

Bringing advanced technology into the body

eHealth implants designed to significantly impact people's lives







Successful IPO on NASDAQ First North, September 2020

Founder specialist surgeon educated at Karolinska

- ✓ Successful track record in the implant business
- Developing the gastric band business to 28% non-US market share
- ✓ Founder invested SEK 800 million in Implantica

The previous invention/venture the adjustable gastric band – a highly successful product



Source: (1) Angrisani L, et al., 2003/2008/2011/2013; Obesity Surgery 2004/2009/2013/2015; Scopinaro N, 1998; (2) LINX magnetic band and Endostim average.

Markets

Global implantable medical device market

The global implantable medical devices market is expected to reach USD 168.3 billion by 2027, representing a compound annual growth rate of 5.5% over the next 5 years.¹

Many patients undergo surgical procedures every year to receive implantable medical devices. Implants are used in a wide range of settings, such as orthopaedics, pacemakers, cardiovascular stents, defibrillators, neural prosthetics or as drug delivery systems.

The rising occurrence of chronic diseases, such as heart failure, arthritis, motor, sensory or cognitive modality etc., that require various types of implants to prolong the life of the patient or improve patient quality of life, are contributing to the growth of the market. Moreover, an increase in the geriatric population across both developed and developing regions of the world has resulted in a rising prevalence of various chronic diseases, further driving demand for implantable medical devices.

Technological advancements and increase in adoption of implants together with a rise in the incidence of chronic cardiovascular diseases are the main drivers in the implantable medical device market segment.

Source:

Implantable Medical Devices Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2022-2027, Research and Market

USD 68 billion

 the forecast size of the implantable medical device market by 2027¹



CEO comments

Revolutionizing Patient Outcomes and Building a Smart eHealth Future

I am pleased to report that 2021 was another year of strong market building and new product development for Implantica. We continued to stay focused on the path of mid-term substantial success.

We made great progress towards our key strategic goals of executing our market development strategy for RefluxStop[™] as well as accelerating the development of our unparalleled product pipeline of smart ehealth based implantable solutions.

Covid-19 has affected all medtech companies and has caused a delay, a hiccup in Implantica's pathway towards building an important medtech success story. However, the potential of Implantica is unchanged and very strong. It is very important for the management to give a loud and clear message that this delay is all about the pandemic situation that has affected us in several areas. The time line of our smart medical implants is delayed due to a shortage of electronic components especially smart miniaturised chips.

This said overall it is a very inspiring period with our new eHealth oriented pipeline, building the foundation for future growth. During 2021 the European approval system has changed from MDD to MDR including limiting the use of clinical data the company doesn't own to promote a market approval, a deadline we missed with UriControl® due to Covid-19.

Building a Culture of High Performance by recruiting the most talented key employees

A great company is built with great people. During the COVID-19 period, we took the opportunity to establish a new organisational structure at Implantica, by attracting and recruiting very talented people with extensive experience relevant for our expansion journey.

We have been working tirelessly to reach the most talented and exceptional MedTech people around the world to join and build Implantica and our unique business needs going forward. During 2021 and the beginning of 2022, we welcomed more than 20 competent new lead members to the Implantica team.

RefluxStop[™] – a Multi-Billion Dollar Opportunity

Throughout 2021, the COVID-19 pandemic continued with several lockdowns in European markets resulting in a careful approach towards opening up elective procedures, especially adoption of new technology procedures. Having said that, we are proud to report that despite significant restrictions, we were able to bring several world-leading KOLs and well-established GERD Centers of Excellence onboard. We are laser-focused on partnering with the absolute best surgeons and centers in the world.

Our number one goal for RefluxStop[™] is to have excellent patient outcomes in line with our 3-year clinical data with highly satisfied patients and surgeons. Based on excellent clinical outcomes, we strongly believe RefluxStop[™] has a great potential to become the new standard of care in acid reflux treatment.

While current markets, Germany, Switzerland and Austria, continued to grow deeper and wider, we set grounds for additional markets, such as UK and Sweden. The first UK surgeries took place during QI 2022.

