
Implantica
2023
Annual Report

Disclaimer

This Report may contain certain forward-looking statements and forecasts based on our current expectations and beliefs regarding future events and are subject to significant uncertainties and risks since they relate to events and depend on circumstances that will occur in the future. Some of these forward-looking statements, by their nature, could have an impact on Implantica's business, financial condition and results of operations [or that of its parent, affiliate, or subsidiary companies]. Terms such as "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements. There are a number of factors that could cause actual results and developments to differ materially from those projected, whether expressly or impliedly, in a forward-looking statement or affect the extent to which a particular projection is realized. Such factors may include, but are not limited to changes in implementation of Implantica's strategy and its ability to further grow; risks and uncertainties associated with the development and/or approval of Implantica's product candidates; ongoing clinical trials and expected trial results; the ability to commercialize RefluxStop™ or the product candidates if approved; changes in legal or regulatory frameworks, requirements, or standards; technology changes and new products in Implantica's potential market and industry; the ability to develop new products and enhance existing products; the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

The factors set forth above are not exhaustive and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment, and it is not possible to predict all factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results.

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Certain information contained herein has been obtained from published sources prepared by other parties that the Company has deemed to be relevant and trustworthy. The Company has not made any independent review of information based on public statistics or information from an independent third party regarding the market information that has been provided by such third party, the industry or general publications.

Risks, uncertainties and assumptions could materially adversely affect the outcome proposed herein. Any forward looking statement may differ from those set forth as a result of various factors (including, but not limited to, future global economic conditions, changes in market conditions, intense competition in the markets in which the Group operates, costs of compliance with applicable laws, regulations and standards, diverse political, legal, economic and other conditions affecting the Group's markets, ability to achieve regulatory clearance or approval for Group products in several jurisdictions, ability to conduct pre-clinical and clinical trials, the ability to deliver market access, the market success of Group's products, timely regulatory approval and granting of reimbursement, ability to launch products according to time plan, market growth according to market assumptions, and other factors beyond the control of the Group,

Implantica's achievements & CEO reflections

Implantica is a unique company with nearly unlimited potential. RefluxStop™ continued to disrupt the field of anti-reflux treatments with its unique breakthrough approach, and excellent patient outcomes.

IMPLANTICA'S FOUNDATION:

RefuxStop™ – our first commercial product

- Our new unique treatment for acid reflux, a field with >1 billion sufferers
- Advanced in convincing the surgical community this is the new upcoming standard of care
- 5-years superior results for PMA in US
- Shown to be most cost-effective treatment according to Journal of Health Economics
- Multibillion dollar business opportunity

Our new eHealth platform

- opens up the possibilities for new more advanced smart medical implants
- designed for treatment control of implants from distance
- targeting a leap in advancing Healthcare

Extensive IP and Pipeline portfolio

- >1000 patent cases worldwide
- >350 granted U.S. patents so far
- >300 inventions of which
- >40 product pipeline candidates have been selected after market and product analysis
- approximately 25'000 pages of patent filing for the eHealth platform

REFLUXSTOP™ CURRENT STATUS:

Clinical Evidence

Over 750 patients of which data has been reported on about 320 patients already:

- Excellent 5-year results from CE study, used for PMA filing for FDA
- Excellent 3-5-year results from University Inselspital in Switzerland
- Excellent 2-year results from two centers in Germany
- Excellent 1-year results from two centers in Switzerland comparing large and small hernia

Superior Health-Economics

- Superior cost-effectiveness compared to standard of care: fundoplication and PPI medical therapy as well as LINX magnetic sphincter augmentation
- Article published in Journal of Medical Economics 2023
- A multitude of articles under preparation and submitted for publication including articles on cost-effectiveness and budget impact in various countries

US launch

- FDA accepted a PMA filing for RefluxStop™ based on our European CE mark study
- First module of three in the PMA has already been filed end of Q1, next module to be filed end Q2
- US cadaver study with successful training of 18 US surgeons for FDA PMA application – very useful also as prelaunch activities
- Many US surgeons convinced and waiting to get started including Prof. John Lipham, Chief of the Division of Upper GI and General Surgery and Professor of Surgery at Keck Medical Center, University of Southern California, Chairman of the American Foregut Society (AFS) Board and Past President of the AFS
- Tremendous interest and participation at the main U.S. congresses SAGES, AFS, and DDW from global GI Surgeons presenting their data and discussing benefits of RefluxStop therapy.

Reimbursement process in Europe

Sales focused on centers of excellence at this stage, today we have 30 active centers in Europe.

- Reimbursement approval process is highly decentralized across European markets. Our reimbursement development efforts are advancing in each key market as commercial accounts are added, which will also support the larger payer requirements in the US in future.
- In Italy and Spain with more decentralised system approvals, 3 centers have achieved the ability to purchase a defined number of RefluxStop™ to full list price. In total 15 centers have started to operate with RefluxStop™ in Italy and Spain.

CEO
Peter Forsell

Going forward

Continuing the reimbursement process in EU and targeting US approval and US launch are our main goals going forward.

RefluxStop™ adoption looks stronger than ever, and we see a strengthened and more active customer base committed to helping GERD patients with RefluxStop™ therapy.

Not only RefluxStop™, but also our eHealth platform and pipeline products are designed to revolutionise healthcare, which is targeted to go through a fantastic transformation going forward.

More input regarding the year 2023 presented after the content page.

Many thanks to all our shareholders, customers, and partners for following us.

Yours sincerely,

Peter Forsell
CEO and Founder, Implantica
Surgeon and Inventor

Content

> RefluxStop™ has all the attributes to become the new standard of care in anti-reflux surgery, supported by the excellent clinical trial results.

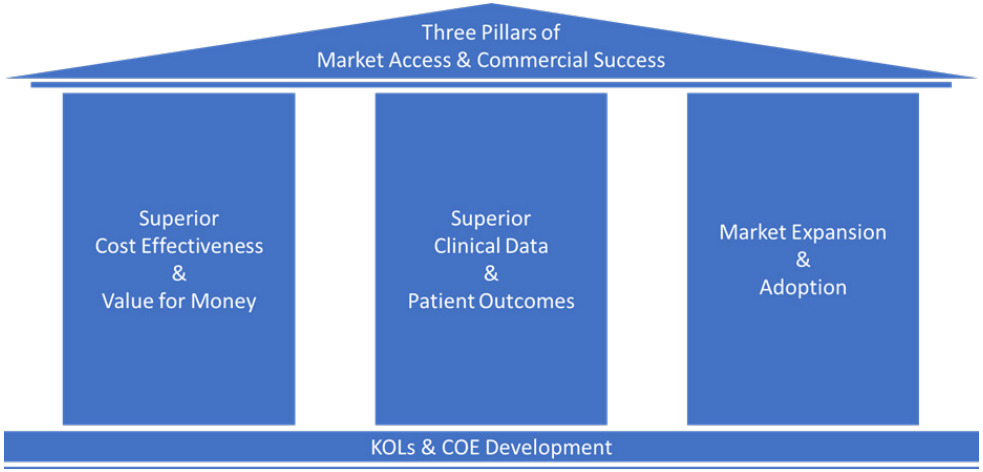
CEO comment– RefluxStop™ success in focus

RefluxStop™ is breaking boundaries and disrupting the field of GERD!

REFLECTIONS ON A FANTASTIC YEAR

Implantica had a very successful and busy 2023. We are well advanced in convincing the surgical community that RefluxStop™* is the upcoming standard of care. The market for RefluxStop™ is truly massive, with 1 billion sufferers, and more than 400 million acid reflux sufferers unable to find relief from medicine. We know there is a large unmet need, and we are confident our device is the solution needed.

Even though RefluxStop™* is approved in Europe, we need to get the healthcare bodies and insurance companies in Europe to agree to reimburse or pay for the device, the steps of which are outlined in our three pillar diagram. This is a slow and steady administrative process, a bit more burdensome post pandemic, but it is essential we follow our plan to ultimately succeed in Europe.



Three pillars for achieving reimbursement, to be paid by the healthcare system, our primary focus in Europe


CEO Peter Forsell

The path to RefluxStop®* FDA approval

While we continued to broaden our commercial footprint across Europe, the US market continues to be our top goal. We made great progress with the FDA during this past year and so far in 2024. We are targeting US approval and have filed the first out of three modules in our PMA application, with the next module anticipated before summer.

Successfully navigating the approval process takes time, but Implantica is taking the process seriously to ensure the smoothest path possible to approval.

As mentioned earlier, the US Food and Drug Administration (FDA) agreed that our RefluxStop Premarket Approval (PMA) submission to obtain US regulatory approval could be based on our existing European CE mark clinical data. The US represents the largest market potential, and all global data will be reviewed under FDA regulatory process.

This is a delicate process for any company and leads us to focus on only the best surgical centers with the top surgeons as we introduce RefluxStop. We continued to work with selected physicians during the year to train them for the RefluxStop surgery. The FDA agreed to a modular submission process for the application, which allows for ongoing review and feedback as the modules are submitted. We sent in the first module at the end of Q1 2024, a major step, putting us in motion for the US launch preparation ahead of the pending FDA approval.

As part of our efforts to push forward in the US and the PMA process, Implantica also completed the Human Factors Validation Study in March 2024 with 16 US surgeons. The goal of the study was to show how surgeons at varying levels of experience carry out the procedure. The data will be key for our FDA submission. This Cadaver lab was truly successful and excellent also from a pre-launch perspective, we have many US centers lined up to start when we get our approval. We will continue the training of US surgeons to help us accelerate commercialization after approval.

We are also starting the U.S. market development process by building a market access and commercial development execution plan for an expedited and scalable U.S. launch. Pending FDA approval, we are actively preparing the US market ahead of launch engaging with top anti-reflux Surgeons, GIs, advocacy groups and limited social media activities. We are thrilled to see a widespread excitement in the RefluxStop technology paving the way for commercial launch as soon as we receive FDA approval.

* RefluxStop® is a registered trademark in U.S. and RefluxStop™ in Europe

CEO Comment cont'd

Traction in Europe for RefluxStop™

In Europe, we are clearly gaining traction with the region's top physicians and acceptance from public healthcare systems. With >750 patients successfully treated in Europe, the medical system is waking up to the potential cost savings and health benefits of RefluxStop™. Collecting long-term clinical data, health economics to prove the societal value, and support from key opinion leaders is critical. An important ingredient in gaining reimbursement is our pan-European ReStore® registry study, and each center that joins is a valuable addition on our path to reimbursement.

We now have 30 centers in Switzerland, Austria, Germany, Italy, Spain, UK, Norway and Sweden.

We gained our first public tender win in Italy with the public hospital Ospedale di Moncalieri with Dr. Gabriele Pozzo in Turin, Italy during the fourth quarter. This was a three-year tender under which the hospital will be funded for the full list price of EUR 5,900 for each device. The tender covers the full cost of 30 devices and is a key milestone for continued success in other regions in Italy and expansion in the EU. In total eight hospitals have started with RefluxStop in Italy.

At the start of 2024, we also announced the first public tender win in Spain with Hospital Universitario de Getafe, a public hospital Madrid. Dr. Juan Carlos Ruiz de Adana and Dr. Alberto Hernández Matías successfully performed ten RefluxStop™ procedures during the past year helping us secure this key milestone in Spain. In total seven hospitals have started with RefluxStop™ in Spain.

RefluxStop surgery in Berlin

In the third quarter, the first implants were performed in the UK at St. Mary's Hospital, London, part of the Imperial Healthcare NHS Trust, one of the more rigorous single payer healthcare systems in the world. UK's National Institute for Health and Care Excellence (NICE), which advises the UK's healthcare body NHS on reimbursement of new health technologies, has now started its review of the procedure safety and efficacy of RefluxStop™. This is a key step for NHS hospitals to adopt our technology with strong international influence. More than 50 RefluxStop™ procedures have been successfully completed across three UK hospitals and several NHS hospitals are likely to start later this year.

During the second quarter Dr. Borbély from Inselspital, Switzerland's largest University hospital, presented his successful RefluxStop™ three- to five-year data at the SAGES conference in Montreal, Canada. He concluded that the excellent data from the CE mark study could be replicated in a real-world setting.

Dr. Joerg Zehetner, from Hirslanden Klinik Beau-Site Bern, Switzerland, presented his RefluxStop™ results at the Digestive Disease Week (DDW) in Chicago. He presented his results on a patient population that has Ineffective Esophageal Motility (IEM), a disorder that often causes swallowing difficulties and pain, and a group that did not have any optimal treatment options before the use of RefluxStop™.

Both the clinical evidence and health economics have developed beyond any expectation, and it looks very promising for RefluxStop™.

The one key scientific congress attended out of the many during the year was the annual American Foregut Society (AFS) meeting in Dallas, Texas, where RefluxStop made a substantial impact. Implantica's team met with the board members of the AFS to introduce the product and discussed the path forward in the US market pending FDA approval. RefluxStop was also the topic of a lunch session attended by more than 100 people. Overall, the AFS meeting was successful and led to many opportunities for collaboration with world-leading clinical GERD centers of excellence experts and helps advance our US-focused market access.

eHealth Advancements

Due to the delay caused by the pandemic, resources initially targeted to rapidly develop pipeline products have been shifted to RefluxStop™ commercialization, however, we steadily and successfully make progress with our smart pipeline implant products, which will be integrated with our two platform technologies, the eHealth and wireless energising platforms. Every single one of these pipeline products has the potential to create a large company and business.

In a nutshell, Implantica is gearing up for a high-execution phase during 2024 and beyond. We expect to deliver on an ambitious plan to build a successful commercial business as well as deliver cutting-edge smart medical devices from our product pipeline in the coming years.

Looking forward

We have an outstanding team that worked hard during 2023 to help us move closer to wider reimbursement in Europe and closer to approval in the US. I'm encouraged by the tremendous progress made. There is still a lot of work to be done, but we have a clear strategy and RefluxStop is a great product.

Many thanks to all our shareholders, customers, and partners for their continued support, commitment, and dedication to advancing Implantica's ambition to significantly transform the lives of millions of patients.

Yours sincerely,

Peter Forsell
CEO and Founder, Implantica
Surgeon and Inventor

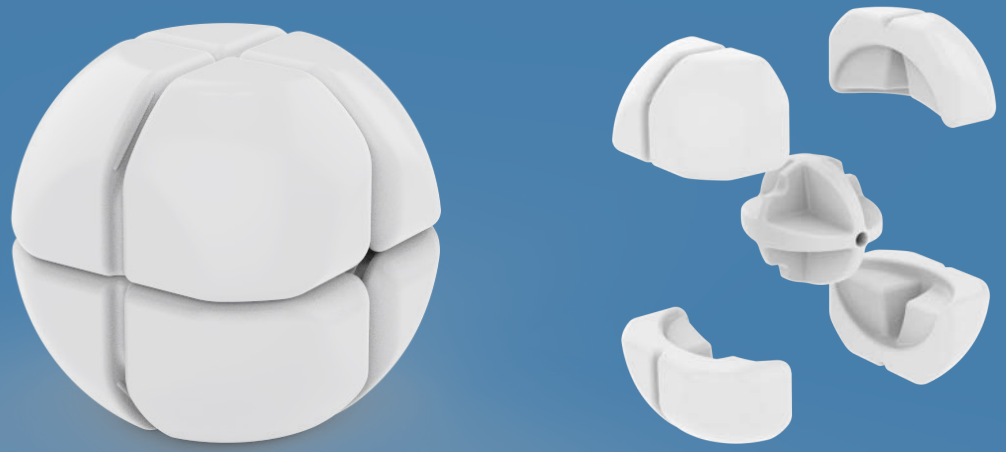
RefluxStop™

Implantica has a multibillion dollar opportunity in its hands – RefluxStop™ treating **HEARTBURN**

RefluxStop™

RefluxStop™ has a unique mechanism of action and all the attributes to become the new standard of care in treatment of acid reflux

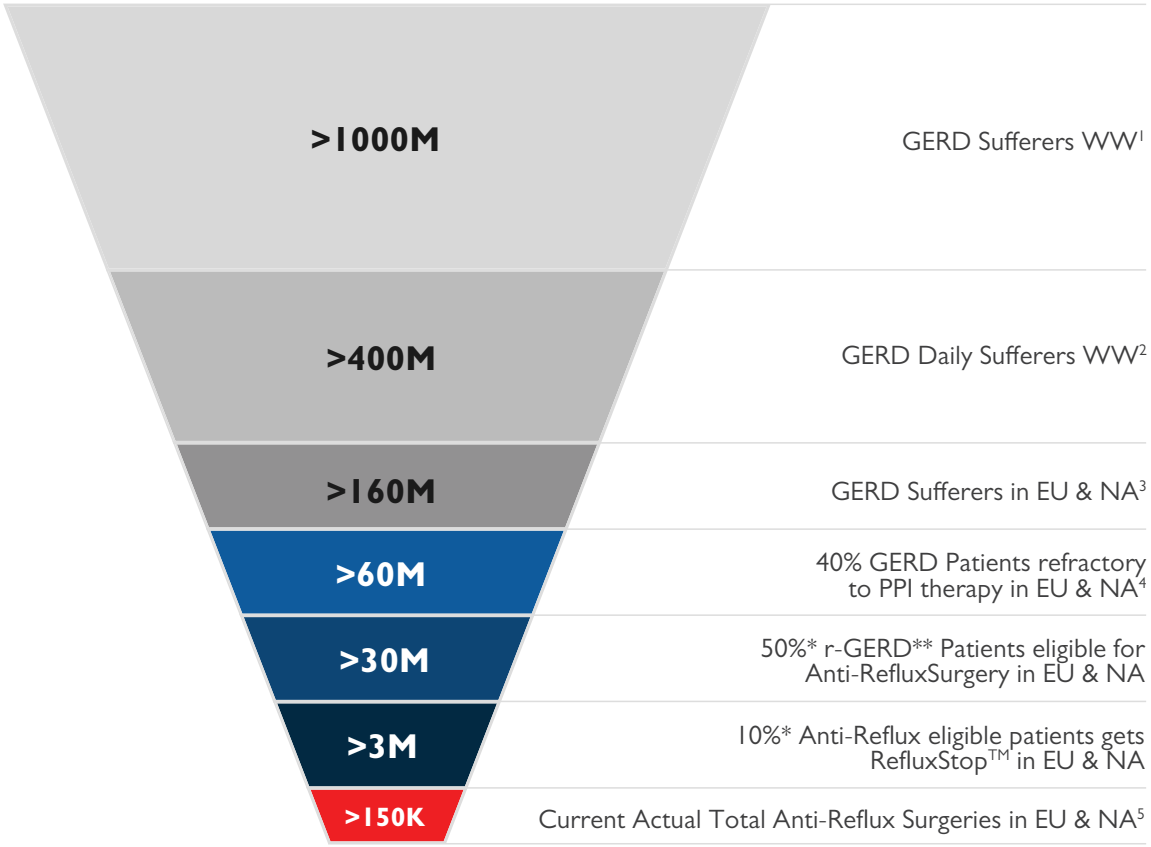
Why does RefluxStop™ provide a multibillion dollar opportunity?



