

FROST & SULLIVAN

IMPLANTICA

2022
TECHNOLOGY
INNOVATION
LEADER

EUROPEAN
GASTROESOPHAGEAL REFLUX
DISEASE THERAPY DEVICE INDUSTRY

Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each Award category before determining the final Award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Implantica excels in many of the criteria in the European gastroesophageal reflux disease therapy device space.

AWARD CRITERIA	
<i>Technology Leverage</i>	<i>Business Impact</i>
Commitment to Innovation	Financial Performance
Commitment to Creativity	Customer Acquisition
Stage Gate Efficiency	Operational Efficiency
Commercialization Success	Growth Potential
Application Diversity	Human Capital

Ushering in a Paradigm Shift in the Treatment of Gastroesophageal Reflux Disease through a Revolutionary Passive Implant

Gastroesophageal reflux disease (GERD), caused by the regurgitation of stomach acid back into the

“The RefluxStop device offers the lower risk of post-procedural complications for patients compared to commercially available surgical devices; it consists of 5 rounded parts to enable optimal flexibility in treating acid reflux, without affecting the functioning of the stomach.”

**- Neeraj Nitin Jadhav,
Industry Analyst**

esophagus, is a highly prevalent chronic disorder affecting an estimated 1.03 billion patients worldwide,¹ significantly impacting their quality of life. Proton pump inhibitors (PPIs), including rabeprazole, omeprazole, and esomeprazole, are the most commonly used non-surgical methods for managing GERD; however, rather than preventing the regurgitation of stomach fluid into the esophagus, these drugs only decrease the acid content. PPIs do not treat the root cause of the condition, resulting in

most patients experiencing GERD symptoms - including heartburn and 24-hour pH measurable reflux episodes, even after daily drug consumption. Furthermore, the chronic use of drugs can lead to malabsorption of magnesium, calcium, and Vitamin B12, increasing the risk of bone fractures. Other

¹ Springer Nature Limited; Scientific Reports; Jorabor Singh Nirwan, et al.; April 2, 2020; [“Global Prevalence and Risk Factors of Gastroesophageal Reflux Disease \(GORD\): Systematic Review with Meta-analysis”](#)

adverse effects associated with GERD medications include developing enteric infections, chronic kidney disease, and community acquired pneumonia. Moreover, surgical methods (with or without devices) used in GERD treatment procedures compress the food passageway, which can result in complications such as difficulty swallowing, vomiting, belching, and gas bloating syndrome.

To address the limitations of PPIs and surgical methods for treating acid reflux disease, Switzerland-based Implantica Group developed its breakthrough RefluxStop™ device, a CE-marked passive, single-use sterile medical implant for acid reflux treatment. During laparoscopic surgery, the RefluxStop device is placed outside of the top part of the stomach (fundus wall), allowing it to reconstruct the angle of His, which is an acute angle at the esophagogastric junction, thus preventing the reflux of the stomach content into the esophagus. Furthermore, the device blocks the movement of the lower esophageal sphincter into the thorax, eliminating the development of weaker pressure and abnormal breathing and preventing acid reflux. The device, therefore, addresses the root cause of the condition, eliminating GERD symptoms and enabling normal pH in the lower esophagus. In addition to preventing the complications associated with the use of PPIs, Implantica's device is designed to eliminate the development of Barrett's esophagus, a precancerous condition caused by GERD that can lead to esophageal adenocarcinoma. Curtailing the use of PPIs after the RefluxStop™ device procedure reduces patients' annual healthcare costs, which were as high as \$12.4 billion² in 2015 in the United States alone, in addition to indirect costs caused by GERD-associated decreased work productivity.