Additional centers in Germany and Austria are scheduled to start performing RefluxStop[™] implantations during Q2. Our top priority for RefluxStop[™] is to accelerate our market access efforts to obtain adequate reimbursement and coverage to unlock the multi-billion dollar commercial opportunity in key markets.



FDA Progress

Implantica achieved a major step forward in U.S. regulatory approval for RefluxStop[™]. The Food and Drug Administration (FDA) agreed to accept a Premarket Approval (PMA) submission based solely on the existing longterm European data for RefluxStop[™]. This is a significant achievement for the Company, and we view this as a strong endorsement of RefluxStop[™].

Implantica has already incorporated a wholly owned subsidiary in the U.S., Implantica Inc. preparing to build market development and commercial teams.

Market Access Development to Unlock Large-scale Commercial Opportunity

In 2021, our top priority was to build a strong and sustainable market access strategy. This includes a commercial development team to develop RefluxStop[™] go-to-market strategy to advance market access with reimbursement, clinical evidence generation & publications, marketing and commercial roll-out.

CEO Comments

Based on our commercial experience so far, it is clear that market access is our biggest enabler to capture the broader Reflux-Stop commercial opportunity.

Healthcare systems around the world are becoming increasingly complex and demanding when it comes to covering and paying for new medical technologies. In many developed countries, recent healthcare reform includes stringent scrutiny to assess medical necessity of a new treatment and ensuring 'value for money' when approving and procuring new technologies.

In case of medical device, reimbursement is defined as mechanism that ensures a payment to the healthcare provider for the cost to procure the medical device and performing the procedure. Therefore, for any healthcare providers (e.g. hospitals), certainty in reimbursement with high coverage has a significant impact on the willingness to adopt any new technology.

Uncertain reimbursement or low coverage are an important barrier in technology adoption, and it also impacts the innovative companies to predict their return on investment. For these reasons, securing timely and adequate market access is our top priority and a critical goal for the Implantica team to achieve.

In the current evolving world, decision making processes by healthcare providers and payor authorities are increasingly evidencebased. The expectation of having a robust clinical and economic evidence from welldesigned studies and real-world setting is also becoming a key requirement. Therefore, to achieve positive market access decision and faster adoption in clinical practice, superior clinical outcomes against standard of care are needed both from randomized clinical trials and real-world observational studies.

To meet this need, the Implantica team has already commissioned a well-designed real-world observational registry study. Furthermore, we are planning a large multinational Randomized Controlled Study in future for which we will be closely working with multiple payers to get feedback and alignment on study design to meet key reimbursement requirements. A solid evidence generation will enable market access and allow us to scale commercialization globally. Our long-term vision for RefluxStop[™] is to establish it as a new evidence-based standard of care for acid reflux treatment and unlock the multibillion potential for the RefluxStop[™] business case. We invite you to join this journey with RefluxStop[™] that has all the attributes to become a first class commercial success.

Unparalleled eHealth platform and Product Pipeline

Implantica has currently engaged more than 50 full time development engineers driving the R&D work streams simultaneously including data infrastructure, food sensor and ecosystem technology. Implantica's new eHealth platform is designed to be able to change advanced treatment on distance bringing a total landmark in the development of new smart implanted eHealth-based medical treatments and saving costs for society.

Implantica is accelerating the integration of the eHealth platform technology in more pipeline products. Incorporating an increased number of treatment areas in the eHealth technology will allow for launching more pipeline products with eHealth functionality. This can be accomplished by leveraging the synergies between products and technologies that occurs when launching products in parallel and is expected to be more cost effective.

We have also increased and enhanced the functionality of our eHealth platform in order to adapt to treat more diseases, focus on more actions and measure more parameters inside the body. This work is very exciting and may have exceptional potential in the future.