RefluxStop™

Multibillion $ opportunity reason 1

One billion sufferers & enormous unmet need



Even if only 10% of anti-reflux surgery eligible pts get RS in EU & NA, the market oppurtunity is huge.

In most countries

<1%

of the indicated patients are receiving anti-reflux surgery

> Worldwide 1,03 billion people are suffering from GERD with an increasing prevalence in western societies and the highest prevalence of 22% in the U.S.

[1] https://www.nature.com/articles/s41598-020-62795-1
[2] https://biomedgrid.com/pdf/AJBSR.MS.ID.000619.pdf
[3] https://www.nature.com/articles/s41598-020-62795-1
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3801364/

* Key Assumptions
** r-GERD means Refractory GERD

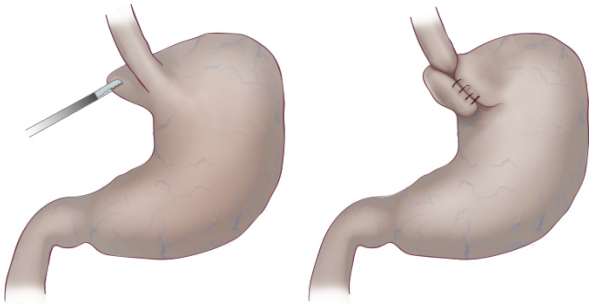
[5] iData Research Report for Implantica

RefluxStop™

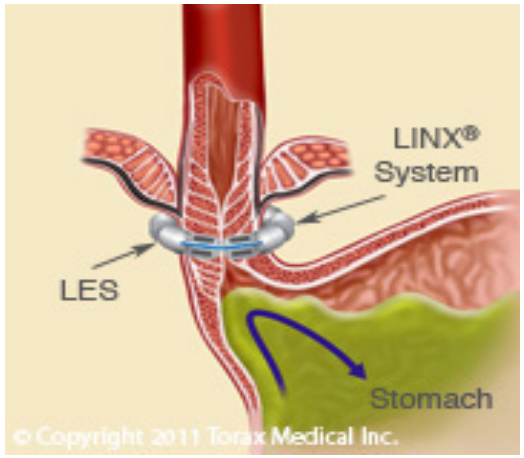
Multibillion $ opportunity reason 2

Existing treatments are suboptimal – only treat the symptoms and cause side effects

Suboptimal results and too many complications associated with existing treatments that encircle and put pressure on the esophagus



Fundoplication used since 1956 encircles the food passageway



LINX-system, our main device competitor from Johnson & Johnson, encircles the food passageway

Side effects:

- Swallowing difficulties
- Inability to belch & vomit
- Gas bloating

RefluxStop™

Multibillion $ opportunity reason 3

RefluxStop™ treats the cause of acid reflux

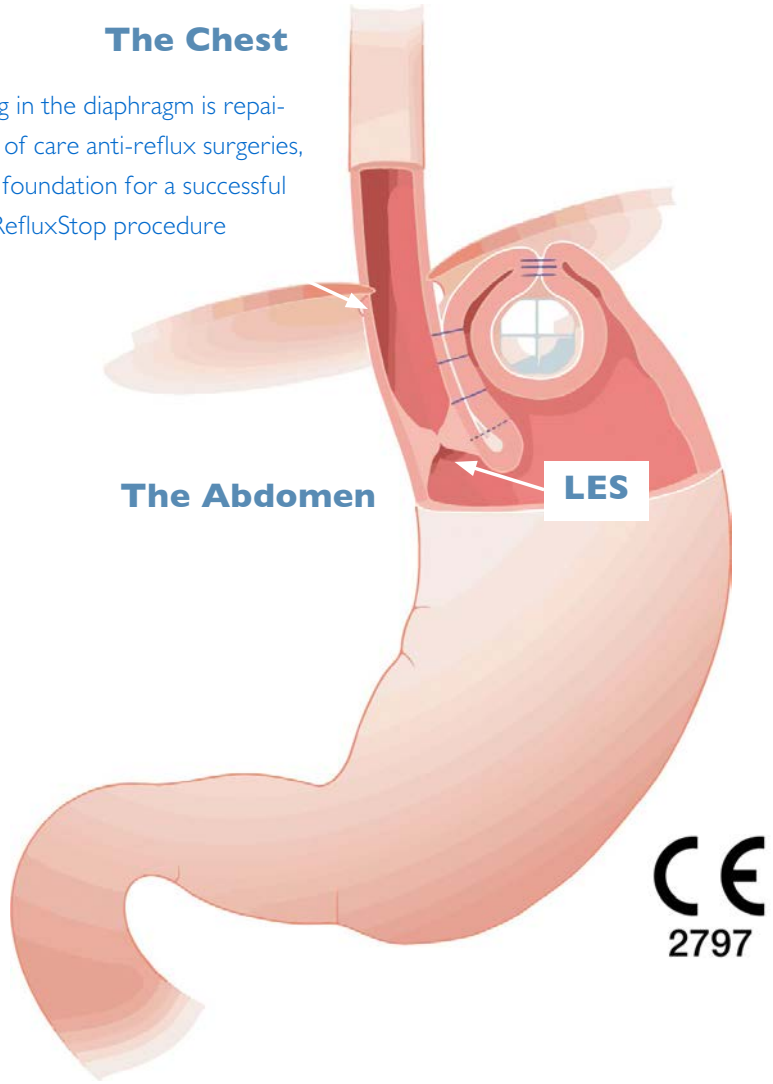
RefluxStop™ is designed to be superior to other treatments – restoring the physiological anatomy

RefluxStop™ repositions and maintains the closing sphincter between the stomach and esophagus away from the opening in the diaphragm

- RefluxStop™ does not encircle and put pressure on the food passageway, reducing side effects compared to existing standard of care
- RefluxStop™ is designed to treat acid reflux more effectively because it corrects the cause of acid reflux and, after a hiatus repair, supports maintaining a normal physiological situation

The Chest

The hiatus opening in the diaphragm is repaired in all standard of care anti-reflux surgeries, which creates the foundation for a successful result also in the RefluxStop procedure

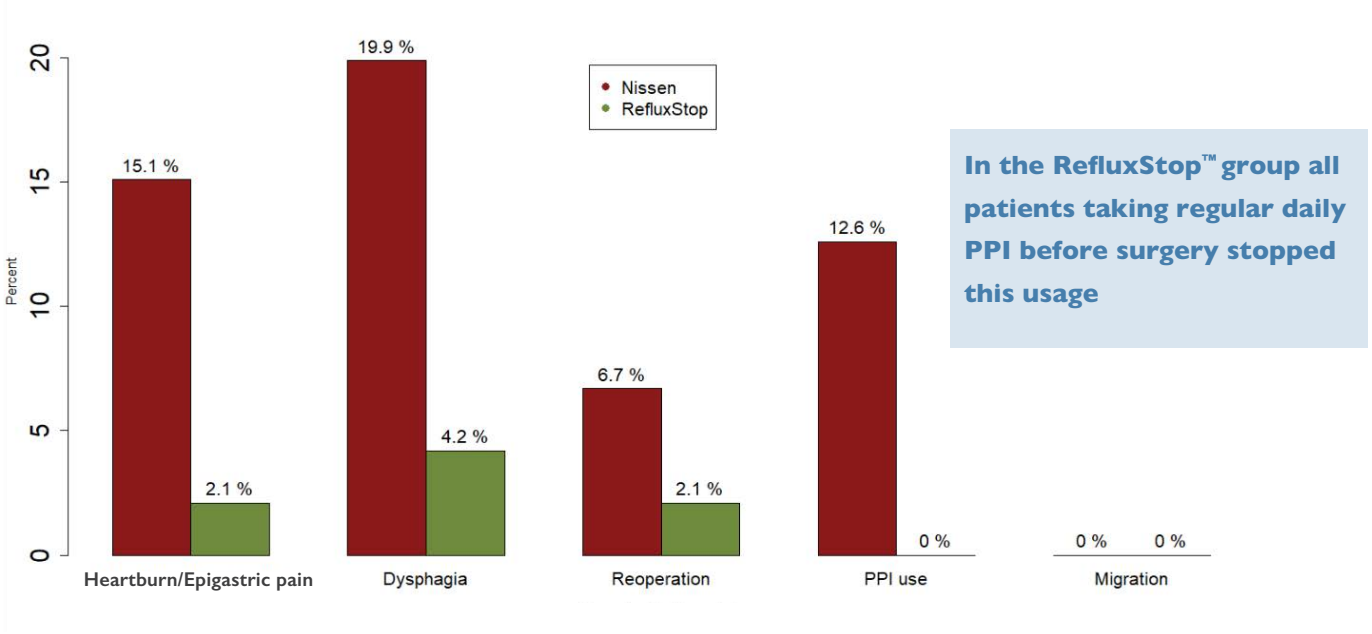


RefluxStop™

Multibillion $ opportunity reason 4

RefluxStop™ presents superior outcomes when comparing its CE study to standard of care surgical treatment Nissen fundoplication, as per a full meta-analysis

Meta-analysis by Karolinska Institute, 2023*, on 67 randomised articles on Nissen Fundoplication compared to RefluxStop™ CE-study



In the RefluxStop™ group all patients taking regular daily PPI before surgery stopped this usage

* In process to be published

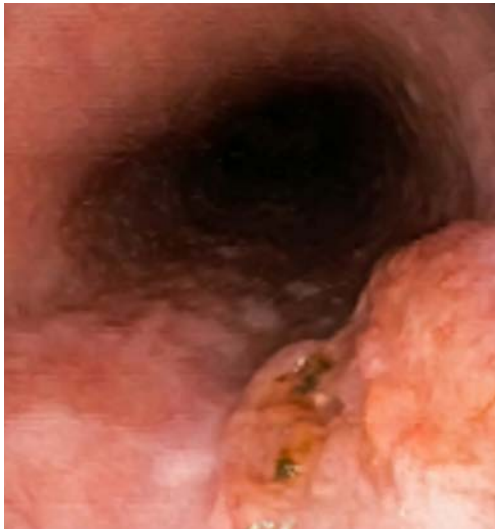
RefluxStop™

Multibillion $ opportunity reason 5

Acid reflux causes cancer – insufficient protection by PPI drugs – better surgery needed!

10 – 20% of acid reflux sufferers develop precancerous changes, so-called Barrett's esophagus[2]

Esophageal adenocarcinoma in men increased tenfold over 40 years despite introduction of PPI[11]



48'000
deaths by esophageal adenocarcinoma in EU + US alone[3]

PPI drugs
do not protect from the cancer risk and death[1]

Acid reflux causes damaging low pH in lower esophagus, causing Barrett's esophagus precancerous changes

- 170 million sufferers in EU+US take PPI p.a.
- 70 million daily sufferers in EU and US alone[12]
- 10 million = 10-20% of daily sufferers develop Barrett's esophagus[2]
- 0.6% develop fulminant cancer annually, according to meta-analysis of 47 articles[3] 84.3% die from their cancer[3]
- **Total annual deaths due to acid reflux in this literature calculation is the magnitude of 50'000. This can't go on like this!**

PPI drugs also cause serious side effects:

- Cardiovascular disease[4]
- Chronic kidney disease[4,8]
- Esophagus cancer[4,5]
- Stomach cancer[4,7]
- Infectious and parasitic diseases[4]
- Small bowel injury[6]
- Dementia[9]
- Osteoporosis[10]

Strong indication that most of the 48'000 deaths in esophageal adenocarcinoma are caused by acid reflux

Source: [1] Karolinska Institute 2020; Brusselaers N et al. 2018 [2] Modiano, Gerson 2007 [3] Yousef F 2008; WHO 2020; Zhang Y 2013 [4] Yan Xie et al. 2019 [5] Rosch P 2010; Brusselaers et al. 2018 [6] Washio et al. 2016 [7] Cheung K. et al. 2017 [8] M.E. Grams et al. 2016 [9] W. Gomm 2016 [10] Moreira Faulhaber 2010, [11] Brown et al, 2015 [12] Eusebi et al. 2018

RefluxStop™

Multibillion $ opportunity reason 6

RefluxStop™ adopted by the important key opinion leader surgeons (KOLs)

Satisfied highly skilled KOLs at the leading European centers have presented their excellent results in the near-term and are under publishing process

HIRSLANDEN KLINIK BEAU-SITE

"RefluxStop™ is a novel treatment option with strong clinical and patient outcomes with none to very minimal side-effects so far."

Dr. med. Jörg Zehetner, Prof. USC
Hirslanden Klinik Beau-Site, Bern

INSELSPITAL
UNIVERSITÄTSSPITAL BERN
HÔPITAL UNIVERSITAIRE DE BERNE

"RefluxStop™ addresses a significant treatment gap for the Acid Reflux patients tired of failing alternative treatment options."

Dr. med. Yves Borbély
Inselspital, University Hospital Bern
University Hospital for Visceral Surgery and Medicine

AKH
Die menschliche Größe

"My RefluxStop™ patients are doing very well so far. I think there is so much potential in this device to help acid reflux patients."

Univ.-Prof. Dr. med. Sebastian F. Schoppmann, FACS
AKH Vienna, University Hospital
Chief Senior Physician of the University Dept. of Surgery
Head of Upper-GI-Service

MEDIZIN CAMPUS BODENSEE

"A novel treatment like RefluxStop™ can help the GERD patients get the right treatment earlier and gain their quality of life back."

Priv.-Doz. Dr. med. Thorsten Lehmann
Klinikum Friedrichshafen
Specialist for General and Visceral Surgery

Krankenhaus Nordwest

"My experience with RefluxStop has only been positive so far, patients are happy and do not come back and complain over side effects."

Dr. med. Moustafa Elshafei

Krankenhaus Nordwest Frankfurt
Specialist for General and Visceral Surgery

RefluxStop™

Multibillion $ opportunity reason 6 cont.

"RefluxStop's study outcomes can be replicated in a real-world hospital setting"

Inselspital, the largest University Hospital in Switzerland, presented excellent patient outcomes with RefluxStop™

RefluxStop™

Multibillion $ opportunity reason 7

RefluxStop™ is most cost-effective shows Health Economic analysis by YHEC, University of York*

* York Health Economics Consortium, University of York

RefluxStop™ is the most cost-effective treatment option against medical and surgical interventions

- RefluxStop™ is the most cost-effective treatment when compared against:
  PPI drugs, LINX & standard of care Fundoplication
- RefluxStop™ is almost budget neutral to the healthcare system, due to higher health benefits

RefluxStop™

Multibillion $ opportunity reason 8

FDA PMA submission module 1 filed in U.S.

