

# Implantica shares a landmark review article on standard of care Nissen Fundoplication anti-reflux surgery – in light of the recently announced excellent RefluxStop™ 5-year results

Implantica AG (publ.), a medtech company at the forefront of introducing advanced technology into the body, including a unique device RefluxStop™ for the treatment of acid reflux, a treatment field with 1 billion sufferers, reports on the results of the recently published landmark study in the [European Surgery Journal](#), “Looking back on a gold standard: a systematic literature review of laparoscopic Nissen fundoplication as an anti-reflux treatment option”.

This study, conducted at Karolinska Institutet (Sweden), a literature review of the standard of care Nissen Fundoplication, is a first-of-its-kind comprehensive analysis ever done since the first Nissen procedure was performed in 1956. This landmark study involved 1,675 screened articles, of which 63 of the highest quality relevant articles from 40 RCT studies covering a total of 2,619 participants were selected and analyzed. This study reports on both intra- and post-operative outcomes with long-term follow-up periods of 1 year, 5 years, and  $\geq 10$  years and is one of the most comprehensive compilation of results of the standard of care acid reflux surgical procedure.

The highest complication rates 5 years post-procedure are the side effects gas bloating (52.7%), inability to belch/vomit (39.8%), swallowing difficulties/dysphagia (28.9%) and heartburn, epigastric/sternal pain (27.0%). Combining medical PPI usage and re-operations can provide an estimation of a failure rate, and this amounted to 20.6% after 5 years.

A simplistic indirect comparison of the Nissen Fundoplication results above to the recently announced RefluxStop™ 5-year results in its CE-mark clinical investigation shows substantial differences. The side effect results for RefluxStop after 5 years are: gas bloating (9%), inability to belch/vomit (0%), swallowing difficulties/dysphagia (2.3%) and the rate of reoperation plus PPI usage (4.5%).

Implantica’s CEO, Dr. Peter Forsell says, “This literature review of the standard of care Nissen Fundoplication is a first-of-its-kind comprehensive analysis involving all of the highest quality relevant RCT articles published on the Nissen procedure since its inception in 1956. Given its vast scope and depth in coverage of relevant data on the Nissen procedure, this landmark study can be potentially used as an indirect benchmark of clinical outcomes for newer surgical methods. Accordingly, RefluxStop™ 5-year results clearly indicate substantially improved patient outcomes that are further reinforced by a large amount of real-world data published from independent studies at different hospitals.”

Dr. Forsell continues, “As the results indicate, the non-encircling nature and unique mechanism of action of the RefluxStop procedure both treat acid reflux better and with much fewer side effects. In comparison to the newly published literature review on Nissen fundoplication, no RefluxStop™ patients had problems to belch or vomit after the procedure, as opposed to 39.8% could not belch or vomit after the Nissen surgery. Only one subject had the adverse event of swallowing difficulties (2.3%), which is a substantial improvement to the standard of care as presented in the newly published literature review of Nissen fundoplication, reporting swallowing difficulties in 28.9% of patients. Gas bloating improved in nearly all subjects in the RefluxStop study and occurred almost six-fold less than in Nissen, where 52.7% reported gas bloating issues. Such complications are highly relevant because they have a great effect on quality of life and patient dissatisfaction following laparoscopic fundoplication most often due to new symptoms such as swallowing difficulties/dysphagia and gas bloating, despite improvement in GERD [1].”

[1] *Humphries LA, Hernandez JM, Clark W, Luberic K, Ross SB, Rosemurgy AS (2013) Causes of dissatisfaction after laparoscopic fundoplication: the impact of new symptoms, recurrent symptoms, and the patient experience. Surg Endosc 27(5):1537–1545.* <http://doi.org/10.1007/s00464-012-2611-y>

**Here is the European Surgery link to the Nissen literature review** “*Looking back on a gold standard: a systematic literature review of laparoscopic Nissen fundoplication as an anti-reflux treatment option*”

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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](http://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 GORD involve encircling the food passageway to support the lower oesophageal 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 oesophageal 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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