Implantica announces successful completion of first RefluxStop® procedures in the U.S.

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, announces that the first RefluxStop® procedures in the U.S. were successfully performed yesterday at the University of Southern California (USC) in Los Angeles by leading U.S. anti-reflux surgeon, Dr. John Lipham, Chief of the Division of Upper GI and General Surgery, Keck School of Medicine of USC and Past President and Co-founder of the American Foregut Society.

The first commercial RefluxStop® procedures in the U.S. mark a major milestone. RefluxStop® is designed to address the root cause of gastroesophageal reflux disease (GERD) by restoring the body's natural anti-reflux barrier, a fundamentally different approach to existing treatments of GERD.

Dr. John C. Lipham said, “Performing the first RefluxStop® procedures in the U.S. marks an important milestone for our patients and our program. The patients are doing well, and I look forward to offering this innovative treatment to many more patients. Reflux is a mechanical problem, and it deserves to be resolved surgically by addressing its underlying anatomical cause.

Traditional interventions primarily focus on reinforcing the lower esophageal sphincter (LES) often resulting in side effects such as swallowing difficulties and has contributed to the reduction of surgical treatment overall. In contrast, RefluxStop® features a unique mechanism of action that restores the natural anti-reflux barrier and as the long-term European clinical data have demonstrated, provides effective reflux control with much fewer side-effects."

Dr. Lipham continued, “With RefluxStop we now have a solution that addresses a significant unmet medical need – not only for the approximately 40% of GERD patients who respond inadequately to medication[1], but also for the more than one-third of sufferers with swallowing difficulties who have no well working treatment today. For decades, we have sought a treatment that provides effective reflux control without compromising patient's natural swallowing.

Medication focuses only on GERD symptoms by reducing acid production and has been shown to potentially cause serious long-term side effects. With this advancement, we finally have an option that treats the disease at its root anatomical cause without compromising esophageal function.”

Dr. Peter Forsell, Inventor of RefluxStop, Founder, and CEO of Implantica, said, “Congratulations to Dr. Lipham and his world-class team at USC on completing the first RefluxStop® procedures in the U.S. It was an honor to observe the procedures and represents a defining landmark moment for the U.S. market and Implantica, but most importantly for the many millions of American GERD patients.”

Dr. Forsell continues, “We are very encouraged to see the strong interest in RefluxStop® among U.S. surgeons, GIs, and patients, and will continue to build the U.S. launch deliberately, center by center, with highest-quality surgeon training and ensuring excellent patient outcomes at the core. These chronic sufferers finally have an effective surgical alternative with limited side effects, as confirmed by the today 39 published articles on RefluxStop®, and we couldn’t be more excited to bring our new treatment to the patients, a disease that affects 78 million Americans.”

1. Delshad, S.D., et al., *Prevalence of Gastroesophageal Reflux Disease and Proton Pump Inhibitor-Refractory Symptoms.* Gastroenterology, 2020. **158**(5): p. 1250-1261.e2.

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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 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.

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