AppetiteControl[™], using the new eHealth technology platform, has undergone an extensive updated IP coverage. To be able to control appetite fully automatically, this device is based on our food control sensor, which is designed to monitor the patient's eating behaviour. The food sensor is an important part of this device and uses a ground-breaking new technology. Another life changing device is UriRestore® for people, such as spinal cord injury patients, who lose their ability to empty their urinary bladder. During 2021, the technology for emptying the bladder has been tested on cadavers.

Going forward

Looking ahead, we have a strong balance sheet to support our key business goals, most importantly, build and scale our top commercial priority RefluxStop[™] while finalising development of the targets in our R&D pipeline.

We are in an exciting phase with our new technology and we foresee Implantica mid-term to be in the forefront of the smart implant and eHealth revolution.

Implantica has all the attributes to become an exceptional growth story and we have an exciting journey in front of us and that's why we manage to attract such exceptional talents to Implantica.

Implantica designs smart devices that make a difference for people and you are welcome to join that journey.

I would like to take this opportunity to thank our employees, partners and shareholders for their continued commitment, tireless efforts, and dedication in executing Implantica's bold strategy to enrich patients' lives with our ground-breaking technologies.

Yours sincerely,

Dr. Peter Forsell CEO Implantica and Founder,

Specialist in General Surgery and Inventor

Implantica Highlights

In 2021, Implantica's focus was on making progress with the FDA in bringing RefluxStop[™] to the US market, recruiting the most talented leading employees to drive the Company's growth and gaining support and adoption from the most important Key Opinion Leaders for our novel anti-reflux treatment solution.

Great progress in U.S. approval

The US approval has taken a giant leap forward since the FDA has agreed to receive a PMA marketing application for RefluxStop[™] based solely on existing European clinical data. If approved, this would allow for U.S. market entry without a premarket U.S. clinical trial. As agreed with FDA, Implantica will provide the FDA with current additional longer-term safety and efficacy data from its ongoing European clinical investigation. In preparation for gaining access to the U.S. market, Implantica incorporated a wholly owned subsidiary in the US, Implantica Inc.

Establishing a new competent organisation by recruiting the most talented key employees

During the pandemic period, Implantica took the opportunity to establish a new competent organisation to drive growth going forward by focusing on reinforcing our team with the most experienced people available. We have been able to attract best-in-class talents to take Implantica to the next level. This includes but is not limited to strengthening the management, commercial, R&D, quality and regulatory affairs, market access and clinical affairs teams with more than 20 super competent and motivated personnel. An extensive onboarding process has begun in order to build a strong company culture dedicated to our vision to provide effective care for serious health conditions and improving patient quality of life by bringing advanced technology into the body.

Continue the process to release the multi-billion dollar potential of RefluxStopTM by gaining adoption from important KOLs

Thanks to excellent clinical results, several international leading anti-reflux surgeons have started to perform the RefluxStop[™] procedure. Basically all correctly operated patients are successfully treated. Leading hospitals in Germany, Switzerland, Austria and the UK are now performing the RefluxStop[™] procedure.

While elective surgeries in hospitals throughout Europe were intermittently put on hold during 2021 due to COVID-19, we have continued to implement our market access plan and, although we are delayed, we currently see very positive trends in the market.

During 2021, RefluxStop[™] started to be implemented in several key hospitals, such as University Hospital AKH Vienna, one of the largest hospitals in Europe where Professor Schoppmann, one of Europe's leading anti-reflux surgeons, began operations with RefluxStop[™]. Another example is Klinikum Friedrichshafen, one of the largest and most prominent anti-reflux centers in Germany, also actively performs RefluxStop[™] surgeries. Several of the UK's most influential anti-reflux surgeons received RefluxStop[™] training, with the first surgeries in the UK took place in the beginning of 2022.



Acceleration of eHealth development

Implantica has accelerated the integration of the eHealth platform technology in its pipeline products and is utilizing the momentum in the digital industry to maintain the goal to be in the forefront of the eHealth transformation. A more comprehensive understanding of the use cases of the eHealth platform has been developed throughout the life cycle of stages of the implant during an innovative eHealth workshop attended by 20 experts from all over Europe.

