

RefluxBand™ Clinical Study Overview

Proprietary			
Title	Summary	References	Page
Prevention of Esophagopharyngeal Reflux by Augmenting the Upper Esophageal Sphincter Pressure Barrier	Objective demonstration that externally applied pressure of 20-30 mmHg prevents reflux above the UES.	Clinical Study Overview Prevention of Eso. Reflux... Published Laryngoscope 2014 Poster	1 3 5 12
Correlation of Externally Applied Cricoid Pressure to Intraluminal Pressure	Objectively demonstrates externally applied pressure of 20-30 mmHg correlates to internally applied pressure.	Clinical Study Overview Poster	1 13
Prospective Study of Upper Esophageal Sphincter Assist Device for Treating Extraesophageal Reflux	Patient-centric, multi-center study demonstrating successful outcomes with significant symptom reduction and high physician satisfaction. Utilized RSI scoring-nationally recognized symptom index tool.	Clinical Study Overview Prospective Study of RB... Published Otolaryngology 2016 Poster	1 14 16 24
Objective Evidence Demonstrating the Significant Reduction of Extraesophageal Reflux Events	Objectively demonstrated significant reduction of induced reflux events measured through direct trans-nasal pharyngoscopic visualization, pharyngeal pH and pharyngeal impedance.	Objective Evidence Demon... Poster	25 27
Efficacy of novel UES assist device in management of supra esophageal complications of reflux disease	Patient-centric study demonstrating symptom improvement with alternative symptom index scoring method, N-GSSIQ which includes nocturnal symptom monitoring.	Clinical Study Overview	1
Safety of an Intentionally Displaced UES Assist Device	Demonstration that the device is safe if displaced over the carotid and jugular arteries. Heart rate, blood pressure and intraocular pressure were measured and shown to be unchanged.	Poster	28
Healthcare-Market Based			
Upper Esophageal Sphincter Assist Device Associated with Symptom Response	Conducted by Northwestern University. Demonstrated patient scoring symptom improvement via RSI First study to also measure reduction in pepsin.	Published Clinical Gastroenterology and Hepatology 2018.	29
Upper Esophageal Sphincter Assist Device Effectiveness in Treating Aspiration Due to Radiation and Surgically Induced Patulous Upper Esophageal Sphincters	Conducted by Medical University of South Carolina. Demonstrated considerable resolution of aspiration due to radiation and surgically induced patulous UES	Poster	38
Prospective 3-Month Evaluation of the Upper Esophageal Sphincter Assist Device on Both Reflux Symptoms and Intraluminal UES Pressure	Conducted by Indiana University. Pilot to consider strengthening ability of Reflux Band on UES. Demonstrated significant increases in baseline UES pressures at 1 and 3 months post-therapy compared to pre-therapy. All RSI symptoms had significant improvement at 1 and 3 months compared to pre-therapy values.	Poster	39
High Economic Burden of Caring for Patients with Suspected Extraesophageal Reflux	Conducted by Vanderbilt University. Comprehensive review of the significant costs of treating LPR (A.K.A. EER), particularly Rx. Co-author Michael Vaezi investigator in other RB studies.	Published in American Journal of Gastroenterology 2013	40