Frost & Sullivan points out that the placement of the RefluxStop™ device on the upper part of the stomach is a critical point of differentiation in the market. This approach restores the body's natural anatomy by keeping the esophageal sphincter permanently in the abdomen, below the diaphragm, and does not compress the food passageway, thus preventing the development of complications that are commonly observed when using competing devices for GERD management. The RefluxStop™ device offers the lower risk of post-procedural complications for patients compared to commercially available surgical devices; it consists of 5 rounded parts to enable optimal flexibility in treating acid reflux, without affecting the functioning of the stomach. The device's solid medical-grade silicone makes it highly durable, allowing it to last for the patient's entire lifespan and preventing frequent implant replacement, subsequently improving patient safety and lowering the financial burden on the patient.

Innovation Pipeline

Implantica is also developing active smart medical implants based on its Wireless Energizing Platform, with proprietary energy transmission designed to power implants directly or recharge them wirelessly through intact skin. In addition, the platform will control the quantity of energy transmitted wirelessly and energy used by the implant, preventing the body from generating extra heat and eliminating potential damage to the surrounding tissue. The platform will continuously transmit body parameters directly to patients and their caregivers, facilitate wireless controls to allow for non-invasive postoperative adjustments, and regulate the implant's operational status.

Implantica is leveraging the platform for use in its pipeline of smart implants in gastrointestinal and urology, including treating urinary incontinence (UriControl®), urinary retention (UriRestore™), erectile

² *Cleveland Clinic Journal of Medicine*; Andrew Young, DO, et al.; April 2020; "[GERD: A practical approach](#)"

dysfunction (PotencyFlow®), fecal incontinence (RectalRestore®), and obesity (AppetiteControl™). In addition, Implantica is developing the e-InVivo™ eHealth platform, which will be an intelligent sensor-based implanted device to collect important health parameters and wirelessly transmit the data to patients and healthcare providers on smart devices (e.g. smart watches or smartphones). Moreover, the platform will be able to take automatic actions to enable the desired treatment effect on the target organ and control bodily functions. The platform will facilitate the simple monitoring of vital health parameters, detect diseases early, and initiate timely treatment to manage conditions effectively. Frost & Sullivan expects the e-InVivo eHealth platform to shift the current reactive care delivery approach to a proactive one, thus improving health outcomes and treatment costs for patients.

Substantial Clinical Benefits for RefluxStop™ and Strategic Collaborations with Key Opinion Leaders and GERD Centers of Excellence to Ensure Scalable Commercial Success

A clinical study³ that evaluated the safety and effectiveness of Implantica's RefluxStop™ device demonstrated favorable outcomes in patients. For instance, out of the 50 subjects implanted with the device, 98% showed normal measured 24-hour pH in the lower esophagus, and the average GERD-Health-Related Quality of Life (GERD-HRQL) score among participants improved 86% from the baseline after 1 year. Moreover, the prevalence of gas bloating and dysphagia were significantly reduced, and the subjects experienced no serious device-related adverse events. The three-year follow-up study of the RefluxStop™ device showed remarkable results; none of the subjects required regular daily use of PPIs, which were consumed by all participants before having the device placed in the upper part of the stomach.

The promising results achieved in the clinical study, coupled with Implantica's focus on partnering with key opinion leaders including highly skilled surgeons and reputed GERD centers of excellence, have spurred the adoption of the RefluxStop™ device among patients. For instance, in March 2022, Implantica partnered with RefluxUK, the largest specialist reflux clinic in the United Kingdom that has the most

"A comprehensive patent portfolio is a cornerstone for the company's growth strategy, built based on significant investments in research and development. The company has developed an extensive intellectual property portfolio of more than 1,000 patents, with each application 5 to 15 times more comprehensive than those filed by competitors."

**- Neeraj Nitin Jadhav,
Industry Analyst**

influential team of anti-reflux surgeons for deploying the RefluxStop device. Furthermore, Implantica has collaborated with prominent anti-reflux centers and hospitals, including Klinikum Friedrichshafen (Germany), University Hospital Vienna (Austria), and Bern University Hospital (Switzerland), in addition to healthcare providers in other countries, such as Spain, Italy, and Sweden, to grow the device's geographical footprint. These strategic partnerships are critical in gaining timely market access and unlocking the full business potential of RefluxStop. The KOL adoption has facilitated robust growth in the company's revenues,

increasing to €387,000 for fiscal year 2021, at a phenomenal year-over-year (YoY) growth rate of 154.6%.

