspension, performed alone or in combination with other surgical procedures has been shown in numerous clinical trials to be a safe and effective therapy for sleep apnea. Siesta's Encore™ System simplifies and improves hyoid suspension to the mandible (hyo-mandibular suspension), a minimally invasive treatment for sleep apnea. The Encore's FDA clearance makes it the only knotless and fully adjustable hyoid suspension system on the market.

Until now, hyo-mandibular suspension has required multiple, difficult suture passes around the hyoid bone and the use of large, fixed knots in the suspension suture when setting suspension tension. Siesta's Encore™ System simplifies the procedure, requiring only one pass around the hyoid bone and allowing the physician to easily optimize and adjust tension during and after the procedure without the need to tie knots.

Dr. Jason Van Tassel with Washington Hospital in Fremont, CA, an expert in airway surgery for sleep apnea commented, "Hyoid suspension with the Encore™ System is much simpler and provides a greater degree of control over the final result than previous products. The patients I have treated with this fully reversible and adjustable minimally invasive procedure are feeling better, snoring less, and their follow up sleep studies show impressive drops in sleep apnea severity."



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"Hyoid suspension is a very effective option for patients with hypopharyngeal obstructions and has broad acceptance in the sleep surgery community. We are very excited about the additional hyoid suspension clearance for the Encore System and believe that it will provide significant benefit to our patients and accelerate our penetration into the sleep surgery market." said Peter Martin, President and Chief Executive Officer of Siesta Medical, Inc.

## **Obstructive Sleep Apnea**

Obstructive sleep apnea is a major health problem in the United States. An estimated 23 million people in United States have moderate to severe sleep apnea (Harvard Medical School, *The Price of Fatigue*, December 2010), which is characterized by frequent awakening during sleep, heavy snoring and daytime sleepiness. If left untreated, sleep apnea increases the risk for cardiovascular disease, including hypertension and heart failure. Despite its prevalence and role as a cardiovascular risk factor, sleep apnea remains largely under diagnosed and treated.

The first line and most common treatment for sleep apnea is continuous positive airway pressure (CPAP) treatment, utilized by an estimated 3.3 million Americans. While effective, CPAP is difficult for patients to use.

Surgical therapy for sleep apnea, though currently less common than CPAP therapy, provides an important and effective alternative for those patients who are not compliant or have difficulty with CPAP therapy. Similar to CPAP, surgical therapy reduces the increased morbidity and risk of death associated with untreated sleep apnea (Weaver, Sleep 2004;27:A208, Marti, Eur Resp J 2002;20:1511-18). There are over 1 million new diagnoses of sleep apnea in the U.S. each year and over 100,000 surgical procedures for sleep apnea performed annually.

### The Encore™ System

The Encore<sup>TM</sup> System is used in minimally invasive surgical procedures where the tongue or hyoid bone is suspended forward with the intent of preventing the tongue from blocking the airway during sleep. The procedure is performed under local or general anesthesia by Ear, Nose and Throat Specialists, also known as Otolaryngologists and typically takes less than 40 minutes to perform.

### **About Siesta Medical**

Siesta Medical is a privately held, medical device company providing minimally invasive implants and tools for obstructive sleep apnea.

For more information about Siesta Medical please visit our website at www.siestamedical.com



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This press release contains forward-looking statements that are based upon management's current expectations and are inherently uncertain. Forward-looking statements are based upon information available to us as of the date of this press release and we assume no obligation to revise or update any such forward-looking statement to reflect any event or circumstance after the date of this release. Actual results and the timing of events could differ materially from current expectations and from any forward-looking statements made by the company.