

Implantica ramps-up production with 10,000 RefluxStop® units in preparation for U.S. launch, pending FDA PMA approval

Implantica AG (publ.), a medtech company at the forefront of introducing advanced technology into the body, including the innovative RefluxStop® device for the treatment of acid reflux, a treatment field with over 1 billion sufferers, announces its strategy to produce 10,000 RefluxStop® devices in preparation for the expected, substantial demand from the U.S. market, following FDA PMA approval.

Implantica is taking strategic and decisive steps to prepare for the global expansion of the RefluxStop® System – aiming to accelerate the commercialization of the RefluxStop® device and ensure a rapid and scalable market entry in the U.S. and other global markets, pending respective regulatory approvals. To support such a level of global demand and de-risk delays to product launch in new markets, Implantica is actively building the infrastructure, inventory, resources, and well-trained teams necessary to deliver a high-growth business.

As part of this comprehensive commercialization strategy, Implantica aims to support a robust U.S. and global launch via establishment of sufficient inventory. This early investment in inventory will significantly enhance Implantica's ability to meet the expected accelerated demand from the U.S. and other global markets. It positions the company to execute a high-velocity market rollout without the delays typically associated with production scale-up, which is a common bottleneck for many innovative medical device companies during the early phase of launch. This milestone reflects Implantica's vision for the large and sustainable growth of the RefluxStop® business and will start with the U.S. launch, pending FDA PMA approval.

Dr. Peter Forsell, founder and CEO of Implantica, says, "The U.S. GERD market represents a tremendous business opportunity, with an estimated 20% of adults affected by this unforgiving disease – a population that remains severely underserved by current treatment options. The urgent clinical need, combined with the scalability of RefluxStop® and our solid preparedness for launch, enables us to quickly monetize a huge market opportunity and create long-term value for our stakeholders. Implantica is not only innovating at the product level—we are also executing a commercialization strategy designed for speed, scalability, and impact."

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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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