U.S. market entry will be a substantial landmark in our commercialization process

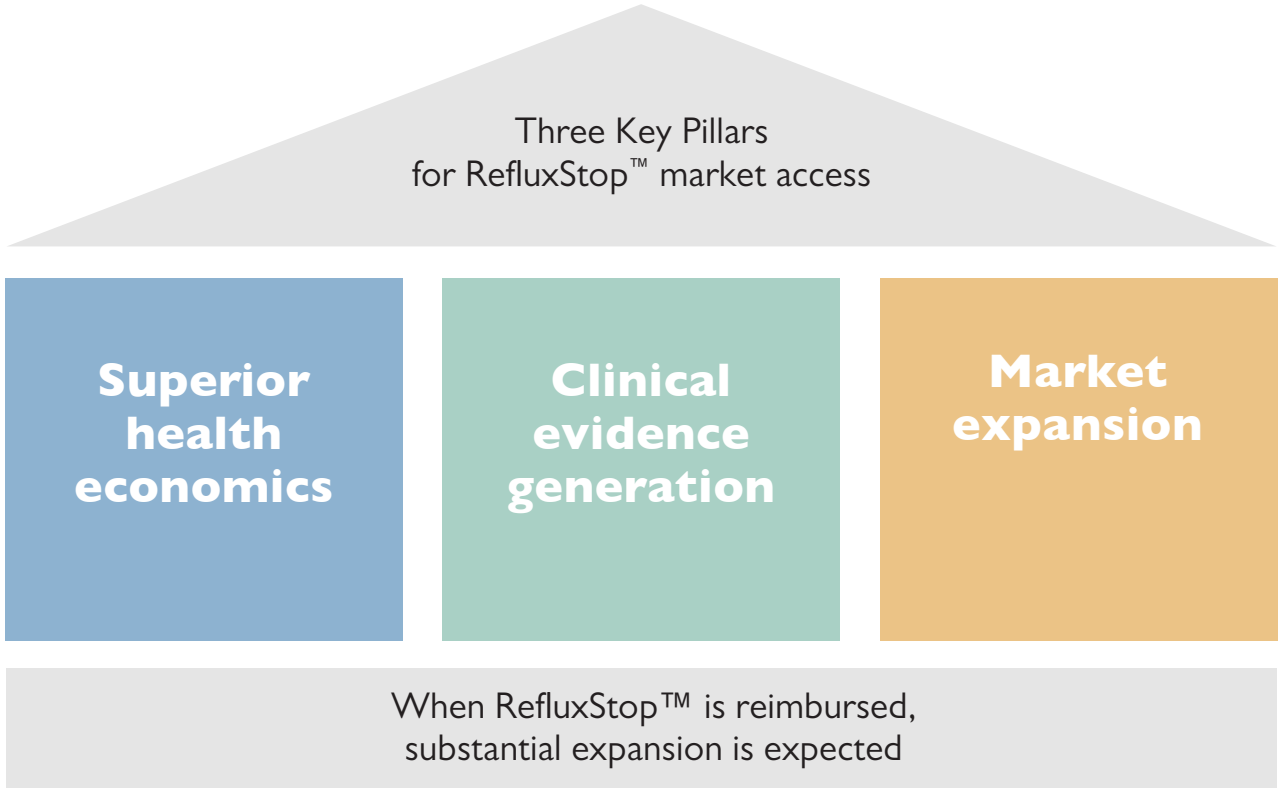
- FDA agreed to recieve a PMA submission based on existing European long-term CE mark study data for RefluxStop – a unique decision

RefluxStop™

Multibillion $ opportunity reason 9

Obtaining reimbursement will unlock commercial success – our three pillar strategy

Health insurance/ government coverage is a necessity and key to unlock the multibillion $ opportunity



RefluxStop™

Multibillion $ opportunity conclusion

RefluxStop™ is unstoppable

Implantica 2023 in brief

Q1

- RefluxStop™ launched in Spain with the first procedures performed in Madrid.
- Ethics Committee approval of the ReStore® registry study achieved in Switzerland with Inselspital Bern and Hirslanden Klinik Beau-Site joining the study.
- The prominent American Foregut Society (AFS) published a white paper outlining the steps of how acid reflux develops, reflecting the core RefluxStop™ treatment principles.

Q2

- RefluxStop™ launched in Italy with four new centers performing procedures located in Napoli, Milan and the Puglia region. Among those is Professor Bonavina, the former president of the European Foregut Society.
- The University of York-led cost-effectiveness analysis, showing RefluxStop is more cost-effective than PPIs, Fundoplication and Magnetic Sphincter Augmentation, was published in the peer-reviewed Journal of Medical Economics.

Q3

- The first NHS RefluxStop™ implants were performed at St. Mary's Hospital, London, part of the Imperial Healthcare NHS Trust, recognized as one of the most rigorous single payer healthcare systems in the world.
- The Interventional Procedures Advisory Committee (IPAC) in UK started its review of the safety and efficacy of RefluxStop™. The IPAC review process is a key step for UK NHS hospitals to adopt the RefluxStop technology with strong international influence.
- A major peer-reviewed article on Large Hiatal Hernia Repair with RefluxStop was accepted in the reputed Journal Surgical Laparoscopy Endoscopy & Percutaneous Techniques (SLEPT), emphasizing the benefit of RefluxStop™ in large hernia patients, a market representing a large unmet need.

Q4

- U.S. pre-launch kicked off with surgeons from over 10 key centers in U.S. starting the standardized RefluxStop™ surgical training program. This was in preparation for the RefluxStop™ Human Factors Validation study for the PMA application to FDA.
- Ersta Hospital in Stockholm, Sweden performed their first surgeries with RefluxStop™.
- > 50 participants including surgeons and GIs from across Europe, U.S., U.K. and Canada attended the 2nd Annual RefluxStop™ Users Meeting.
- Two new key health-economics and clinical peer-reviewed papers published: a budget impact analysis of RefluxStop™ in U.K. and RefluxStop™ results in large hiatal hernia patients.
- RefluxStop™ cost-effectiveness research received top recognition at ISPOR, the leading European health-economics conference. Economic analyses for 4 additional countries completed with the key finding: RefluxStop™ is more cost-effective than the competition.
- Nearly 2,000 surgeons attended and up to 100,000 streamed (approx. 90,000 international viewers) a live RefluxStop™ surgery performed at the 34th Congress of Digestive System Surgery in Rome.

Events after the end of the financial year

- First of three modules of the RefluxStop™ Premarket Approval (PMA) application submitted to U.S. FDA (next filing within three months targeted end Q2).
- U.S. Human Factors Validation Study for RefluxStop™ was completed with 16 U.S. foregut surgeons participating. The results of the study will be submitted as part of the U.S. FDA PMA process.
- The first-ever public tender win for RefluxStop™ was achieved by Ospedale di Moncalieri Turin, Italy. The 3-year public tender provides the hospital to be funded full list price by the public healthcare system.
- A second major public hospital purchase agreement win for RefluxStop™ was achieved by IRCCS Saverio De Bellis in Bari, Puglia, Italy.
- First public tender win in Spain achieved by Hospital Universitario de Getafe in Madrid.
- First RefluxStop™ surgeries performed at Akershus in Oslo, Norway, MIC Hospital in Berlin and Artemed Klinikum in Munich, Germany, three important centers of excellence.

Implantica history in brief

Implantica

Implantica was officially founded by Dr. Peter Forsell, specialist surgeon from Karolinska and the principal owner and CEO, when he contributed the two platform technologies, 40 products and >1000 patent cases to the company at cost with all debt written off.

Official founding of Implantica

Finalized the extensive patent portfolio and eight years of development of the energizing and eHealth platforms

Scanned the entire human body for suitable product applications, ultimately creating a large patent portfolio of over 1,000 patents

Large pipeline portfolio selected after market- & product-analysis as well as prototyping.

2018

CE-mark (approval to sell in Europe) achieved for RefluxStop™

2019

Implantica passed the more advanced MDSAP audit for its quality system

Launched new RefluxStop Deployment tool

2020

Successful listing in NASDAQ First North-Stockholm, increasing shareholder base with reputable shareholders

RefluxStop™ trial showed exceptional three-year follow-up results

2021

A phase of growth and structural development

RefluxStop™ adopted by highly influential KOLs

2022

Robust health economic analysis of RefluxStop made by University of York's Health Economic Consortium

First AppetiteControl food sensor clinical trial successfully performed

Comprehensive eHealth patent applications filed encompassing about 25,000 pages

2023

RefluxStop operated in 25 hospitals in Europe

Launch and public tender wins in Italy and Spain for full price reimbursement of RefluxStop

First NHS public hospital surgeries performed

Sweden and Norway perform their first surgeries

FOUNDER

Dr. Forsell developed the Swedish Adjustable Gastric Band (SAGB) – an innovative gastric band to treat obesity. It was commercialised in his previous business, Obtech Medical AG, and sold to Johnson & Johnson for CHF 175 million in an early stage before US FDA approval. Obtech gained 28% non-US market share of all obesity surgery with sales in 32 countries.

Dr. Forsell has contributed over EUR 100 million to Implantica.

Implantica is listed at Nasdaq First North Premier Growth Market since September 2020. (ticker: IMP A SDB)

Vision, Mission, Strategy

Vision

Become the world leader in smart medical implants

Based on our deeply analysed pipeline and our two platform technolgies, the eHealth and Wireless Energising platforms, Implantica provides a huge potential.

Mission

Provide medical implant solutions to millions of patients with substantial medical needs and at the same time save costs for society

Implantica develops novel medical treatment solutions to improve patients' quality of life with the aim to contribute to reducing healthcare costs.

Strategy and priorities

Implantica's strategy is based on the following priorities:

- Maximize commercial success through dedicated market access strategy.
  Set the foundation for RefluxStop™ global growth through focused market development activities.
- Go global with RefluxStop™ within our geographic focus.
  Submit US FDA PMA application for RefluxStop™
- Advance flagship R&D & eHealth programs to optimize time to market for prioritized products.
  Develop and launch eHealth platform and prioritized products.
- Focus on clinical evidence to support our products.
  Continue to gather robust RefluxStop™ clinical evidence through registry study and randomized clinical investigation.
- Ensure all core technology is protected by solid patents.

Implantica in brief

Bringing advanced technology into the body – RefluxStop™

Implantica's lead product, RefluxStop™, is a CE-marked implant for the prevention of gastroesophageal reflux disease (GERD) that has all the attributes to create a paradigm shift in anti-reflux treatment as supported by successful clinical trial results and key opinion leader (KOL) feedback.

RefluxStop™

RefluxStop™ treats the cause of acid reflux and is based on a completely different method than existing surgical treatments

- Designed to provide better results without complications often associated with existing GERD treatments
- Currently being commercialized in Europe
- On path toward US market approval first PMA module filed end Q1 2024

17% EU

19% US

percent of population affected weekly by acid reflux

→ Has all the attributes to become the new standard of care, supported by excellent clinical trial results and KOL feedback

Implantica in brief

Bringing advanced technology into the body – eHealth pipeline

Implantica's new eHealth platform is designed to be able to change advanced treatment on distance, which is a landmark and has all the attributes, when launched, to bring Implantica to the forefront of the eHealth revolution.

Implantica's 2 platform technologies:

Wireless energising technology

- Power active medical implants through intact skin

Bringing advanced technology into the body requires sufficient energy to enable a device to function long-term inside the body

Implantable eHealth platform

Designed to:

- Monitor and take automatic action to cause desired treatment effect
- Control bodily functions
- Communicate with caregiver and patient
- Adjust treatment on distance

Changing treatment on distance is expected to reduce the need for hospital stay and hospital visits

These platform technologies are at the heart of Implantica's goal of improving healthcare and target a substantial cost reduction for society

➔ Providing all the attributes for Implantica to take the lead in the eHealth healthcare revolution

eHealth

eHealth Market – Bringing advanced technology into the body

Implantica's eHealth platform is designed to be able to change advanced treatment on distance, aiming to take the lead in the eHealth revolution.

USD 230 billion eHealth market forecast 2027[1]

Source: 1 Allied Market Research

Patents

Patents – a key element of Implantica's business strategy – 358 granted US patents so far

Implantica's products and development devices are underpinned by an intellectual property portfolio. Patents have primarily been filed in the largest global markets such as Europe, US, Canada, Australia, Mexico, Brazil, China and Japan.

Comprehensive IP protection

A robust and multi-layered approach to patent protection preserves the value of Implantica's medical technology and is a key element of the business strategy. Filed for:

- Design of device
- Device methods of action
- Technologies used by sub-components and tools associated with device

Seventy people over 3 years make market analysis, product analysis and prototyping and selected 40 out of > 300 inventions as solid product candidates, an exceptional achievement

➔ Helping to build a solid foundation for future potentially outstanding business growth

Implantica strategically covers core technologies with IP protection

>25,000 pages

Implantica's eHealth patent filing

Markets

Global implantable medical device market

The global implantable medical devices market is expected to reach USD 179 billion by 2030, representing a compound annual growth rate of 7.2%.[1]

The rising occurrence of chronic diseases 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.

USD

179

billion

– the forecasted size of the implantable medical device market by 2030[1]

Source:
[1] Allied Market Research March 2022

RefluxStop™ treating GERD

What is GERD?

GERD occurs when stomach acid regurgitates back up into the esophagus. This acid reflux irritates and damages the tissue in the esophagus and leads to heartburn, trouble swallowing and general chest pain. Unfortunately, acid reflux is also associated with cancer due to acid repeatedly damaging esophageal tissue. The incidence of esophageal cancer, has significantly increased in the last 40 years and is growing rapidly in the western world with approximately 48,000 deaths annually in the EU and US alone.

GERD is among the top two most widespread chronic diseases in the world, impacting 17% of the EU and 19% of the US population with over 1 billion people suffering. The high prevalence of GERD presents a significant financial burden for the world's healthcare system and employers.

The American College of Gastroenterology reported that GERD symptoms cost the US nearly USD 2 billion per week in lost productivity. In the US alone, GERD accounts for direct and indirect costs of approximately USD 15-20 billion.

Current treatment of GERD

The most common way to treat GERD is through pharmacological treatment. Proton pump inhibitors, or PPI drugs, are considered to be the most efficient non-surgical treatment for GERD, even though they only treat the symptoms and not the cause – reflux with lower acidity is still present. Also, 59% of the drug users experience heartburn now and then and almost 40% of GERD patients continue to experience 24-hour pH measurable reflux episodes despite daily PPI use. (Becker V et al. 20007). This is probably the reason why it has not been possible to show that the cancer risk in esophagus is reduced by drug therapy.

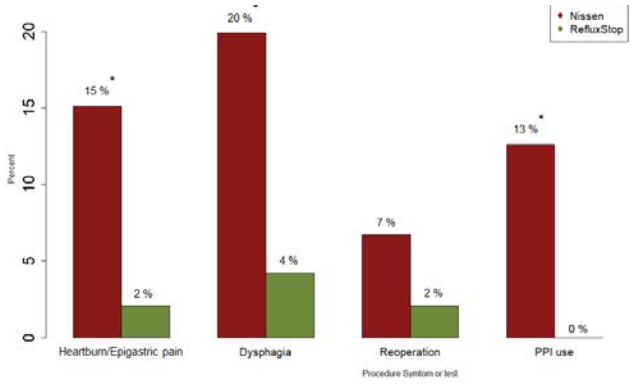
Also, in recent years several observational studies pointed out association between chronic PPI use and development of different serious adverse conditions, such as; chronic kidney disease, acute kidney disease, osteoporosis, stomach cancer, small bowel injury, intestinal infections etc (Yan Xie et al. 2019). It has been estimated that prescribed medications for GERD, PPI drugs, account for over 50% of prescriptions for all digestive diseases.

Surgical treatment of GERD has been around since the 1950s, LNF, Laparoscopic Nissen Fundoplication, is the original fundoplication procedure developed by Dr. Nissen in 1956 and considered the current Gold Standard surgical treatment alternative for GERD.

In LNF, the top part of the stomach (fundus) is wrapped around the LES with the intention to reinforce and to support and compress a weak LES.

LNF is used as a comparison for safety and performance of the RefluxStop. The literature review by Karolinska Institute identified and summarized safety events and performance outcomes reported in relation to the LNF, presented and under publication. This literature review and meta-analysis comprises 989 articles and whereof 67 randomised articles were used, which makes it a strong and valid platform for a comparison with the standard-of-care surgical treatment for acid reflux. See figure below.