These increased revenues are primarily attributed to anti-reflux surgeons rapidly adopting the RefluxStop device due to its immense benefits, which is a significant accomplishment despite elective surgeries in

³ National Library of Medicine: National Center for Biotechnology Information; Miloš Bjelović, et al.; July 20, 2020; ["Non-active implantable device treating acid reflux with a new dynamic treatment approach: 1-year results"](#)

hospitals across Europe being intermittently put on hold in 2021 because of the COVID-19 pandemic. Furthermore, Implantica has taken a major step forward in gaining US regulatory approval for the RefluxStop device, with the US Food and Drug Administration (FDA) agreeing to accept a Premarket Approval (PMA) submission based solely on the existing long-term European data for the device. Frost & Sullivan commends Implantica for this huge achievement and strong endorsement of the device's utility.

A comprehensive patent portfolio is a cornerstone for the company's growth strategy, built based on significant investments in research and development. The company has developed an extensive intellectual property portfolio of more than 1,000 patents, with each application 5 to 15 times more comprehensive than those filed by other competitors. Implantica has adopted a robust and multi-layered approach that provides better patent protection for the invention related to the product design, device methods of action, and the technologies deployed by device sub-components. With such a huge patent portfolio and patents filed in key markets such as Europe, the United States, Canada, Mexico, Australia, Brazil, Japan, and China, Frost & Sullivan analysts conclude that Implantica has clearly built a strong foundation to achieve outstanding business growth in the near future.

Conclusion

PPIs to manage GERD do not prevent the regurgitation of stomach fluids into the esophagus and only lower the fluid acid content. Furthermore, their chronic use can cause severe drug-related adverse effects in patients, and surgical methods that compress the food passageway can cause procedure-related complications in patients.

To overcome these challenges, Implantica developed its groundbreaking RefluxStop device that is placed on the upper part of the stomach to treat the root cause of GERD, thus eliminating symptoms and resulting in normal pH in the lower esophagus. Through the RefluxStop device procedure, patients can curtail the use of PPIs and the subsequent complications associated with their consumption. The device's unique design and the use of solid medical-grade silicone offer optimal flexibility and durability, providing maximum safety and lowering the economic burden on patients.

Frost & Sullivan commends Implantica's ability to develop a medical implant that restores the natural anatomy of the esophageal sphincter and successfully treats GERD without affecting the food passageway, in turn improving patients' health outcomes and their quality of life. With its strong overall performance, Implantica earns Frost & Sullivan's 2022 Technology Innovation Leadership Award in the European gastroesophageal reflux disease therapy device industry.

What You Need to Know about the Technology Innovation Leadership Recognition

Frost & Sullivan's Technology Innovation Leadership Award recognizes the company that has introduced the best underlying technology for achieving remarkable product and customer success while driving future business value.

Best Practices Award Analysis

For the Technology Innovation Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Technology Leverage

Commitment to Innovation: Continuous emerging technology adoption and creation enables new product development and enhances product performance

Commitment to Creativity: Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

Stage Gate Efficiency: Technology adoption enhances the stage gate process for launching new products and solutions

Commercialization Success: Company displays a proven track record of taking new technologies to market with a high success rate

Application Diversity: Company develops and/or integrates technology that serves multiple applications and multiple environments

Business Impact

Financial Performance: Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at <http://www.frost.com>.

The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.

[Learn more.](#)

Key Impacts:

- **Growth Pipeline:** Continuous Flow of Growth Opportunities
- **Growth Strategies:** Proven Best Practices
- **Innovation Culture:** Optimized Customer Experience
- **ROI & Margin:** Implementation Excellence
- **Transformational Growth:** Industry Leadership



The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.

Analytical Perspectives:

- **Mega Trend (MT)**
- **Business Model (BM)**
- **Technology (TE)**
- **Industries (IN)**
- **Customer (CU)**
- **Geographies (GE)**