Successful fundraising and downstream merger

Implantica successfully raised approximately SEK 600 million in a directed new share issue to speed up the commercialization of RefluxStop[™] and to accelerate bringing our eHealth platform technology to the market. The Company performed the unanimously decided downstream merger with its holding company, Implantica MediSwiss AG, not affecting the capital of the listed shareholders. Implantica's new Chief Market Access & Strategy Officer, Amit Kukreja, discloses how to secure market access success

Implantica's top priority is to attain best-in-class patient outcomes and accelerate market access

For any MedTech company with breakthrough technology, securing market access with adequate reimbursement and coverage is becoming one of the biggest and most crucial challenges to unlock the significant commercial market opportunity.

Obtaining timely market access is necessary to successfully launch the product, achieve broad-scale commercialization, and help establish the therapy as a new standard of care in the long run. Needless to say, Market Access is at the heart of a successful business strategy for any innovative MedTech company.

"My role at Implantica is to build and drive our global Market Access Strategy to ensure our groundbreaking treatment solutions that are safe, effective, and well-proven, are adequately reimbursed by healthcare systems, and timely accessible to eligible patients. Our ultimate goal is to help further advance clinical practice and establish our treatment solutions as a new standard of care based on robust and best-in-class patient outcomes data", says the new Chief Market Access & Strategy Officer at Implantica, Amit Kukreja.

The role of the Market Access function has rapidly evolved over the past 10 to 20 years, primarily due to the increasing regulations, scrutiny, and stringent requirements for the reimbursement approval process for new disruptive medical technologies. Amit explains, back in the day, once a new device received regulatory approval based on safety and efficacy data, it was sufficient to convince physicians to use the device and eventually get reimbursement from payers in most markets. However, the world has changed a lot in the past decade or so.

Today, for a new device to obtain reimbursement and broad coverage from payers or insurance companies, the product must meet several additional layers of requirements, such as:

- Strong support of leading surgeons and well-recognized research hospitals
- Adequate proof of long-term patient outcomes in a large, well-designed clinical trial
- Proven patient benefit and satisfaction in the uncontrolled, real-world setting
- Strong support of key professional medical societies and expert groups
- A positive economic impact of the new treatment for healthcare system/payers



We have a multi-billion-dollar business opportunity with our first disruptive commercially available RefluxStop solution, a paradigm shift in the treatment of GERD. With the right strategy and execution, RelfuxStop has a great potential to become the new standard of care for GERD surgical treatment options.

Amit Kukreja Chief Market Access & Strategy Officer

"We are very actively working on our evidence generation, publication, and communication strategy. We hope to see a series of key milestone publications and conference abstracts starting in the later part of 2022 and continuing thereafter. New developed clinical and cost-effectiveness data will help advance and strengthen RefluxStop's value perception. This data will also help inform and educate the broader surgical and medical community, patient advocates, policymakers, and ultimately payer agencies responsible for approving reimbursement," says Amit.

FOCUSED MARKET ACCESS TO MAXIMISE GROWTH

Countries in our Market Access plan



Focus is on top KOLs & Centers of Excellence in:

- Germany
- UK
- Switzerland
- Austria
- Italy
- Spain
- Sweden / Norway

Expanding to:

- France
- US (pending FDA approval)
- Canada
- Japan



Sustainability

Sustainability is an integral part of our business

Implantica's mission to provide medical implant solutions to millions of patients with extensive healthcare needs contributes to the UN's Global Sustainable Development Goal "Good Health and Well-being".

Through Implantica's unique technology platforms and product portfolio, the company will be an important link in the effort to create modern and efficient healthcare for all, which not only benefits the development of society at large but also creates the conditions for people's fundamental right to well-being.

Good health is a fundamental prerequisite for people to reach their full potential and to contribute to the development of society. People's health is influenced by economic, environmental and social factors. UN Goal 3 includes all dimensions and reaches people of all ages.

Over the past decades, great strides have been made to improve human health globally. Implantica's key sustainability area is embedded in our mission to provide medical implant solutions to millions of patients with extensive healthcare needs. Developing new and improved medical devices designed to provide effective care for serious medical conditions, as well as improving the quality of life for patients around the world, also means working towards a more sustainable world.

