



# **Implantica submits FDA PMA application Clinical Module 2 for RefluxStop™ for U.S. market approval**

**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 submission of the second clinical module of the Premarket Approval (PMA) application to the US FDA for RefluxStop™ along with responses to the FDA's findings from the first module.**

The second module submitted earlier this week for the RefluxStop™ PMA is the most crucial module of the three-module process for FDA approval. The outcome of our clinical study submitted to FDA shows fantastic positive results, which has echoed around the surgical community, fueling a vibrating interest in RefluxStop among surgeons and GIs all around the world and especially in the U.S. Together with Module 2, responses to the FDA's findings from Module 1 were also submitted, which the company believes are minor findings. In addition, the finalization of Module 3 is ongoing. The US FDA has agreed to a modular submission process for the RefluxStop™ PMA application, which allows for ongoing review and feedback from the FDA as each module is submitted.

Dr. Peter Forsell, CEO of Implantica, says, "The incredible enthusiasm for RefluxStop™ among top surgeons at the recent annual American Foregut Society and European Foregut Society meetings is a testimony to the immense demand for innovation in the surgical treatment of GERD. This support is growing fast, fueled by RefluxStop's excellent clinical outcomes, both in our pivotal 5-year study but also supported by multiple centers around Europe presenting their equally excellent results. This even further demonstrates the potential of RefluxStop™ to become the standard of care for GERD patients in the U.S. pending final FDA approval."

Dr. Forsell continues, "We're thrilled to mark this crucial milestone in bringing an urgently needed innovative surgical treatment for GERD to patients in the U.S., the world's largest anti-reflux procedures market. We're sincerely grateful to the FDA for allowing Implantica to participate in the expedited module process based on the excellent 5-year clinical results from the RefluxStop™ CE mark study. As of today, nearly 1,000 patients have been treated with RefluxStop™ across more than 35 centers in Europe, and we can't wait to get this treatment to the US patients in large need."

In the U.S. today, approximately 27% of the adult population deals with the painful symptoms of GERD<sup>1</sup>, and 40% of GERD patients don't respond to the most common medication to treat the disease, PPIs.<sup>2</sup> RefluxStop™ treats the root cause of GERD by surgically restoring the natural physiology of the body, thus eliminating the need for PPIs to manage GERD symptoms, as seen in the 5-Year RefluxStop™ CE mark study participants. What has become clear from our 5-year study data is that RefluxStop™ both treats acid reflux much better and that with substantially reduced complication rates compared to standard of care Nissen fundoplication.

## Reference:

1. 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/>
2. Kahrilas PJ, Boeckxstaens G, Smout AJ. Management of the patient with incomplete response to PPI therapy. Best Pract Res Clin Gastroenterol. 2013 Jun;27(3):401-14. doi: 10.1016/j.bpg.2013.06.005. PMID: 23998978; PMCID: PMC3761380.

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*The information was sent for publication, through the agency of the contact person set out above, on November 14, 2024, at 08:30 a.m. (CET).*

## 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. Its 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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