

Implantica completes Human Factors Validation Study for RefluxStop™ as part of the US FDA Premarket Approval Process

Implantica AG (publ.), a medtech company at the forefront of bringing advanced technology into the body, announces completion of the Human Factors Validation Study with 16 US surgeons as part of the US FDA Premarket Approval (PMA) process for RefluxStop™.

In March, 16 foregut surgeons in the United States (U.S.) participated in a Human Factors Validation Study of the RefluxStop™ procedure at Northwestern University's Simulation Lab in Chicago. RefluxStop™ is an innovative new surgical procedure for the treatment of gastroesophageal reflux disease (GERD).

The goal of the study is to demonstrate how surgeons at varying levels of surgical experience from academic, community, and private clinics in the US, carry out the RefluxStop™ procedure.

In the next step of the study, an independent third party is evaluating the data collected during testing in Chicago. Findings are included in Implantica's application for an FDA PMA for RefluxStop™. The completion of this Human Factors study marks a critical milestone, which Implantica hopes will significantly help advance the US market approval process and ultimately result in the widespread availability of RefluxStop™ in the US.

Dr. Peter Forsell, CEO of Implantica says, "We're very grateful to the independent US surgeons and healthcare professionals who participated in the Human Factors Validation study, a key milestone for the FDA approval process. We extend our sincere thanks to each one of the participants for their commitment and support in bringing RefluxStop™, a disruptive surgical treatment for GERD, to patients in the U.S. An estimated 27% of the adult population in the United States struggle with GERD¹ and 40% of GERD patients don't respond to PPIs, the most common medication to treat the disease.² This leaves tens of millions of patients with limited treatment options to treat the relentless, painful symptoms of GERD and even worse, 48'000 people die in esophageal adenocarcinoma in the US and EU alone, with strong indications in the literature to be caused by acid reflux. Over 750 cases of the RefluxStop™ procedure have now been conducted in Europe with great success and RefluxStop™ fills a very strong unmet need for GERD patients in the US and around the world."

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

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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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