Meta-analysis by Karolinska Institute, 2023, on 67 randomised articles on Nissen Fundoplication compared to RefluxStop™ CE-study*



* Statistically significant improvement

Our main device treatment competitor, Magnetic Sphincter Augmentation, in its FDA trial has tenfold as many treatment failures 42% compared to 4% in the RefluxStop™ CE trial, when measuring objective pH over 24-hours in lower esophagus

This is a band that encircles and normally puts pressure on the food passageway at the end of the esophagus to support its closing. Such surgical methods, however, have one major drawback – they all affect the food passageway – thereby they can cause swallowing problems. Recent clinical opinion is divided about the adverse events with Magnetic Sphincter Augmentation in relation to its benefits.[1]

[1] Bortolotti M. Magnetic challenge against gastroesophageal reflux . World J Gastroenterol 2021; 27(48: 8227-8241 [PMID: 35068867 DOI: 10.3748/wjg.v27.i48.8227]

RefluxStop™

RefluxStop™ fills an unmet medical need

1 billion

The amount of people suffering from GERD worldwide[1].

almost 40 %

of patients with persistent GERD symptoms continue to have measurable 24-hour pH reflux episodes despite daily PPI use[2].

USD 15-20 billion

USD 15-20 billion[3] – annual direct and indirect costs of GERD in the US.

48,000

Approximately 48,000 deaths[4] occur annually in the EU and US alone due to adenocarcinoma in the lower esophagus.

The size of the RefluxStop™ is 25 millimeters (1 inch).

[1] Global Prevalence and Risk Factors of Gastro-oesophageal Reflux Disease (GORD), Singh Nirwan et al. Nature Scientific Reports volume 10, (2020)

[2] Becker et al. 2007

[3] American College of Gastroenterology

[4] Yousef F 2008; WHO 2020; Zhang Y 2013

> Successful patient treatment is our core focus.

RefluxStop™

RefluxStop™ has all the attributes to become the new standard-of-care procedure for acid reflux treatment as supported by clinical trial results and surgeon feedback

RefluxStop™ is Implantica's lead product and addresses the serious, debilitating problem of acid reflux or gastro esophageal reflux disease (GERD) with 1 billion sufferers globally. RefluxStop™ is a specially-designed, passive silicon device that is surgically inserted and fastened to the upper part of the stomach through laparoscopic (key hole) surgery. The device is designed to treat acid reflux without affecting the food passageway and restores and maintains normal anatomy of the stomach region, a novel method that will possibly create a paradigm shift in acid reflux treatment.

The device was granted CE-mark approval in 2018 on the strength of a multi-center clinical investigation in which the safety and effectiveness of the device in patients was demonstrated. RefluxStop™ not only treats the symptoms of acid reflux but, unlike drug therapy, it also eliminates or reduces the regurgitation of stomach fluid. The clinical investigation and literature review supports that complication rates are reduced with RefluxStop™ compared to standard of care treatment Nissen fundoplication.

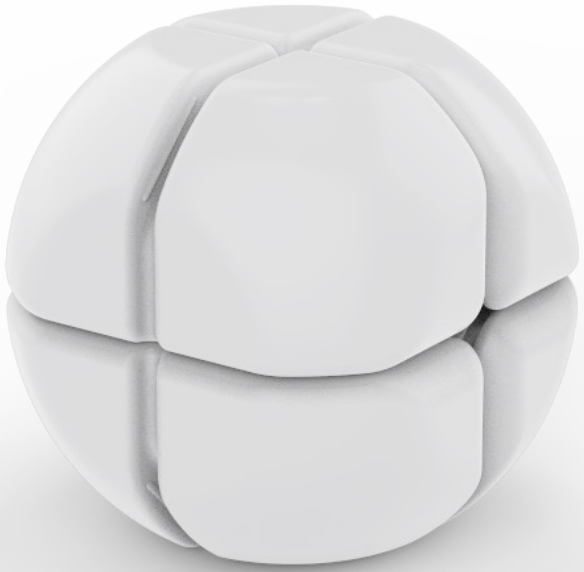
Designed to achieve, supported by clinical trial results:

Significant reduction in the disease activity
in terms of symptom, pH normalization, swallowing difficulties/dysphagia and reduced PPI use etc.

Significant improvement in patient's quality of life

Significant reduction in healthcare resource utilization
in terms of reduction in general practitioner – consultant visit, emergency visit, length of stay, and re-hospitalization

Leading to a reduction in the risk of esophageal carcinoma
when acid reflux is eliminated and pH in lower esophagus is normalized (connection between acid reflux and precancerous changes is supported in the literature)



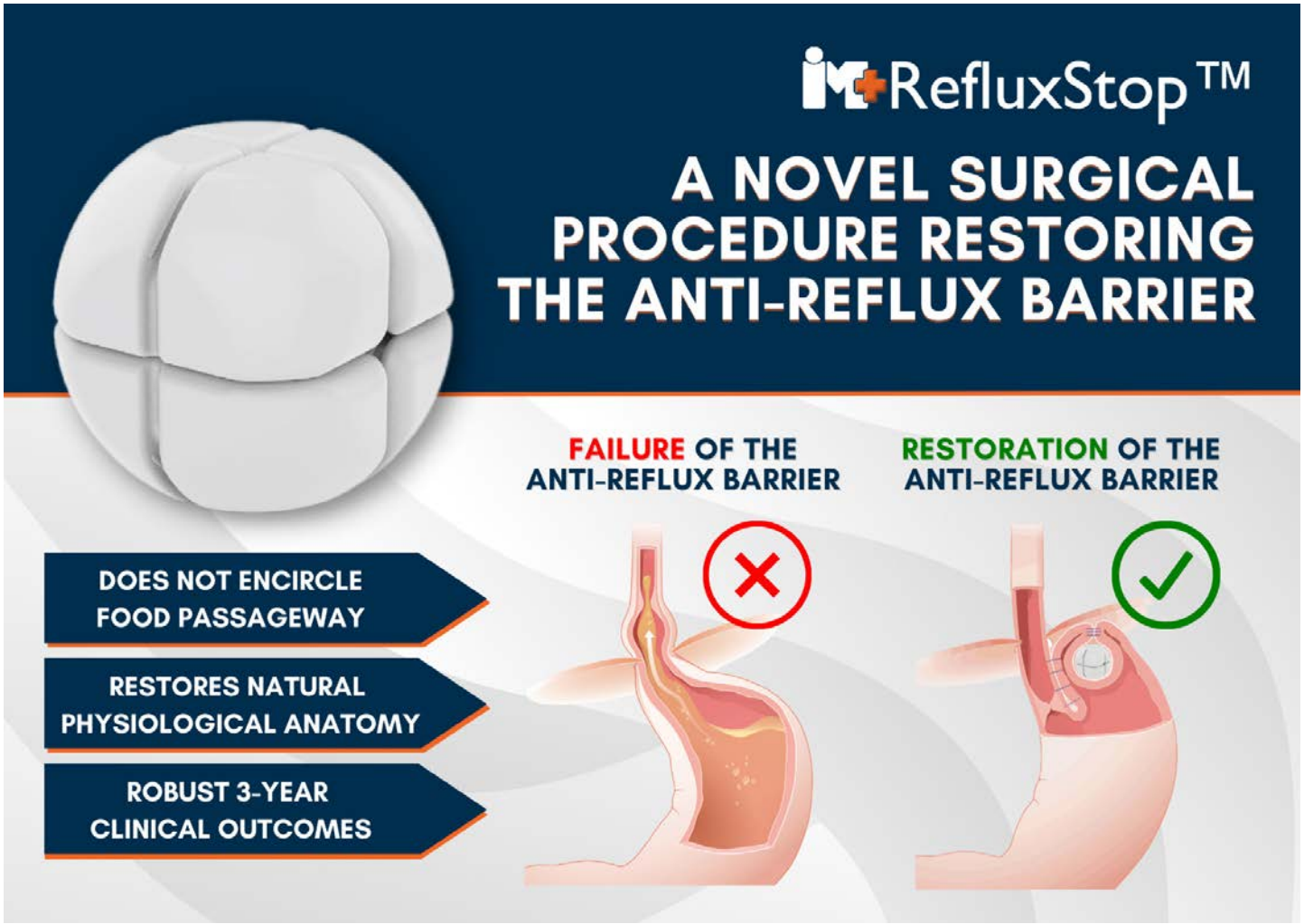
RefluxStop™

RefluxStop™ is designed to treat the cause of acid reflux

CE 2797

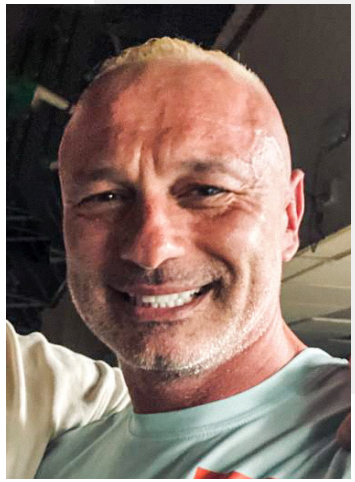
RefluxStop™ is designed to treat acid reflux without affecting the food passageway and restores and maintains normal anatomy of the gastroesophageal junction, a novel method designed to create a paradigm shift in acid reflux treatment, affecting 17% of the European population weekly.

All three components of the anti-reflux barrier are restored and RefluxStop is designed to create a normal physiological situation in the body, which treats the cause of acid reflux. Our unique mechnism of action has shown excellent clinical trial results from a multitude of studies presented at congresses, with articles published or under submission.



Jeff Cohen, RefluxStop™ Case Study

"I am now absolutely cured of my acid reflux and swallowing problems."



***Londoner Jeff Cohen, 45*, a father of two who owns a vehicle leasing business, has become one of the first people in the country to have a revolutionary operation for chronic acid reflux on the NHS.**

Now completely cured following decades of acid reflux from the age of 18, Jeff's problems progressively worsened until he experienced severe pain, regurgitated food and the discomfort and embarrassment of food getting stuck and not going down, for nearly 8 years. Now he's symptom free and last took proton pump inhibitor (PPI) medication for his condition the day before he had the RefluxStop™ procedure, September 11 2023.

"I was taking a high dose of a PPI – 60mg of Lansoprazole every day at one point, If I missed it, I couldn't keep food down at all, but the medication didn't stop my acid reflux. Most days even with the medication, if I ate a meal, I would bring most of it back up. The food was sitting in my pipe and wouldn't go down, causing major discomfort and social issues.

Now Jeff needs no medication and is completely well. He started with his GP and from there found RefluxStop™ available at St. Mary's Hospital.

"I went to my GP surgery in Hayes first. They referred me to Hillingdon Hospital, and from there, eventually I heard about a new procedure called RefluxStop™, being offered to selective patients with severe, chronic reflux, at St Mary's Hospital in Paddington.

"I had already been offered an operation called a fundoplication, which involves wrapping part of the stomach partially or fully around the sphincter which stops stomach acid coming up into your throat, but this operation is not usually offered to people with swallowing problems or issues with digesting food, as the procedure can tighten the food pipe, and make these symptoms worse.

"I read up about RefluxStop™, and it sounded potentially better than the standard treatment for someone like me with problems pushing food down to the stomach. I decided to go for it and I haven't looked back. I am now absolutely cured of my acid reflux and swallowing problems.

"I am so grateful to my consultant Mr. Ahmed and all his team at St Mary's Hospital for their amazing treatment and support."

"There is a basic misunderstanding about this condition – it is not due to bad food choices – it is a disease and it needs to be treated before it can progress to more serious conditions like Barrett's oesophagus and even oesophageal cancer.

"I want to speak out and stop the ignorance people have about heartburn. Occasional heartburn may well becaused by bad food choices, but when you get it all the time, it's a serious condition.

You need to see your GP urgently and ask for the best, long-term treatment for you. For me that treatment was RefluxStop™ and it could work for you too. Talk to your doctor today!

There is a basic misunderstanding about this condition - it is not due to bad food choices - it is a disease and it needs to be treated.

Peter Van der Eijk, RefluxStop™ Case Study

"I feel as healthy and fit as I was before I developed reflux 20 years ago and I don't have to take medication anymore."

Peter Van der Eijk, *72*, a veterinary surgeon from North Yorkshire, has a long history of reflux.

"About 20 years ago, I started to develop problems with reflux. I had the feeling of burning in my chest after every meal and at night. So I did the usual things like changing my diet which helped a little but didn't resolve the problem."

Peter started with his GP who presecribed a Proton Pump Inhibitor medication called Omeprazole. It helped control his reflux but he still had very unpleasant symptoms at times.

He continued with the medication until about six years ago his heartburn was nearly constant and very painful. He explains, "The sensation of acid was worse when I lay down to sleep at night, the condition was severely affecting my ability to sleep and, consequently, I was tired all the time and that affected my performance at work." He had an ultrasound which showed an esophageal ulcer and Barrett's esophagus which can increase the risk of cancer.

"I knew I had to do something different and look for a surgical solution. I decided to go private to speed things up. "I saw a number of specialists, including a Professor based in the north of England, who wanted to perform Fundoplication, or stomach wrap surgery. "I was not keen to do this, as I knew that Fundoplication could leave some people with an impared ability to swallow, especially if they already had stomach damage from reflux.

"I looked at having a Linx surgery but it's not suitable for someone like me who has poor contractions of the oesophagus. Then we thought about another option, anterior partial fundoplication, but I wasn't too keen on that either. It seemed that all the surgical options available at that time had significant risks of long-term side effects."

"I kept searching for a solution and found RefluxUK, a specialist clinic based in the south of England. They offered RefluxStop™, which at that time was quite new in the UK. "As a veterinary surgeon, the mechanical design of RefluxStop™ struck more than just one chord. It seemed to address various shortcomings of the other procedures I looked at which seemed to rely on scar tissue keeping the lower oesophagus aperture closed to keep stomach acid in the stomach.

"RefluxStop™ is different, it's essentially a small medical implant made of medical grade silicone. It's implanted in the top of the stomach in a fashion that, by light pressure, aids the closure of the lower oesophagus thereby keeping the stomach acid where it belongs. I felt most confident that RefluxStop™ would work for me.

Right after the keyhole surgery I was able to eat. I started with small portions and worked on up from there. All went well and has stayed well. Now I tend to eat somewhat less, which is no problem."

"I am extremely grateful that I ended up with Nicholas Boyle at Reflux-UK, who was comfortable with performing this new type of reflux surgery, the RefluxStop™. Obviously, we need to wait for the long-term results, but as the other procedures have a high relapse rate, I am well prepared to take that risk."

Right after the keyhole surgery I was able to eat. I started with small portions and worked on up from there.

Patient testimonials

"RefluxStop™ saved my career. I have had no further problems whatsoever with reflux or my voice."

Nataša Tasić Knežević is the soloist of the Opera of the Serbian National Theater. She was born in Belgrade. She sang for years in the church of St. George as a soloist, and then as a scholarship holder of Princess Jelisaveta Karađorđević, she enrolled in the Academy of Fine Arts, solo singing department. She is finishing her specialist studies at the Faculty of Music Arts in Belgrade in the class of Professor Višnja Pavlović. During her studies, she was a scholarship holder of the SOROS Foundation and in 2012 she was declared one of the most prominent Roma women in the world by the OSCE.

I am an opera singer. I am a soloist in the Serbian National Theatre Opera and a guest soloist in the National Theatre in Belgrade.

Back in 2013 or 2014 I couldn't swallow or eat properly. I had a spasm in my throat and my voice was completely broken.

I spoke in a whisper. I couldn't speak loudly at all and obviously I couldn't sing.

I went to see an otolaryngologist. This doctor said I may have a problem with stomach acid. I had no idea that stomach acid could cause problems with your voice.

In June 2016 I cancelled my appearance as Musetta in La Bohème at the National Theatre of Belgrade because I couldn't sing or speak.

My gastroenterologist said okay: we will change your medication, but nobody told me that there is surgery that can solve all my problems.

Two months after the cancellation of my performance I went to see a Professor of Surgery and a Consultant Upper Digestive and Bariatric Surgeon in Belgrade. He fixed my hiatus hernia and I had a RefluxStop procedure at the same time.

The RefluxStop operation is one of the best things that has ever happened to me.

The following April I was singing concerts again.

What can I say, reflux is one of the most damaging conditions a singer can have, but there is now a solution.

Key opinion leader surgeons (KOLs) have been convinced about RefluxStop™

A multitude of excellent results will be published in the near-term

"RefluxStop™ addresses a significant treatment gap for the Acid Reflux patients tired of failing alternative treatment options. After nearly 5-years, the patient outcomes and lack of complications have been impressive."

Dr. med. Yves Borbély
Inselspital, University Hospital Bern
University Hospital for Visceral Surgery and Medicine

"A novel treatment like RefluxStop™ can help the GERD patients get the right treatment earlier and gain their quality of life back."

Priv.-Doz. Dr. med. Thorsten Lehmann
Klinikum Friedrichshafen
Specialist for General and Visceral Surgery

"My RefluxStop patients are doing very well so far. I think there is so much potential in this device to help acid reflux patients."

Univ.-Prof. Dr. med. Sebastian F. Schoppmann, FACS
AKH Vienna, University Hospital
Chief Senior Physician of the University Dept. of Surgery
Head of Upper-GI-Service

"RefluxStop™ is a novel treatment option with strong clinical and patient outcomes with none to very minimal side-effects so far."

