

## Clinical Study Overview

### Reflux Band™ UES Assist Device

The Reflux Band™ UES Assist Device is designed to eliminate or mitigate the reflux of stomach contents into the pharynx and lungs by applying a slight external pressure (20-30 mmHg) to the upper esophageal sphincter (UES), which results in the reflux not being able to pass beyond the UES barrier. To assess the safety, effectiveness, and clinical utility of the Reflux Band system, the following clinical studies were conducted over the last five years that demonstrate the Reflux Band is safe and effective, and provides both physiological and symptomatic benefits.

#### ***Prevention of esophagopharyngeal reflux by augmenting the upper esophageal sphincter pressure barrier<sup>1</sup>***

**Published:** The Laryngoscope, VC 2014, The American Laryngological, Rhinological and Otological Society, Inc

**Authors:** Reza Shaker, Arash Babaei, Sohrab Rahimi Naini

**Institution:** Medical College of Wisconsin, Milwaukee, WI

Incompetence of the upper esophageal sphincter (UES) is fundamental to the occurrence of esophago-pharyngeal reflux (EPR), and development of extra-esophageal manifestations of reflux disease. This clinical study demonstrated that acid reflux events into the throat and lungs commonly referred to as EERD or LPR are prevented by the application of a slight external pressure at the cricoid region of the neck (20-30 mmHg). The study found that when reflux patients were not wearing the device, they experienced a significantly greater number of reflux events into the throat and lungs, compared to when they were wearing the device.

#### ***Correlation of externally applied cricoid pressure with luminal upper esophageal sphincter pressure<sup>2</sup>***

**Presented:** DDW, 2014

**Authors:** Arash Babaei, Hongmei Jiao, Ling Mei, Mark Kern, Reza Shaker

**Institution:** Medical College of Wisconsin, Milwaukee, WI

This clinical study determined the correlation of externally applied pressure at the cricoid cartilage region and the intraluminal UES pressure that is transferred to the UES. External pressure was applied at the cricoid region in both upright (fitting posture) and supine posture (treatment posture).

This study confirmed that the UES pressure increase is significantly correlated with external cricoid pressure. For example, by applying 20 mmHg pressure externally at the cricoid region of the neck, the patient will experience a similar 20 mmHg pressure increase intraluminally at the UES.

#### ***Multi-center prospective study of the Reflux Band™ UES assist device for the treatment of acid reflux into the throat and lungs<sup>3,4</sup>***

**Presented:** DDW 2014, AAO-HNSF 2014

**Authors:** Stacey Silvers, Michael F. Vaezi, Nimish B. Vakil, Alan R. Raymond, Michael J. Schmalz

This multi-center study assessed the safety and effectiveness of the Reflux Band when worn by patients who have been clinically diagnosed with esophago-pharyngeal reflux with extra-esophageal symptoms (i.e., chronic cough, choking, aspiration, chronic post nasal drip, globus, sore throat, throat clearing).

The safety of the Reflux Band was determined by assessing the incidence, type, severity, and duration of adverse events reported for all patients at the time of each follow-up, and as reported by patients in between those visits. Comparing the initial Reflux Symptom Index (RSI) score, a validated patient questionnaire, to the RSI score at the final follow-up, assessed effectiveness. In addition, patient and physician satisfaction was assessed.

Study results demonstrated that the Reflux Band is a safe and effective method for the treatment of esophago-pharyngeal reflux. 86% of patients had a successful outcome with significant reduction in symptoms after two weeks. Physicians reported being satisfied with the Reflux Band 92% of the time and patients were satisfied 75% of the time, with 59% being very satisfied. The change in the RSI score from baseline compared to the final follow-up, as well as, the other secondary endpoint measures, provide evidence that the device provides clinical

utility and effectiveness. Adverse events were generally mild, short-lived and typically reported as not being related to the device. There is no indication of any significant risk to the patient while using the Reflux Band.

Study results indicate that the Reflux Band is a non-invasive method that provides benefit within the first two weeks and the benefit is maintained. There is no indication that there is any residual or cumulative risk with the use of this device.

### ***Efficacy of a novel UES assist device in management of supraesophageal complications of reflux disease<sup>5</sup>***

**Presented:** DDW, 2012

**Authors:** Arash Babaei, Sohrab Rahimi Naini, Walter J. Hogan, Megan DeMara, Tracy Kaczanowski, Robert M. Siwiec, Jason E. Gonzaga, Mukund Venu, A. Aziz Adam, Nikhil Shastri, Benson T. Massey, Reza Shaker

**Institution:** Medical College of Wisconsin, Milwaukee, WI

The effectiveness of the UES Assist Device to manage extraesophageal reflux was evaluated using a commonly used, validated patient questionnaire for reflux research. Patients

with a variety of extraesophageal symptoms of reflux disease (throat burning, globus, regurgitation, hoarseness, chronic cough, post-nasal drip) who had not satisfactorily responded to acid suppressive therapy and lifestyle modifications participated in the study. The effectiveness was assessed by the use of the validated Nocturnal Gastroesophageal Reflux Disease Symptom Severity and Impact Questionnaire (N-GSSIQ).

The study concluded that the UES Assist Device is safe, effective and well-tolerated in controlling and significantly improving extraesophageal reflux symptoms, thereby providing clinical utility.

### **OVERALL CONCLUSIONS**

The Reflux Band is clinically proven to be safe and effective based upon a cohort of clinical studies done over the last five years. Functional studies show that when external pressure is applied at the cricoid region, reflux is kept from passing through the UES. Symptom-based studies show patients reporting significant improvement in their pulmonary, pharyngeal and laryngeal symptoms.

<sup>1</sup> Shaker R, et al. Prevention of esophagopharyngeal reflux by augmenting the upper esophageal sphincter pressure barrier. *Laryngoscope*. 2014 Oct;124(10):2268-74.

<sup>2</sup> Babaei A, Jiao, H, Mei L, Kern M, Shaker R. Correlation of Externally Applied Cricoid Pressure With Luminal Upper Esophageal Sphincter Pressure Augmentation; Effect of Posture and Technique. *Gastroenterology* May 2014; Vol. 146, Issue 5, S-856.

<sup>3</sup> Vaezi MF, Vakil NB, Schmalz MJ, Raymond AR. A Multi-Center Prospective Study of the Upper Esophageal Sphincter (UES) Assist Device for the Treatment of Extraesophageal Reflux. *Gastroenterology*. May 2014, Vol. 146, Issue 5, S-128.

<sup>4</sup> Silvers S. Nonrandomized prospective study of an upper esophageal sphincter (UES) Assist Device for treating laryngopharyngeal reflux. *Otolaryngol: Head and Neck Surg*. Sept 2014, Vol 151(S1), P44.

<sup>5</sup> Babaei A, Naini SR, Hogan WJ, DeMara M, et al. Efficacy of a Novel "UES Assist Device" in Management of Supraesophageal Complications of Reflux Disease: the Results of a Limited Clinical Trial. *Gastroenterology*. May 2012; Vol. 142, Issue 5, S-102.

NOTE: The Reflux Band™ was formerly known as the Reza Band®

## RefluxBand™

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