Innovations for a better quality of life

While all Implantica products contribute in one way or another to good health and well-being, we would like to highlight two examples that we are convinced will lead to an improved quality of life for the millions of people affected.

UriRestore® is a remote-controlled implant that enables people who are unable to urinate - such as patients with spinal cord injury (SCI and multiple sclerosis (MS - to urinate on demand, using Implantica's wireless platform. By reducing the need to use a catheter, which must be manually inserted into the urethra, UriRestore® limits the risk of infection. Thanks to this implant, which is controlled via a remote control, the patient can initiate urination by pressing a button that mechanically acts on the bladder.

The StomaRestore® product has been developed to eliminate the need for ostomy bags for patients in need of ostomy surgery or existing ostomy patients, thus significantly improving their quality of life. Some medical conditions require surgery to remove part of the bowel with the consequence that the intestinal wall has to protrude through the abdominal wall. These patients are then forced to use a plastic bag that collects the fecal matter outside the abdominal wall. StomaRestore® is designed to offer a completely new solution for these patients, who will no longer need to use ostomy bags. Getting rid of these plastic bags is in itself also a win for the environment while eliminating the annual cost of about USD 3 billion.

In other words, by developing innovative implant technology, we can improve preventive care, and enable remote and cost-saving treatments for patients who currently receive no treatment.

Our most important contribution to the UN's GlobalGoals is to enable access to safe and effective treatments. Implantica strives to be a credible and reliable supplier, a long-term partner for its customers and business partners, an attractive employer and a good investment for its shareholders.



Sustainability

Our three sustainability initiatives

We are delivering on our promise to contribute to sustainable development through three key initiatives in which we have both an obligation and an opportunity to make a difference by:

- Ensure patient access to effective treatment by supporting the medical community, working actively on pricing, reimbursement, regulatory approvals and market expansion.
- Offer treatments that are safe for both patients and the environment. This is achieved by adhering to high medical standards, promoting responsible purchasing and taking environmental responsibility. The safety profile and monitoring of our products is an important area of sustainability for us. By adhering to the highest medical standards, we strive to provide products and treatments that meet the medical community's high expectations for quality and regulatory compliance.
- Act responsibly and ethically in everything we do by adhering to high standards in research, business ethics and policies aimed at creating a sustainable organisation that contributes to the good development of society.

Implantica's sustainability mission is complemented by measures for the company's environmental and social responsibility.

Environment

Implantica is committed to the preservation and protection of the environment in all aspects of its operations. The company strives to minimize its direct and indirect negative environmental impact, as well as continuously reduce its environmental impact by maintaining good working practices and using environmentally friendly technologies.

The company's environmental responsibilities can be described in the following areas:

I. Production and products

- Working on safe, resource-efficient and environmentally friendly production and development

- Use natural resources efficiently and use green electricity whenever possible
- Reduce energy consumption and greenhouse gas emissions in all parts of the organisation, both during the development and production of components
- Following environmental criteria when selecting suppliers
- Strive to recycle all components of Implantica's products and packaging to the extent possible

2. Travel and transport

- Following environmental criteria when selecting suppliers
- Strive to communicate digitally and always evaluate the possibility of travelling in an environmentally friendly way
- Use electric transport wherever possible

UN Sustainable Development Goals and Global Compact

Implantica wants to deepen, structure and engage the whole company - and thus achieve a greater impact - around Implantica's sustainability work. As part of this, Implantica is exploring the possibility of linking its work to some of the UN Global Goals for Sustainable Development at the local company level. Implantica operates in a manner consistent with the principles of the UN Global Compact.

Implantica is evaluating the possibility of signing the UN Global Compact, as well as reporting on its sustainability work in the framework of the Global Reporting Initiative (GRI).





Implantica's products have great potential to save and improve lives, reduce hospital costs and provide remote care. This gives sustainability an even wider meaning.