Dr. med. Jörg Zehetner Professor (USC)
Hirslanden Klinik Beau-Site, Bern

"My experience with RefluxStop has only been positive so far, patients are happy and do not come back and complain over side effects."

Dr. med. Moustafa Elshafei

Krankenhaus Nordwest Frankfurt
Specialist for General and Visceral Surgery

Reflections: Dr. med. Yves Borbély, surgeon at Switzerland's largest University hospital

"After nearly 5 years, the patient outcomes and lack of complications have been impressive."

Dr. med. Yves Borbély is a Specialist in Visceral Surgery at the University Clinic for Visceral Surgery and Medicine Inselspital, Switzerland

Why did you initially decide to use RefluxStop™, and how do you feel after five years of experience today?
From the beginning, RefluxStop's concept of treating acid reflux by restoring the natural physiologic anatomy of the body was quite intriguing to me. The mechanism of action is completely different from traditional surgical procedures, as it does not encircle the food passageway, and therefore does not cause the severe complications caused by other anti-reflux surgical procedures. I performed the first RefluxStop procedure in September of 2018 in Bern, Switzerland at Inselspital University Hospital where I practice as a specialist in visceral surgery. After nearly 5-years, the patient outcomes and lack of major complications have been impressive. From my experience, I can say yes, I am glad I made the decision to be one of the first surgeons worldwide to start implanting the RefluxStop device. Based on the long-term data I see today; I am convinced I made the right decision. That is why I am continuing to implant RefluxStop with confidence in patients that are suffering from reflux, joined the national registry launched in early 2023 as Principal Investigator, and am soon publishing on my long-term experience and patient outcomes. By the end of 2023 I have performed 65 RefluxStop procedures.

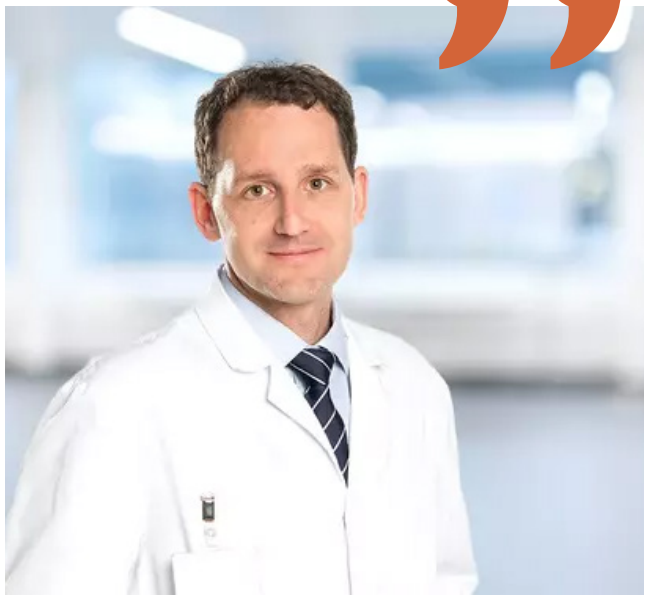
As many other surgeons using RefluxStop therapy are now reporting positive outcomes in line with your experience, can you please shed light on your long-term data?
We started collecting patient outcomes data right from the start. The first patients I operated on in 2018, are almost 5 years out and as that data becomes available, will be reported via conference abstracts and journal papers. The 4-year data currently available that I recently presented at SAGES conference in Cleveland shows very promising and robust results.

The median age of the patients treated between 2018 and 2021 was 50.8 years. These patients were definitely not the "easy" ones. Of the patients 27% had pre-cancerous changes called Barrett's esophagus, 18% had severe inflammation i.e. esophagitis grade C and 45% had problems with motility or excessive sphincter contraction in the lower esophagus called motility disorder, which often causes swallowing difficulties.

There was a significant reduction in the mean of total GERD-HRQL questionnaire score at 3-5 years follow-up after surgery compared to before surgery (23.9 and 2.8 ($p < 0.001$)). PPI use by all patients before surgery was reduced to 0 patients taking PPI for GERD at 3-5 years follow-up. 2 patients took PPI for reasons other than GERD, gastritis and chemotherapy. **Typical symptoms disappeared in 94% of patients. Dysphagia and pain disappeared in 93% of the patients.**

As RefluxStop uniquely corrects the anatomical misalignment of the anti-reflux barrier in its entirety, and does not encircle the food passageway, many of the side effects from traditional surgery are avoided, including dysphagia, gas bloating etc. As a result of this benefit of not encircling the food passageway we are also able to treat dysmotility patients, a patient population that were left with inadequate treatment options prior to RefluxStop and again, to my surprise the results in dysmotility patient group is very impressive across leading centers using RefluxStop, which is very good news for our patients.

PPI use by all patients before surgery was reduced to 0 patients taking PPI for GERD at 3-5 years follow-up



Could you describe your experience with dysmotility patients, as a subgroup of your patient cohort?
I performed RefluxStop surgery on 32 dysmotility patients. Quite surprisingly the overall results are almost similar between dysmotility and normal motility patients. Similar improvement of quality-of-life scores and disappearance of active reflux symptoms. RefluxStop is an exciting product with a very strong prospect of becoming a therapy of choice for many GERD patients.

Dr. med. Thorsten Lehmann

Center Director and Chief Physician of the Clinics for General and Visceral Surgery

Academic Faculty at University of Tuebingen Medical School

Surgical Residency at Charite Berlin, Germany

Gene research at University of North Carolina, Chapel Hill

Graduated from the Medical School at the University of Heidelberg, Germany

Notes from the world's most experienced RefluxStop™ surgeon

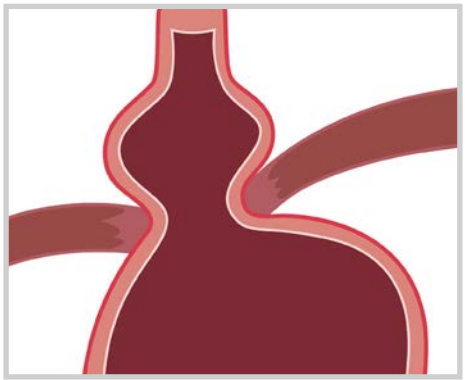
Dr. med Thorsten Lehmann has completed 180 successful RefluxStop™ procedures, making him the largest RefluxStop™ user in the world. As the leading expert on performing the RefluxStop™ procedure, Dr. Lehmann has a unique view of the benefits of this procedure and what it means to his patients and practice. We interviewed him to get his take on GERD and RefluxStop™.

Why do you recommend RefluxStop™ to your patients, and what are the benefits over current treatments in your experience?

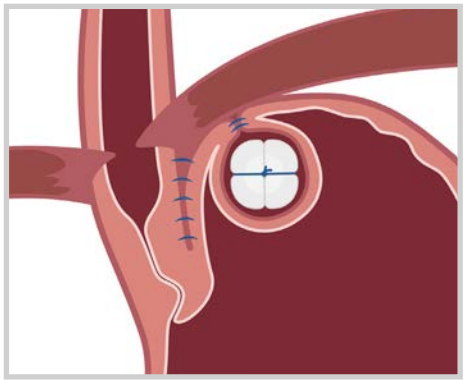
"Current anti-reflux surgical procedures are designed to treat a malfunctioning lower esophageal sphincter located at the bottom of the food passageway, where it connects to the stomach. These procedures are all based on the same principle. Encircle the food passageway, tighten it around the lower esophageal sphincter, and stop stomach content from pushing back up into the food passageway. This includes procedures such as Fundoplications or magnetic sphincter augmentation (LINX).

The unique mechanism of action of the RefluxStop™ procedure is the main reason I recommend it to my patients. It returns the body to its normal physiology by putting the anti-reflux barrier back into its natural position so it can function normally, stopping acid reflux from occurring, without encircling or putting pressure on the sphincter."

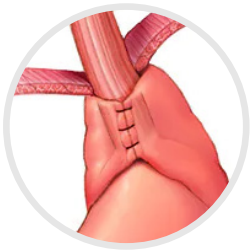
COMPROMISED ANATOMY



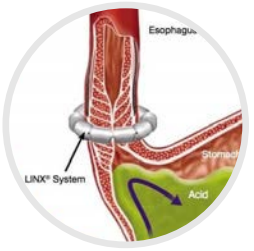
RESTORED WITH REFLUXSTOP™



FUNDOPLICATION



LINX



”The RefluxStop™ procedure offers various advantages over current surgical treatment options:

- Many of the undesirable side effects often experienced with current anti-reflux procedures are avoided, as RefluxStop™ does not encircle the food passageway. This includes symptoms like dysphagia (difficulty swallowing) and gas bloating.
- RefluxStop™'s innovative mechanism of action provides access to a large percentage of patients that previously would not have been considered candidates for surgery. A large portion (20-40%) of patients that suffer from acid reflux also have moderate to severe esophageal motility disorders (muscles of the esophagus are impaired). Therefore, a procedure encircling and putting pressure on the esophagus such as magnetic sphincter augmentation or fundoplication might not be the perfect choice for those patients, as it could make their swallowing difficulties worse. We are convinced that offering RefluxStop™ is the best option for a young patient with reduced esophageal motility. At least 20% of our patients are younger than 45 years of age with bad esophageal motility.
- Hiatal hernia recurrence as well as GERD reflux recurrence represent major long-term problems after traditional anti reflux surgeries resulting in a significant number of redo procedures all possibly associated with negative side effects. RefluxStop™'s unique mechanism of action seems to be an optimal technique that both provides relief from GERD as well as stable long-term outcomes. Should it become necessary to remove the device, early data shows that redo or conversion is not a problem. The device is removed and replaced with a traditional operation with the same results expected from an initial traditional procedure.”

Over the last decade, (2006 – 2016) there has been a significant increase in the proportion of younger patients with GERD, especially those within the age range of 30–39 years.

Age Group	Increase in GERD
20–29	2.2%
30–39	5.5%
40–49	3.5%
50–59	2.6%

Current Anti-reflux Operations

30% develop a recurrence after **10** or more years

Could you tell us about the results you see post RefluxStop™ surgery?

”It's still too early to talk about long-term results of 10 years and more. However, within the first three years after the implantation we don't see any severe side effects typically experienced with other anti-reflux surgical procedures.”

- Dysphagia is almost absent.
- Weight loss due to difficulty swallowing does not occur.
- Bowel movements are not affected.
- Bloating is not a big issue, mostly absent.”

”Most importantly, reflux control is phenomenally effective in most patients and only a very small minority take PPIs within the first years after the procedure.”

Tell us about the future of surgical procedures for treating GERD in your opinion?

”We have seen an increase in GERD patients considering surgical solutions.

Treatment of GERD is not a one size fits all approach. Medication, Proton Pump Inhibitors (PPIs) is typically the initial go to treatment, but as we know, it merely manages symptoms, it does not correct the problem.

Furthermore, PPIs, are not always effective and thus these patients could qualify for surgery. Others develop side effects and cannot use the medications, while some are just not willing to take PPIs for decades. Awareness of the comorbidities attributed to long term PPI use is increasing and although data is still being challenged, many patients are actively searching for alternative solutions.

What do your patients say about RefluxStop™ after they have recovered and are back to their normal day-to-day activities?

”Most of our patients tell us that the procedure was life changing and that for the first time in years they are now again leading a normal life without acid reflux. They come back excited and satisfied, their joy of life is back, and they are positive about their future. It’s very, very rewarding.

We hardly see any recurrence of GERD; we hardly see any patient on PPIs within the first three years after operation.”

What would you say to other surgeons thinking of offering RefluxStop™?

”Go ahead and assess the outcomes for yourself!

The procedure is relatively straight forward; however, the implantation requires some technical skills that you will become comfortable with during the certification process. Implantica requires RefluxStop™ specific product training and certification to get started.

Personally, I am very comfortable offering the product to patients as we haven’t observed any serious side effects or complicated reoperation; nor have we seen any device related complication leading to intervention or risk of mortality.”

”RefluxStop™ is a great promising procedure option and should be evaluated by foregut surgeons.”

”Patients practically forget about their previous problems with reflux and the burden they had with daily PPI use.”

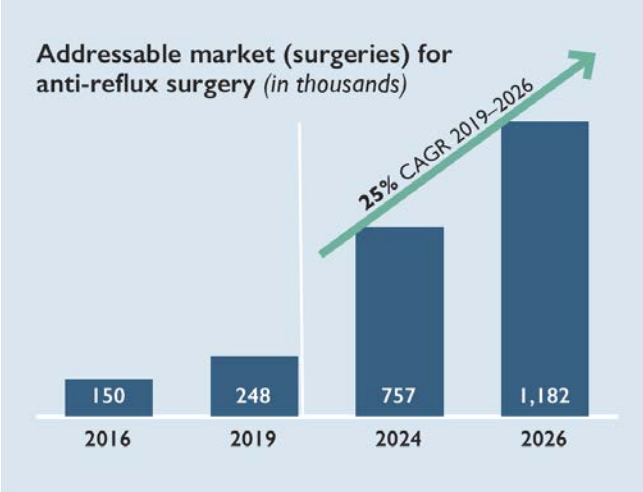
Sources & References:
1. Yamasaki T, Hemond C, Eisa M, Ganocy S, Fass R. The Changing Epidemiology of Gastroesophageal Reflux Disease: Are Patients Getting Younger? Journal of Neurogastroenterol Motil 2018;24:559-569. https://doi.org/10.5056/jnm18140

RefluxStop™ addressable market

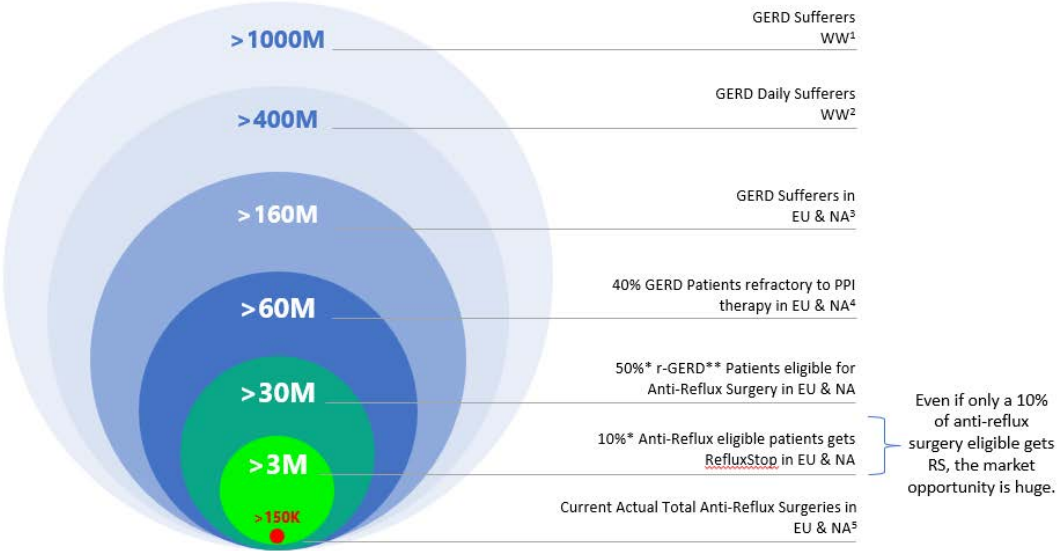
According to a recently published global study in Nature[1] medical journal, there are more than 1 Billion people suffering from reflux disease. The awareness of complications from PPI use are becoming more widely recognized, and these complications are more dangerous than previously anticipated, leading to serious diseases and even death. Most dangerously, the cancer risk with acid reflux remains during drug therapy, and combined with the complication profile, the market for surgical procedures is expected to grow.

Due to the many complications associated with currently available procedures, only 248,000 patients opt for anti-reflux surgical procedures each year of which over 150,000 were in the North America and European countries. Implantica's new device treats acid reflux without encircling the food passageway and has the potential to create a paradigm shift in acid reflux treatment. Once a viable treatment is available, two third-party sources in average expect the surgical treatment addressable market to grow substantially and expect the addressable market of GERD procedures to expand to reach 1.2 million operations per year.

Prognosis pre-pandemic forecasted substantial expansion of number of anti-reflux surgeries



With up to 40 %[6] of GERD sufferers not well treated with PPI medication, RefluxStop™ is designed to improve treatment outcomes and thereby improve quality of life for millions of patients in Europe and North America. RefluxStop™ has the potential to become a multi-billion dollar business. If RefluxStop™ proves to prevent the incidence of esophageal cancer – which causes the loss of about 48,000 lives annually in the EU and US alone, the number of sufferers is so large that the market has the possibility to reach many millions of surgeries each year.



[1]https://www.nature.com/articles/s41598-020-62795-1
[2] https://biomedgrid.com/pdf/AJBSR.MS.ID.000619.pdf
[3] https://www.nature.com/articles/s41598-020-62795-1
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3801364/

*Key Assumptions
** r-GERD means Refractory GERD

[5] iData Research Report for Implantica

[6] Becker et al. 2007

Implantica submits RefluxStop® FDA PMA module 1 in U.S.

