

# Implantica announces new real-world Swiss study on 99 RefluxStop™ patients comparing small and large hiatal hernia, confirming equally excellent long-term results

Implantica AG (publ.), a MedTech company at the forefront of introducing advanced technology into the body, including the unique device RefluxStop™ for the treatment of acid reflux, a treatment field with 1 billion sufferers, announces the publication of a new independent real-world <u>study</u> from Switzerland demonstrating RefluxStop™'s consistent long-term outcomes irrespective of large or small hiatal hernia size before surgery, proving it to be a favorable option for patients also with large hernia.

The study entitled, "A safety and effectiveness evaluation of RefluxStop in the treatment of acid reflux comparing large and small hiatal hernia groups: Results from 99 patients in Switzerland with up to 4-year follow-up," was jointly conducted by Dr. med. Yves Borbély of Inselspital University Hospital in Bern, Switzerland, and Dr. med. Joerg Zehetner of Hirslanden Clinic Beau-Site, Bern, Switzerland. This is the first independent study in large hernia patients treated with RefluxStop™ procedure that was published in the acclaimed journal *The World Journal of Hernia and Abdominal Wall Surgery*.

Patients with large hernia, where the stomach protrudes through the opening of the diaphragm, have so far been difficult to treat with existing methods. The key finding from this paper shows RefluxStop™ is safe and effective in both large and small hernia size patient groups, with no significant difference in adverse events. Furthermore, all patients reported a significant improvement in their GERD-HRQL scores after the RefluxStop™ procedure, including those with large hiatal hernia (4-10 cm).

Large hiatal hernia is very common and a well-known predictor of treatment failure after traditional anti-reflux surgery¹ and RefluxStop™ seems to serve this difficult-to-treat population very well with its unique mechanism in which the implant acts as a mechanical stop against upward movement of abdominal structures and hernia recurrence.²

Implantica founder, Dr. Peter Forsell, adds, "I'm grateful for the work of world-renowned surgeons like Dr. Borbély and Dr. Zehetner, who focus their high-quality research on RefluxStop™ and innovation in the surgical treatment of GERD. The results speak for themselves. This study demonstrates that patients with both large and small hiatal hernias showed improvement in GERD-HRQL scores for the longest follow-up duration of up to 4 years after the procedure. This research study is a testament to the interest and quickly growing demand for innovative & effective treatment solutions for such hugely underserved GERD patients."

Dr. Forsell goes on to say, "Over 17% of Swiss adults, nearly one million persons, suffer from GERD.<sup>3</sup> We're proud to lead the way to a possible paradigm shift in the surgical treatment of GERD via RefluxStop<sup>™</sup>, a safe and effective treatment for GERD."

- Armijo PR, Pokala B, Misfeldt M, Pagkratis S, Oleynikov D. Predictors of Hiatal Hernia Recurrence After Laparoscopic Anti-reflux Surgery with Hiatal Hernia Repair: a Prospective Database Analysis. J Gastrointest Surg. 2019 Apr;23(4):696-701. doi: 10.1007/s11605-018-04073-0. Epub 2019 Jan 7. PMID: 30617774.
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- 3. Schwenkglenks, M., Marbet, U.A. & Szucs, T.D. Epidemiology and costs of gastroesophageal reflux disease in Switzerland: a population-based study. *Soz.-Präventivmed.* 49, 51–61 (2004). http://doi.org/10.1007/s00038-003-2090-y

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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 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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