

Implantica announces publication of the landmark RefluxStop® 5-year clinical study results demonstrating excellent long-term success

Implantica AG (publ.), a medtech company at the forefront of treatment for acid reflux with its unique device RefluxStop®, a treatment field with 1 billion sufferers, announces the publication of RefluxStop's extraordinary 5-year clinical data for food passageway-related outcomes in the prestigious journal, Surgical Endoscopy, an official journal of SAGES (American Gastrointestinal and Endoscopic Surgeons) and EAES (European Association For Endoscopic Surgery).

The 5-year study results, where the first published article is about food passageway sequelae, show remarkable outcomes in relation to standard of care, supporting a paradigm shift in treatment of acid reflux sufferers.

The 5 year and end of study results show:

- 97.9% of patients without any Adverse Event Dysphagia (difficulty swallowing)
- 97.9% of patients without any Adverse Event Odynophagia (painful swallowing)
- 95.7% of patients in the study with gas-bloating eliminated, improved or equivalent
- 100% of the study patients maintained the ability to belch or vomit

In addition to publication in *Surgical Endoscopy*, this study titled, "Food passageway-related sequelae in the RefluxStop prospective multicenter trial: Patient-centric outcomes of dysphagia, odynophagia, gas-bloating, and inability to belch and/or vomit at 5 years," was the subject of a very successful SAGES 2025 (California, USA) oral presentation by Dr. med. Jörg Zehetner of Kinik Beau-Site Bern, Switzerland.

Implantica CEO and founder, Dr. Peter Forsell, says, "A few data points from a large recently published literature review on standard of care Nissen fundoplication are helpful to provide an indirect comparison and offer some perspective on how extraordinary the RefluxStop® 5-year results are. Nissen fundoplication at 5 years presented with: Dysphagia in 28.9%, gas bloating in 52.7%, and inability to belch and vomit in 39.8%. The difference in outcomes are of such magnitude that they support an edict to a paradigm shift in acid reflux treatment. Publication of this study marks the dawn of a new era in the surgical treatment of GERD, one in which patients will have an innovative surgical treatment available that can restore the natural function of their body with minimal food passageway-related sequelae."

Dr. Forsell continues, "With a potential U.S. approval, pending FDA approval, in the near future, we are very excited about the opportunity to bring RefluxStop® to highly underserved GERD patients in the U.S. (where the disease affects 22-27% of the U.S. population) where RefluxStop's unique non-encircling mechanism of action reduces side effects."

- 1. Zehetner J, Hoffsten J, Das S, Schoppmann SF, Lipham JC. Looking back to a 'gold standard': A systematic literature review of laparoscopic Nissen fundoplication as an anti-reflux treatment option. *Eur Surg.* 2024.
- 2. Antunes C, Aleem A, Curtis SA. Gastroesophageal Reflux Disease. [Updated 2023 Jul 3]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: http://www.ncbi.nlm.nih.gov/books/NBK441938/

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Implantica is listed on Nasdaq First North Premier Growth Market in Stockholm.

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About Implantica

Implantica is a MedTech group dedicated to bringing advanced technology into the body. Implantica's lead product, RefluxStop®, is a CE-marked implant for the prevention of gastroesophageal reflux that will potentially create a paradigm shift in anti-reflux treatment as supported by successful clinical trial results. Implantica also focuses on eHealth inside the body and has developed a broad, patent protected, product pipeline based partly on two platform technologies: an eHealth platform designed to monitor a broad range of health parameters, control treatment from inside the body and communicate to the caregiver on distance and a wireless energizing platform designed to power remote-controlled implants wirelessly through intact skin. Implantica is listed on Nasdaq First North Premier Growth Market (ticker: IMP A SDB). Visit www.implantica.com for further information.

About RefluxStop®

RefluxStop® is a new innovative treatment that has the potential to spur a paradigm shift in anti-reflux surgery. It's unique mechanism of action differentiates it from standard of care and current surgical solutions. Longer established surgical options for GERD involve encircling the food passageway to support the lower esophageal sphincter's closing mechanism and are commonly associated with side effects such as swallowing difficulties, pain when swallowing and inability to belch and/or vomit.

In contrast, the RefluxStop® device treats the cause of acid reflux without encircling and putting pressure on the food passageway. It restores and maintains the lower esophageal sphincter in its original, natural position.

The RefluxStop® mechanism of action is focused on reconstructing all three components of the anti-reflux barrier, that if compromised could possibly result in acid reflux. It restores and supports the natural anatomical physiology of the body allowing the body to itself solve the problem with acid reflux.

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