FDA AGREES TO RECEIVE A PMA SUBMISSION BASED ON OUR EXISTING EUROPEAN CE MARK STUDY

U.S. MARKET ENTRY WILL BE A SUBSTANTIAL LANDMARK IN OUR COMMERCIALISATION PROCESS

The U.S. FDA has agreed to a modular submission process for the RefluxStop PMA application. This process provides for ongoing review and feedback from the FDA as the modules are submitted. The second and third (final) modules are anticipated to be submitted to the FDA in three-month intervals later this year.

PRE-LAUNCH ACTIVITIES STARTED

FDA Human Factors (Usability) Study completed

A Crucial U.S. Pre-Launch Milestone

Implantica submitted the first module of the FDA PMA application end of Q1 2024, taking a huge step forward in the U.S. market approval process.

As part of our next key FDA application modules, Implantica must prove that RefluxStop® is safe and effective for use by the intended users. Given that RefluxStop® has already been successfully performed >750 patients during the last 5 years in Europe, we are confident that we can meet FDA requirements based on the excellent safety and efficacy data from the European CE clinical study and commercial use real-world experience.

This leaves Implantica with the burden of proof to demonstrate that surgeons in the US can successfully conduct the RefluxStop® procedure after completing the RefluxStop® surgical training program. To accomplish this objective, last year FDA asked Implantica to plan a US Human Factors (Usability) Study with 16 US Anti-Reflux Surgeons (with pre-defined study participation criteria). This was also a huge opportunity for Implantica to build trust with the top surgeons in the US and train them on the RefluxStop® surgical technique, not only for the Human Factors study but also to lead to faster commercial adoption upon market approval.

The Human Factors Validation Study for RefluxStop® was successfully completed in March 2024 at the Northwestern University simulation lab in Chicago. Four RefluxStop® expert European surgeons proctored 16 esteemed US foregut surgeons representing a broad range of career experience levels and hospital categories (e.g., Academic/Community) for the study.

After completing RefluxStop® specific procedure training to become certified in performing the RefluxStop® surgery, each US surgeon independently performed the procedure while observed by a third-party independent human factors assessment contractor. The independent Human Factors contractor evaluation focused on the US surgeon's ability to perform the critical steps necessary for successful outcomes, their knowledge related to key surgical steps, and key post-procedure considerations.

Photos of select participants and proctors in training during the Usability Study included here.

RefluxStop®* Lead Study Advisor (US)

Professor Dr. John Lipham
Chairman of the AFS Board and Past President of the American Foregut Society and Chief of the Division of Upper GI and General Surgery and Professor of Surgery at Keck Medical Center, University of Southern California

"It's been an honor and a great experience advising and supporting Implantica for the RefluxStop FDA Human Factors study and conducting the first RefluxStop® cadaver surgery in the US. **The RefluxStop® procedure has a unique mechanism of action that restores and maintains all three components of the body's natural Anti-Reflux Barrier (ARB), allowing it to function normally."**

Prof. Lipham continues, "As RefluxStop® does not encircle the food passageway, it could lead to a significant reduction in undesirable side effects. **It could also further expand the patient population that previously would not have been seen as ideal candidates for anti-reflux surgeries.** I am excited for RefluxStop to become available in the US, hopefully soon, as patients deserve to choose from the best treatment options that can address their urgent medical needs."

RefluxStop®* User & Study Proctors Team Member (EU)

Professor Dr. med. Sebastian Schoppmann
Professor of Surgery, Medical University of Vienna, Austria Chairman of the Board of the European Foregut Society and President of the Austrian Society for Minimally Invasive Surgery

"It was exciting to participate as one of the independent Proctors in the Human Factors study, training leading US Surgeons on this innovative RefluxStop® procedure and ultimately helping advance the FDA approval process for this device. Giving US surgeons and patients access to **RefluxStop® can help address a large unmet need in the field of acid reflux."**

He goes on to say, "The unique mechanism of action of the RefluxStop®, **already successfully used in more than 750 patients in Europe over the past 5 years,** allows anti-reflux surgeons to close a gap that wasn't possible before. Several new clinical studies including rigorous multi-center randomized studies are being planned, and newly available data continues to demonstrate the long-term value of this promising treatment option."

A comprehensive study report will be submitted to the FDA as part of the upcoming second FDA module later this year. We hope that the results from this study will give the FDA adequate assurance in managing the risk associated with the new device procedure. In addition, this usability study also allowed us to have high confidence in the US foregut surgeons, who are quick to learn the RefluxStop® surgical approach and will enable a quicker ramp-up during the commercialization phase.

We sincerely extend a hearty thanks to the group of pioneering US surgeons for making this crucial milestone HF study a reality.

In summary, we are thrilled to see the completion of the US Human Factors study that will be a key focus of our next FDA module. We hope it will significantly help advance the US market approval process and ultimately result in the widespread availability of RefluxStop® in the US, where more than 20% of the population struggles with GERD.

A fantastic pre-launch activity.

> RefluxStop® can help address a large unmet need in the field of acid reflux.

*RefluxStop is a trademark in EU and registred trademark in US

US Market Access Strategy: Building the Foundation of RefluxStop® Commercial Success

Throughout 2023, Implantica kicked-off and extended several key Market Access initiatives while simultaneously managing the extensive FDA PMA application filing process.

These critical initiatives include training selected top tier upper GI Surgeons for our FDA Human Factors Study along with analysis and development of Reimbursement Coding, Payment Rate, and Coverage strategies.

Each of these initiatives is critical to a successful and scalable US commercial launch once we secure FDA approval for RefluxStop®.

What do Payers require for Reimbursement Approval?

Although Payers care about product safety, they mostly rely on the FDA to verify and control this aspect.

Instead, they focus on:

- comparative patient outcomes & satisfaction
- quality of long-term clinical evidence base, and
- overall affordability and cost-effectiveness of a new treatment over time

While each Payer may give a different weight to the evidence provided, their core principles remain consistent.

Most payers focus on the following key issues:

a) How do patient outcomes and satisfaction compare to the standard of care?

b) Is there sufficient, consistent, and robust published clinical evidence on patient benefit?

c) Does it meet medical necessity requirements (per clinical guidelines/experts' consensus)?

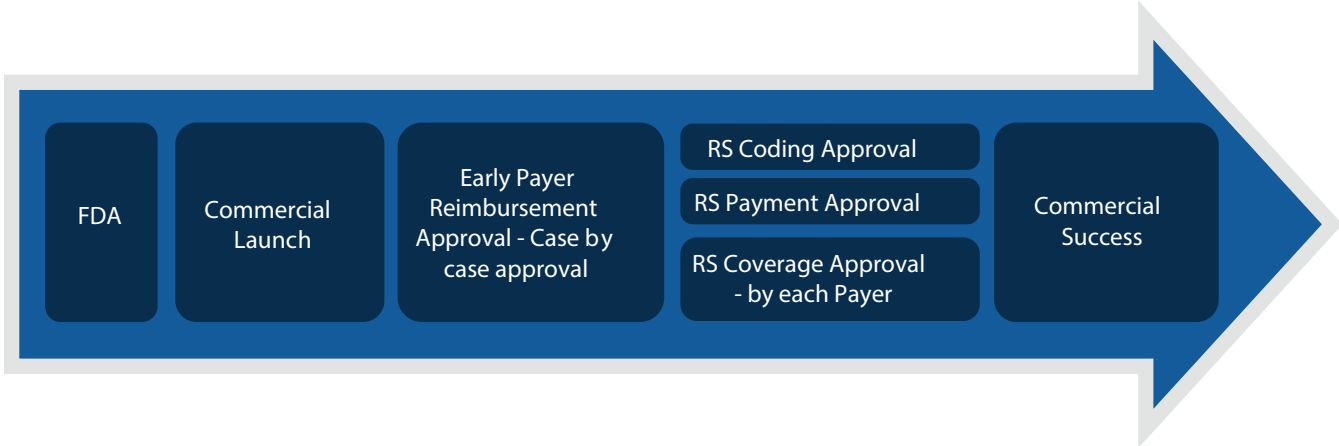
d) What is the economic impact, is it affordable and cost-effective (especially for private/commercial payers)?

Key US Payer Categories for Reimbursement:

- Government Payers (e.g. Medicare, Medicaid, TRICARE)
- Commercial/Private Payers (e.g. Aetna, Cigna, United Healthcare, Blue Cross Blue Shield)

With more than 900 commercial/private health insurance companies operating throughout the United States, payer coverage requirements, processes, and approval timelines can vary for each Payer.

900+ Commercial/private health insurance companies operating throughout the United States



Engaging Key Market Access Stakeholders:

The following five strategic stakeholder initiatives work together to earn the trust of members of key US Payer, scientific, and patient community. These groups directly or indirectly influence reimbursement and payer adoption decisions for a new therapy.

The opinions formed by these key stakeholders ultimately will impact the ability to access RefluxStop® for most US patients. The importance of these initiatives cannot be overstated.

Our continued partnership with more than 25 centers in Europe that have now successfully completed over 750 RefluxStop® cases provides us the opportunity to further validate consistent and positive clinical outcomes of RefluxStop® therapy. This will directly support the key data requirements of US & European reimbursement agencies, payers, surgeons, and patients, ultimately paving the way for RefluxStop® to be widely reimbursed and accepted as the new standard of care in surgical GERD treatment.

With rapidly growing interest in RefluxStop® from patients worldwide, we are more than ever focusing on patient awareness, education events, and social media communications to keep patients informed, engaged, and aware of key developments.

25 centers in Europe

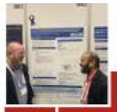
Implantica will continue to drive forward strategic market access development in Europe both to expand commercialization and to help support a speedy and successful US commercial launch.

Medical Societies & Congresses

- Attend key medical society meetings in 2024 to share latest scientific data & familiarity with American Surgeons
- Gain Support for appropriate long-term reimbursement approval for Coding, Payment, and Coverage for RefluxStop® therapy
- Society of Gastrointestinal and Endoscopic Surgeons (SAGES)
- Digestive Disease Week (DDW)
- American Foregut Society Annual Meeting

US KOLS – Surgeons & GIs

- Demonstrate clinical evidence and patient outcomes to build trust with US surgeons
- Engage GI community
- 16 US Surgeons participated in Usability Study
- Create educational touchpoints to engage and involve medical experts



US Payers – Govt. & Commercial

- Develop scientific outreach to US Payers to educate & demonstrate the value of RefluxStop®
- Share clinical efficacy, robust long-term patient outcomes, and positive economic impact data
- Establish clear understanding of specific needs of top payers and tailor scientific dossiers to each
- Continue to participate in ISPOR, The Professionals Society for Health Economics and Outcome Research

Patient Advocacy

- Build a community of stakeholder in medical societies, healthcare and patient advocacy organizations
- Support patient advocacy groups
- Support educational forums such as Esophageal Cancer Action Network, International Foundation for Gastrointestinal Disorders, American Gastrointestinal Association, American Foregul Society

Social Media & Awareness

- Expand social media and disease awareness communications, compliant to US regulations
- Support and create GERD awareness campaigns reflecting recognition days like GERD Awareness Week, World Health Day, etc.
- Partner with advocacy organizations to promote larger patient and HCP educational programs
- Create patient awareness on RefluxStop® therapy progress

Implantica, 1 year in Italy

About 7,600 reflux procedures are performed every year in Italy, a number limited by the important side effects of standard reflux surgery (such as Nissen fundoplication), principally the risk of dysphagia. The potential market size in Italy can easily exceed the current level by more than 5-10X with more effective surgical therapies designed to reduce the current side effects, according to Prof. Bonavina. This is the advantage that Italian surgeons see in RefluxStop™, allowing them to expand their patient base.

During 2022, Implantica started commercial activity in Italy with Andrea Arduini, who left the position of Country Business Manager of the Pelvic Health division of Medtronic Italy to take the position of Business & Therapy Development Director Italy in Implantica.

The new market development strategy has led to strong collaboration and partnership with the most important KOL centers in the country, positioning RefluxStop™ as the therapy of choice in the new centers.

Pictured from left to right: Prof. John Lipham, Prof. Sebastian Schoppmann, Dr. Joerg Zehetner, Dr. med Thorsten Lehmann, and Prof. Luigi Bonavina.

Prof. Luigi Bonavina Leads the Way

Among the first to use RefluxStop™ was Prof. Luigi Bonavina, full professor of Surgery at the University of Milan, who works at the IRCCS San Donato hospital in Milan, current President of the European Foregut Society (EFS) and of the Italian Association of Esophageal Research (AIRES). At the end of the first two interventions, he declared "The procedures went exceptionally well."

Prof. Bonavina went on to say, "We are excited to be at the forefront of implementing novel treatment methods, and RefluxStop's™ unique approach to restore natural anatomy offers great hope for the larger medical and patient communities. In Italy, about 20% of the population suffers from gastroesophageal reflux disease and few of these patients are aware that there are surgical treatment solutions available. Many patients continue to be inadequately treated with long-term medication or traditional surgical methods with unsatisfactory symptom relief. This must change soon. It is important that surgeons are offering disruptive treatment solutions with such encouraging early outcomes".

Prof. Bonavina has been invited for two consecutive years to demonstrate the RefluxStop™ technique with a live surgery during the International Congress on Digestive System Surgery in Rome, assisted by Prof. Davide Bona of the University of Milan and Prof. Joerg Zehetner of Bern; both are among the first in the world to implant RefluxStop™.

More than 90,000 surgeons from around the world were connected on line to watch the live surgeries at each congress.

Expanding Access in Italy

"Implantica announced the first RefluxStop™ public tender win in February 2024 followed by another major public hospital purchase agreement win in March 2024, further strengthening RefluxStop™'s broader acceptance in public healthcare systems in Europe and most importantly paving the way for permanent reimbursement in Italy," says Dr. Peter Forsell, CEO Implantica

There are currently eight active Centres in Italy, six of which started in 2023, and several additional are planned to be ready to start in the coming months. In Italy, RefluxStop™ therapy is offered to patients by the National Health System, at no cost to the patient, through a public tender sales process. The hospitals that offer the therapy are in Milan, Naples, Turin, Castellana Grotta (Bari), Rovereto (Trento), Conegliano, Palermo, all are destination medical centres for gastroesophageal reflux disease in each province/region.

Implantica, 1 year in Italy cont.

Each time the first RefluxStop™ cases are completed at a new location, the Center receives a lot of media attention due to new technology introduction, which always generates a lot of interest in the local media and in 2023 there were two interviews featured on Italian national television.

From a scientific point of view, all active Centres have expressed their willingness to participate in Implantica's European Registry for data collection: two hospitals are already enrolled in the registry and others are awaiting authorisation from their Ethics Committee. In addition, three Centres have proposed to Implantica a collaboration for additional clinical trials.

Dr. Leonardo Vincenti Opens Dedicated Clinic

After he saw one of the national TV interviews, Dr. Leonardo Vincenti, Head of Surgery of the largest hospital specialized in gastroenterology in Italy, the "De Bellis" in Castellana Grotte, and Center of excellence in Puglia region, decided to open an outpatient clinic dedicated to RefluxStop™ patients. This was to better manage the high number of requests coming in from local patients and those from neighboring regions. "Unlike traditional surgeries, RefluxStop™ has no side effects such as difficulty swallowing the food bolus, gas bloating, etc." said Dr. Vincenti.

Italian Scientific Congresses

Implantica has been present in 8 national scientific congresses of surgery and surgery of the upper digestive tract, both with an institutional presence and with clinical presentations or demonstrations in live surgery.

Clinical Trials

Local clinical trials are a key factor in the development of the therapy, demonstrating to the payers both the clinical efficacy of RefluxStop™, its role in the therapeutic algorithm, and its cost-effectiveness. Clinical trials demonstrate the potential economic savings of the Health System in the medium to long term.

Gastroesophageal reflux disease has an estimated prevalence of 20% of the adult population and a current indication for surgery of less than 0.1% due to side effects (mainly dysphagia). The economic impact of RefluxStop is important, especially due to the daily use of PPIs, which are provided free of charge by the Italian HealthCare System to about 16% of the adult population. The introduction of RefluxStop™ in the Italian market is therefore viewed with great positivity since it is viewed by the Italian surgeons to offer a solution without major side effects to a chronic and high-cost problem.

Implantica Iberia S.L.

In 2023 Implantica Iberia S.L. was formed as a subsidiary of Implantica Trading AG under the project leadership of Juan José Gómez, Business & Therapy Development Director of Spain & Portugal at Implantica.

Implantica Iberia S.L. was created with two critical goals in mind. First, to be able to present RefluxStop™ to public tenders for the hospitals of the Spanish Health System and second, to gain access to electronic invoicing through the FACe payment platform used by the public administrations of the Spanish State.

