

Implantica receives FDA approval for RefluxStop® – Opening the U.S. market

Implantica AG (publ.), a medtech company at the forefront of introducing advanced technology into the body, announced today that the U.S. Food and Drug Administration (FDA) has granted Premarket Approval (PMA) for RefluxStop®, the company's implant-based treatment for gastroesophageal reflux disease (GERD). The approval allows Implantica to begin commercial launch activities in the United States, the world's largest medical device market.

FDA approval represents a transformational milestone for Implantica and follows the FDA's full review of the RefluxStop® PMA application, including the long-term clinical evidence supporting the 5-year safety and effectiveness of the therapy.

RefluxStop® is designed to address the underlying cause of acid reflux by restoring and maintaining the natural anatomy of the gastroesophageal junction, without encircling or applying pressure on the food passageway.

Dr. Peter Forsell, CEO and founder of Implantica, says, "FDA approval of RefluxStop® is a defining landmark for Implantica and the culmination of many years of clinical development, scientific work, and rigorous regulatory review. Most importantly, it means that we can now bring RefluxStop® to the United States, where an estimated 78 million people suffer from acid reflux¹.

We enter the U.S. market from a position of strength, with a substantially more mature clinical and commercial foundation than is typical for a newly approved medical device. RefluxStop® already has several years of commercial experience in Europe, close to 1,800 patients treated, more than 60 Centers of Excellence across nine European countries and published five-year clinical outcomes. Combined with our longstanding scientific engagement with many leading U.S. surgeons and experts, we believe this provides a strong foundation to launch and scale RefluxStop® in the U.S. market.

FDA approval changes our focus from preparation to execution. As the world's largest medtech market, the United States represents a substantial commercial growth opportunity for Implantica, and we are very excited to begin the U.S. launch of RefluxStop®. The initial rollout will be targeted, focusing on selected leading U.S. centers and reflux surgeons. Commercial adoption is expected to build gradually, reflecting the physician training and site activation required to establish RefluxStop® at each center. Our focus will be on disciplined execution, high-quality surgeon training, and building a solid commercial foundation for sustainable long-term growth."

1. El-Serag, H.B., et al., *Update on the epidemiology of gastro-oesophageal reflux disease: a systematic review*. Gut, 2014. **63**(6): p. 871-80.

For further information, please contact:

Nicole Pehrsson, Chief Corporate Affairs Officer
Telephone (CH): +41 (0)43 505 20 57
nicole.pehrsson@implantica.com

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

The company's Certified Adviser is FNCA Sweden AB, info@fnca.se

This information constitutes insider information that Implantica AG is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on August 20, 2026, at 23:05 CEST.

About Implantica

Implantica is a medtech company focused on bringing advanced implantable technologies into the body designed to improve patient outcomes and quality of life. The company's lead product, RefluxStop®, is an FDA approved and CE-marked implant for the treatment of gastroesophageal reflux disease (GERD) with the potential to transform the standard of care in anti-reflux surgery, supported by strong long-term clinical outcomes.

In addition to RefluxStop®, Implantica has developed a broad, patent-protected product pipeline partly incorporating two platform technologies: an eHealth platform designed to enable communication with and remote monitoring and control of implants inside the body, and a wireless energizing platform designed to wirelessly power implantable devices through intact skin. These investigational devices are intended to facilitate remote changes to treatment, potentially saving cost for society.

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 treatment for GERD designed to address the root cause of acid reflux. Conventional anti-reflux surgical procedures typically rely on encircling the esophagus and are often associated with side effects such as swallowing difficulties, inability to belch or vomit, and gas bloating. RefluxStop is different and aims to restore and maintain the lower esophageal sphincter in its natural anatomical position without encircling or applying pressure on the food passageway. Commercial performance from a multitude of centers supports the clinical study data collected and shows that the RefluxStop® device can successfully treat GERD without wrapping or constricting the esophageal sphincter, thereby avoiding the side effects commonly seen with the other current treatment approaches. Long-term 5-year clinical outcomes on RefluxStop® have been published in peer-reviewed scientific journals and support that a significant portion of the patient population will achieve clinically meaningful results, with minimal risks, when used in accordance with the indications for use.

Indications for Use: RefluxStop® is an implantable sterile medical device intended to treat acid and non-acid reflux in patients diagnosed with gastroesophageal reflux disease (GERD). The device ensures maintenance of a normal physiological situation for the gastroesophageal junction (GEJ) in a defined intra-abdominal position, allowing natural physiological function of the lower esophageal sphincter (LES), thereby reducing or eliminating acid and non-acid reflux. The RefluxStop® Deployment Tool is indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD), defined by abnormal impedance pH and/or pH testing, and indicated for RefluxStop® implantation.

Community

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Media Contact:

Implantica AG

Juanita Eberhart, VP Marketing & Advocacy

M: +1 925-381-4581

juanita.eberhart@implantica.com