The Path to Public Tender & Accessing FACe

Throughout 2023, the Implantica Iberia S.L. team set up systems and processes to support commercial expansion of RefluxStop™ to Spain and Portugal. The sales process for Implantica Iberia S.L. was designed to maintain the traceability of each of the units placed on the market and to comply with the requirements of the QMS and Implantica's standards.

We completed one of the key milestones to be ready to bid in public tenders, earning ISO-14001 environmental accreditation.

In June 2023, Implantica Iberia S.L. became the first subsidiary of Implantica to achieve this important environmental accreditation.

In Q4 2023, we celebrated the first public tender in Spain, at the University Hospital of Getafe, for a total of 14 units. Going through our first public tender in Spain has prepared Implantica for many future tenders in the Spanish market.

> "We're so pleased that Hospital Universitario de Getafe has secured the first ever RefluxStop™ public tender in Spain, becoming the third public hospital in Europe to win a substantial public funding agreement for RefluxStop™ treatment for their patients. This is undoubtedly a major step forward in helping more chronic GERD patients in Spain with broader implications over wider Europe to access the treatment they need and deserve."
>
> - Dr. Peter Forsell

Commercial Expansion in Spain

With nearly 15% of population (more than 7 million) suffering with GERD in Spain, the market for acid reflux is on the rise and new effective treatment options are urgently needed.

During 2023, four Public University Hospitals added RefluxStop™ to their portfolio of treatments for gastroesophageal reflux disease. Hospital Univ. Getafe started offering RefluxStop in January.

Introducing RefluxStop™ to more physicians in Spain

The Hospital Univ. Getafe hosted two clinical sessions, in June and September 2023. We invited expert surgeons in the treatment of reflux from Madrid and neighbouring regions to see the new technique implemented at the hospital.
In October, Hospital Universitario Ramón y Cajal and Hospital Universitario Infanta Sofía completed their first RefluxStop cases. Followed by Hospital General La Mancha Centro offering RefluxStop™ in November. A total of 17 RefluxStop™ procedures were completed in Spain in 2023!

17 RefluxStop™ procedures were completed in Spain in 2023.

The hospital's Digestive Service also participated in these meetings. This coalition strategy between surgery and digestive services in each centre is a valuable driver of the number of patients who are candidates for surgery. Patient referrals have fallen recent years due to the poor results of traditional surgical treatment. With RefluxStop™, confidence in surgical treatment is recovering among the surgeons because of the excellent results enjoyed by patients treated to date.

These clinical sessions were an invaluable asset to provide an in-depth introduction to RefluxStop™ paving the way for new centres. Representatives from the other three centres to implement RefluxStop™ later in 2023 attended these meetings.

After the first cases are completed in each new centre, the hospital's communications team successfully completed PR campaigns in the local media including updates published on the official websites of each of the regions where RefluxStop™ has been implemented (Madrid and Castilla la Mancha in 2023).

Implantica Iberia S.L. at Congresses

Implantica's presence in scientific activities related to reflux management has been very important throughout the year, participating in the main national and international congresses and events:

- LXII Surgery Update Course, Seville (8-10 February)
- XXVIII Digestive Pathology, Seville (8-10 June)
- VIII Esophagogastric and Obesity Conference, Getafe (6 October)
- XXIV National Surgery Meeting, Alicante (24-27 October)
- XXXI Meeting of the Spanish Association of Neuro-Gastroenterology and Motility, Madrid (3-4 November)
- VL Congress of the Spanish Society of Digestive Endoscopy, Seville (9-11 November)

Interest in RefluxStop™ treatment is growing among surgeons, patients and referring physicians. We plan to continue to add high quality centres in 2024 and will offer more clinical sessions to further drive interest from top surgeons.

The number of centres in Iberia will only increase in the years to come as about 15% of adults in Spain struggle with GERD[1]. Each of them deserves to get access to the best possible treatment option and we're proud to answer this urgent call with RefluxStop™.

1. Ponce J, Vegazo O, Beltrán B, Jiménez J, Zapardiel J, Calle D, Piqué JM; Iberge Study Group. Prevalence of gastro-oesophageal reflux disease in Spain and associated factors. Aliment Pharmacol Ther. 2006 Jan 1;23(1):175-84. doi: 10.1111/j.1365-2036.2006.02733.x. PMID: 16393295.

Marketing & Education

Key Market Access Pillars, Driving both Adoption and Demand

We continued executing our strong marketing plan that includes PR, Social Media, Medical Conferences, and well-designed Marketing Material to support numerous therapy education and awareness campaigns in key global markets.

Our laser focused marketing plan is built on six key strategic drivers of success:

> "As RefluxStop™ continues to gain traction in various countries, we have seen first hand the impact that education and patient demand generation has on market access. Not only is this correlation impactful, but it is vital in gaining access to key stakeholders in key markets."

What we consider when creating a country specific PR/Marketing education plan:

When creating a PR plan and content for a certain market, we understand and appreciate it is not a one size fits all approach. To not only reach, but create value for our audience, we tailor our messaging to the locale. In order to do this, we identify WHO we want to reach, WHEN our target audience is most likely to hear our message, WHERE they get their news, and WHAT would resonate and build trust with them. Finally, we execute and measure the impact so we can learn and grow from it.

AN EXAMPLE FROM THE UK

A strong marketing plan uses all possible platforms to drive market access via education and key messages into the market. This includes but is not limited to using Press Releases, Public Relations, Social Media and Medical Conferences as platforms to present impactful educational pieces, publications, graphics, patient stories and more.

WHO is our audience?

With a couple of active clinics and a big push for NHS adoption, we drove a strong awareness and educational campaign across UK market, designed and aimed to capture the attention of surgeons, patients, and regulators (NICE).

WHEN would our message have the largest impact on the UK population?

Our goal is to have a big, widespread educational impact in the UK

During Christmas of 2022, the section of the NHS's website that gave advice specifically for GERD/Acid Reflux, was viewed once every 13 seconds according to NHS England. It was the most searched-for health condition on that site over the festive period.

- Public Seeking Knowledge

NHS England expressed concern at the high prevalence of acid reflux and lack of awareness of long-term risks.

- NHS Paying Attention

First NHS hospital conducting RefluxStop™ surgery - St. Mary's hospital, Dr. Ahmed Ahmed in Sep 2023

- NHS Hospital performed RefluxStop™

Taking all of this into consideration, our well designed PR campaign covered many major news channels featuring RefluxStop™ treatment availability and outcomes during late 2023 with significant news and media coverage around Christmas time, leading up to New Year.

We also engaged Heartburn Cancer UK, Guts UK, and OPA Cancer Charity, patient advocacy groups to help generate general awareness and developed a fluid working partnership. We tied our social media to theirs and co- promoted messaging referring to them on our platforms. https://gutscharity.org.uk/

The marketing team also created educational website and social media content that the active clinics could use on their marketing platforms to educate and attract patients.

WHERE to message for the largest impact?

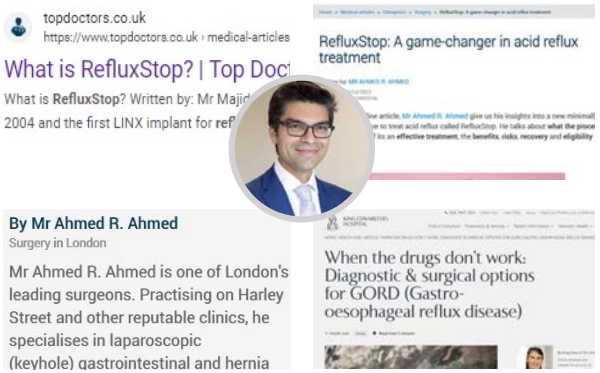
RefluxStop™ received great coverage in and around RefluxStop™ Clinics in UK across the most popular channels on radio, television, print, and online material, enabling significant reach and impact of each story.

We utilized the NHS 2022 statistics for identifying the readership interest in the high prevalence areas and targeted national holidays to help drive PR adoption (Esophageal cancer awareness week and suicide prevention week).

BBC Radio Meyerside
218,000 Listeners

BBC Radio Leicester
101,000 Listeners

Go **BIG** – Identify the platforms that could render the highest impact!



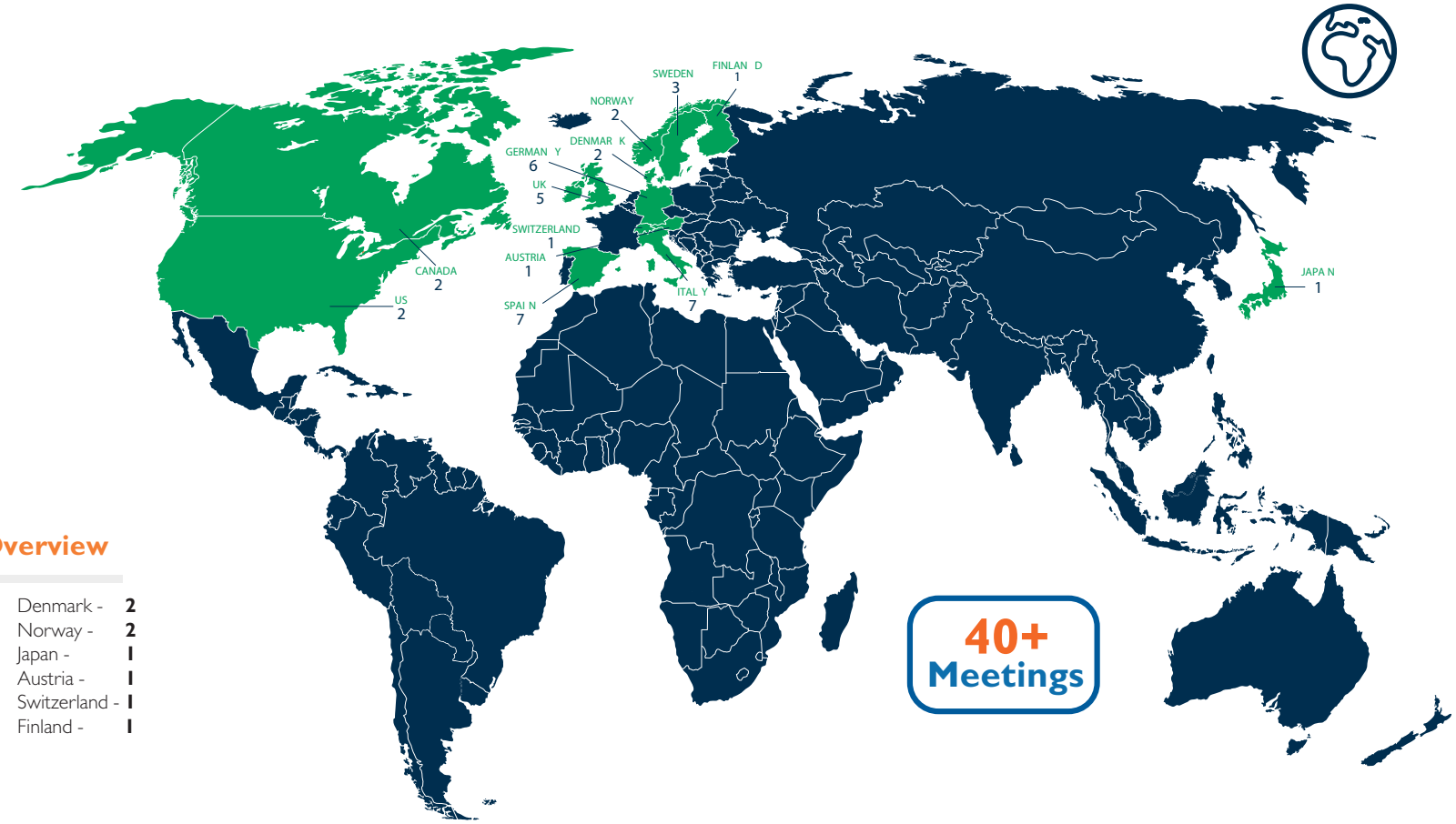
WHAT DELIVERED by WHO?

When stakeholders speak to their peers, they automatically highlight what is important from their perspective. This message will be much more readily related to and accepted.

Our surgeons from leading NHS hospitals and other reflux centers speaking to other reflux surgeons and experts, the articles featuring surgeons and their patients, patient stories broadcasts and patients speaking to other patients are some examples demonstrating self-evident and growing interest and confidence in RefluxStop™ therapy and outcomes.

Why RefluxStop™ - because RefluxStop is designed to restore body's natural anti-reflux barrier.

RefluxStop™ Conference World Presence **2023**



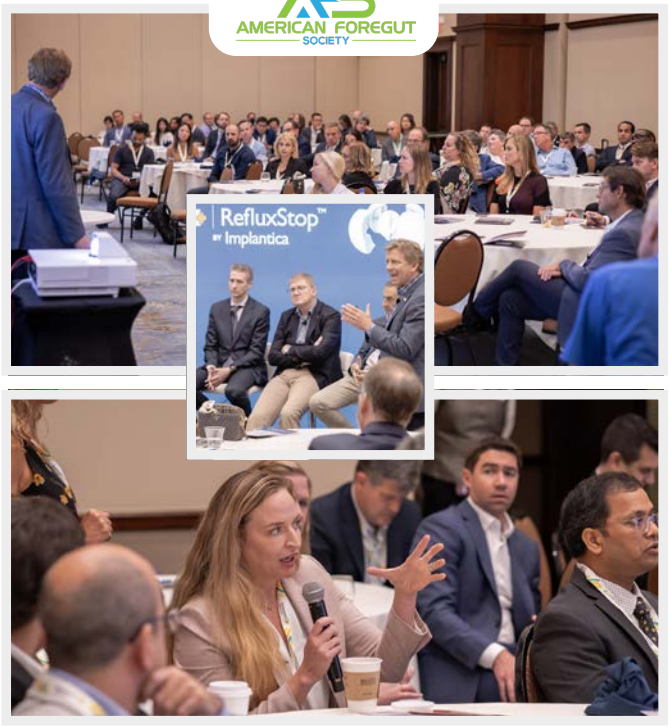
Key Meeting **Overview**

Italy -	**7**	Denmark -	**2**
Spain -	**7**	Norway -	**2**
Germany -	**6**	Japan -	**1**
UK -	**5**	Austria -	**1**
Sweden -	**3**	Switzerland -	**1**
US -	**2**	Finland -	**1**
Canada -	**2**		

Select **Notable** Conferences in 2023

SAGES / DDW / AFS / EFS / Kirurgveckan / ACOI / DGVS / AUGIS / RNC

AFS 2023 Meeting



AFS - a huge success for RefluxStop!

To further amplify our technology introduction at the AFS Annual Meeting, we hosted a panel discussion moderated by Prof. John Lipham. It included a description of the mechanism of action, surgical technique, and a review of European outcomes data. Among the panel of esteemed surgeons was Prof. Luigi Bonavina (President of the European Foregut Society), Prof. Sebastian Schoppmann, Dr. med Thorsten Lehmann, and Dr. Joerg Zehetner. The room was packed to the brim with eager listeners, requiring some to be standing in the back, to learn more about RefluxStop™ from the experts who have seen its impact on patients' lives' firsthand.

EFS 2023 Meeting & RefluxStop™ User Meeting

EFS European Foregut Society

In November RefluxStop™ hosted its 2nd annual Global User Meeting in conjunction with the Annual EFS Meeting. It could not have been more successful or better received. The meeting consisted of more than 50 attendees including current and upcoming RefluxStop™ surgeons as well as gastroenterologists' from across Europe, the UK, US, and Canada.

Current, past, and upcoming Presidents of the medical societies EFS (European Foregut Society) and AFS (American Foregut Society) were in attendance, including several societies' board members. It was an honor to bring together such an inspiring community to discuss RefluxStop™ topics including real-world data on nearly 600 treated patients, excellent long-term patient outcomes from the CE-mark study, surgical technique, and results from the leading centers of excellence in Europe.

> "Based on this meeting's outcome, it is clear that RefluxStop™ offers a unique surgical option to treat patients with gastroesophageal reflux disease."
>
> - Dr. Peter Forsell

Left to right: Dr. med. Yves Borbély, Dr. med Thorsten Lehmann, Dr. Joerg Zehetner, Prof. Luigi Bonavina,

Left to right: Dr. med. Yves Borbély, Dr. med Thorsten Lehmann, Prof. Luigi Bonavina, Prof. Sebastian Schoppmann

EXECUTE & MEASURE

PROMOTIONAL AND EDUCATIONAL EFFORTS IN THE UK IN 2023

RefluxStop™ was first featured in The Daily Mail! An educational piece, combined with a patient story. The Daily Mail is considered the most read newspaper in the world. To put it into perspective, The Daily Mail's average readership is 1.1 million per issue.

Next, two surgeons that are actively performing RefluxStop™ procedures, were featured in interviews on BBC Radio within the areas of their practice reach, one on BBC Merseyside and another on BBC Leicester. Statistics show that BBC news output across all its platforms reaches 73% of all UK adults, with BBC continuing to be the most used source as well as the single most important source for news. In total, both interviews combined reached over 320,000 listeners.

To wrap up 2023 and as per our plan, maximizing the impact in the final quarter. The announcement of the launch of RefluxStop™ in the NHS was covered on Sky news, a channel with a viewership of 52,230 people.

This was just the beginning. RefluxStop™ was featured in SAGA Magazine, a magazine with over 627,000 readers per month. Then the Daily Mirror, Daily Express and Reader's Digest, publications with a combined worldwide readership of 71 million.

In these articles and interviews, the goal was to educate and spread awareness about RefluxStop™ and its benefits. Readers were able to read the stories of real-life patients, people whose symptoms and grievances with acid reflux could be related to. It is so easy to focus on the business so much that you forget the impact a treatment like RefluxStop™ has on real people's lives. Without proper nutrition, living in pain and discomfort, becoming socially isolated, and not being able to sleep is just the beginning of most of our patients' stories. Some suicidal and others suffering from pre-cancerous conditions like Barrett's esophagus, living in fear of their lives daily. A large percentage of patients with limited options due to poor motility (ability to swallow). These patient stories support us in gaining market access, but more importantly reminds us why we do what we do every day!

Daily Mail


How a silicone 'table tennis ball' implant in the stomach can ease chronic heartburn

- The device can reduce pain in chest caused when stomach acid leaks back up
- The damage heartburn causes to oesophagus can have serious complications

Acid reflux pills are linked to worrying side-effects... but is surgery REALLY the answer?

By LOIS ROGERS
PUBLISHED: 15:30 EST, 18 September 2023 | UPDATED: 11:36 EST, 22 September 2023

Share 100 shares 144 View comments

Readership: 965,667 Daily Print
Circulation: 134,184 Average issue

DAILY EXPRESS

Readership. 548,000 Mon-Sat
Print Circulation. 311,000 Average
Mon-Fri 65p Sat: 90p.

Reader's Digest

Its worldwide circulation including all editions has reached 17 million copies and 70 million readers.

Daily Mirror

Mirror.co.uk is ranked #6 in the News & Media Publishers category and #649 globally in October 2023.
The Mirror (audience of 23.3 million)

Leveraging social media to amplify the impact

Online sources are the second most used platforms for news behind broadcast TV, used by over two thirds (68%) of UK adults. Social media is an important driver for this, with just under half (47%) of UK adults using social media for news nowadays.[1]

Coupled with the above PR educational efforts, we used social media to make a huge push in the UK. In summary, over 15,000 people saw the social media posts Implantica published about the news stories in the UK. Compared to the average post from Implantica, the posts were seen by 25% more people. In addition, the posts featuring these UK news stories had 34% more people click on them than the typical Implantica post.

In December 2023, typically a very slow time for social media, 77% more people saw Implantica's posts as compared to November 2023.

Posts promoting the Readers Digest story were seen by an average of 128% more people and on average 280% more clicked on them. The campaign to support the feature story in SAGA magazine was seen by an average of 114% more people and an average of 160% more clicked on these posts. The BBC Tees posts wereseen by an average of 238% more people and 260% more clicked on them.

In 2023, 18% more people saw the Implantica social posts in Q4 vs. the average in Q1, Q2, and Q3.

So what does this all mean? The impact of PR & education on patient inquires and market access:

How does our UK push tie into the importance of market access? To put it frankly, after our PR run in Q4 2023, the increase in patient inquires was substantial. We had the highest numbers of quarterly inquiries in the UK, beating the previous record by 50%. The inquires from patients in 2023 represented a 125% increase from 2022. Finally, 89% of these inquiries came from Q4. Note: These numbers do not include who went directly to a surgeon that was featured in a published story. These numbers are proof that our efforts in raising awareness and education have a direct impact on generating patient demand.

A facility could offer the RefluxStop™ surgery, but if patients with GERD do not know about it, does it matter? Is it impactful?

Marketing's role is to not only generate awareness of the RefluxStop™ product on all possible platforms, but to drive the desired business growth by amplifying all RefluxStop™ news. This includes clinical data development, regulatory accomplishments, commercial achievements, engineering feats, and market access triumphs.

JOIN US

in stopping reflux with RefluxStop™ !!!

Top 15 UK Media Outlets

We were published in FOUR major outlets

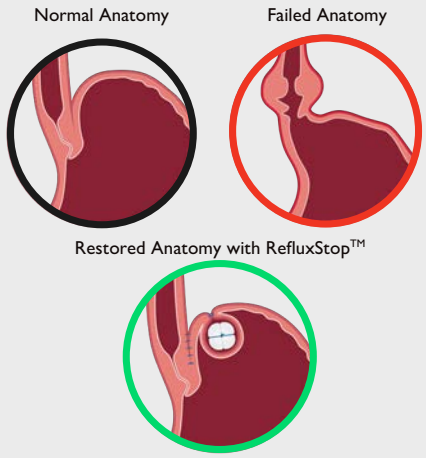
	Newsbrand	Audience	change (%)	reach (%)
1	BBC	38.3m	1%	77%
2	Mail Online	24.9m	17%	50%
3	The Sun	23.6m	-18%	48%
4	Mirror	22.8m	-3%	46%
5	The Guardian	22m	2%	44%
6	The Independent	21m	8%	42%
7	Sky News	17.2m	-13%	35%
8	ITV	15.5m	20%	31%
9	Metro	14.7m	-16%	29%
10	The Telegraph	13.8m	-24%	28%
11	Money Saving Expert	13.5m	-1%	27%
12	Daily Express	12.6m	-19%	25%
13	Birmingham Live	12.5m	4%	25%
14	Times & Sunday Times	12.1m	-20%	24%
15	Manchester Evening News	11.9m	-33%	24%

Majid, A. (2024, April 2). Top 50 UK news websites: Most brands report audience dip in February. Press Gazette. https://pressgazette.co.uk/media-audience-and-business-data/media_metrics/most-popular-websites-news-uk-monthly-2/

Audience Reach

Daily Mail	24.9 million
Daily Mirror	22.8 million
sky news	17.2 million
Daily Express	12.6 million

Treating the root cause of acid reflux.



Sources and References:
1. Ofcom. (2023, July 20). News consumption in the UK: 2023.

RefluxStop™ market access

Market access strategy to ensure scalable commercial success:

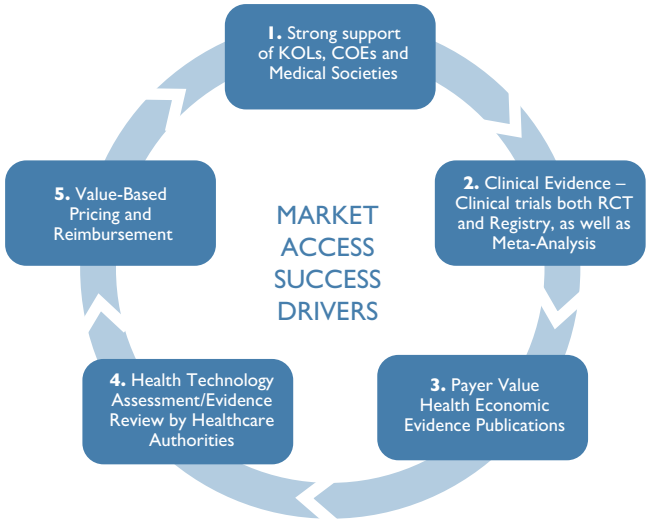
RefluxStop™ has a unique potential to fill the significant treatment gap and potentially become a standard of care, resulting in a remarkable commercial business opportunity.

Having said that, any significant commercial growth and success could only be achieved with a robust established market access pathway – reimbursement approval by insurance companies and public healthcare systems. However, the commercialization process for a novel and disruptive medical device has changed rapidly over the past years. While medical devices have always been highly regulated, **reimbursement agencies and health insurers have raised their standards for reimbursement and coverage approval** and require a significantly higher level of clinical and economic evidence than regulatory agencies.

Reimbursement systems vary significantly in healthcare system design, funding, priorities, and decision-making approach by country, wherein Europe is generally more difficult than the U.S. Establishing adequate market access pathways, therefore, is usually a very time consuming and resource demanding process. Meanwhile, due to lack of adequate reimbursement, healthcare providers are not able or can be reluctant to use a new technology due to lack of funding.

To enable the desired business growth, our biggest priority for RefluxStop™ is to ensure that patients are getting access to this device and the cost of the device is adequately covered by the respective healthcare system.

Key drivers of successful market access approval process:



Market Access starts with partnering with highly skilled surgeons/ **Key Opinion Leaders (KOLs)** and reputed centers of excellence (COEs) that are early adopters and fully committed to study, utilize, and advance clinical evidence development for a new treatment. Therefore, a significant part of our RefluxStop commercial efforts has been focused on bringing many of the best KOLs onboard. These KOLs help educate the broader medical professional community and also professional societies to build the necessary consensus on the key clinical value and overall system impact of introducing a new treatment option.

At the same time, we are expanding our regulatory approval to also be able to sell RefluxStop in the U.S. Before achieving U.S. FDA approval all complications of a new procedure must be reported to FDA making it even more essential to **only use centers of excellence to ensure good patient outcomes**. Also markets far away or other markets more difficult to follow, where outcomes could not be as closely monitored, have to be put on hold.

Successful broad-scale adoption of a new technology among reimbursement agencies and also in the wider surgeon community requires proof of patient outcomes. As a result, it is important to carefully design and **construct evidence generation clinical trials** to demonstrate RefluxStop's substantial long-term clinical benefit in both a controlled environment and in a real-world setting.

Nowadays, most developed countries are setting additional criteria relevant to economic value of the new treatment. This requires us to provide additional economic data to **demonstrate the 'value for money'** of the cost spent on a new technology. Therefore, cost effectiveness and budgetary impact analyses are needed to explain that a new technology is providing acceptable value for money.

RefluxStop™ market access

In order to disseminate the value proposition of our treatment with payers, medical societies and policymakers, we need to **publish our data in reputed medical journals** and conferences. Most payers require data to be published in peer-reviewed scientific journals to be considered in the reimbursement decision process. The RefluxStop™ publication strategy is a primary component for obtaining market access, and we will announce several landmark research publications this year as well as several abstracts and whitepapers. With a growing number of KOLs and COEs joining the RefluxStop™ community, we foresee significant growth in the published evidence base for RefluxStop™ that should pave the way for accelerating market access approvals in years to come.

Over the past decade, there has been a strong trend of evidence-based reimbursement decision for new technologies. To objectively assess the value of a new technology/treatment, **payers conduct an in-depth evidence review, commonly referred as "Health Technology Assessment (HTA)"**, of the clinical, economic, and societal value of the new treatment compared to the current alternative available options. An HTA approval can play a huge role in justifying the pricing of a new device, supporting adequate reimbursement approval, and ultimately, help accelerate broader product adoption by providers and KOLs.

In summary, we believe RefluxStop™ is a game-changing opportunity for the Acid Reflux market. It has all the attributes to transform patient outcomes and become a new standard of care as supported by clinical evidence.

RefluxStop™ is our core commercial priority with a multi-billion dollar market opportunity in a 1 billion-sufferer marketplace and will be ripe for substantial market growth once we have successfully established market access and reimbursement in key markets.

RefluxStop™ real-world performance - straight from the world-leading reflux experts:

We continue to expand our collaboration with the world-leading reflux experts from the well-renowned Reflux centers of excellence around Europe who are committed to bringing RefluxStop™, our disruptive therapy for GERD, to patients safely and effectively.

The most important goal of our strategy is to ensure RefluxStop™ patients and surgeons can achieve excellent outcomes and are happy with the treatment receiving adequate funding for the procedure.

Accelerating RefluxStop™ adoption by proven cost-effectiveness and economic evidence - *generated in partnership with top EU institutions*

University of York's Health Economic Consortium has evaluated the cost effectiveness of different treatments for acid reflux (GERD). In the cost-effectiveness analysis, RefluxStop showed favorable outcomes compared with PPI based Medical Management (MM) Laparoscopic Nissen Fundoplication (LNF) and Magnetic Sphincter Augmentation (MSA).

The study has been published in the highly renowned Journal of Medical Economics (Harper et al., 2023). https://pubmed.ncbi.nlm.nih.gov/37042668/. This is a significant milestone for the commercialisation of RefluxStop.

The base case incremental cost-effectiveness ratios compared with MM, LNF, and MSA were £4,156, £6,517, and £249 per QALY gained, respectively. At the UK cost-effectiveness threshold of £20,000 per QALY gained, since the incremental cost-effectiveness ratio is well below the UK cost-effectiveness threshold, **the probability that RefluxStop is cost-effective against MM, LNF, and MSA was 100%, 93%, and 100%, respectively.**

The last decade brought a significant shift in evidence-based reimbursement decisions regarding new technologies.

Payers now engage in Health Technology Assessments (HTAs) to impartially evaluate the worth and value for money of a new technology or treatment. These assessments are exhaustive reviews of evidence diving deep into the clinical, economic, and societal aspects of the new treatment in comparison to existing alternatives.

It's no exaggeration to say HTA approvals are crucial milestones for RefluxStop™ commercial success. Therefore these cost-effectiveness results are invaluable for RefluxStop.

This approval is needed from each payer organization or insurance group. HTAs hold immense significance in setting the price of a new device, securing adequate reimbursement, and thereby speeding its adoption by providers and key opinion leaders (KOLs).

Implantica is generating country specific economic data substantiating the value proposition of RefluxStop™ and supporting evidence for HTA approvals.

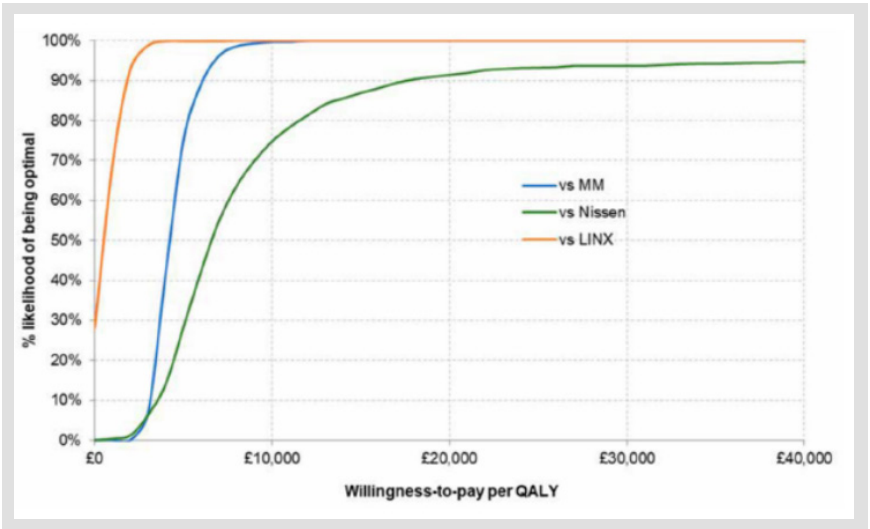


Figure 1. Cost-effectiveness acceptability curve for RefluxStop where probability of being cost-effective against MM, LNF and MSA were 100%, 93% and 100%

Additionally, YHEC completed a budget impact analysis to assess the budgetary impact associated with introducing RefluxStop™ as a treatment option into the National Health Service (NHS) in England and Wales.

Over 5 years, introducing RefluxStop™ in UK NHS will allow the avoidance of 347 surgical failures, 39 reoperations, and 239 endoscopic esophageal dilations.

This second study has been published in the highly regarded Journal of Health Economics and Outcomes Research (Harper et al., 2024).

EU Studies

In 2023, the Health Economics and Payer Evidence team completed two major projects to generate evidence for specific EU countries:

- Cost-effectiveness analysis of RefluxStop™– Sweden, Norway, and Switzerland
- Budget impact analysis of RefluxStop™ in Italy

The study results have all been developed as full manuscripts in association with country specific surgical experts at several centres of excellence. The results are currently in either the submission stage or the peer review process.

- *The review of cost-effectiveness in Sweden found that "RefluxStop has a high likelihood of being cost-effective against Nissen fundoplication and PPI-based medical management."*
- *In Switzerland, "RefluxStop had a high probability of being cost-effective, with probabilities of 100%, 97%, and 100% against PPIs, Nissen fundoplication, and the LINX system, respectively."*

Harper S, Grodzicki L, Mealing S, Gemmill E, Goldsmith P, Ahmed A. Budget impact of RefluxStop™ as a treatment for patients with refractory gastro-oesophageal reflux disease in the United Kingdom. *JHEOR*. 2024;11(1):1-7. doi:10.36469/jheor.2024.90925

JHEOR Journal of Health Economics and Outcomes Research

Gastrointestinal Conditions

Budget Impact of RefluxStop™ as a Treatment for Patients with Refractory Gastro-oesophageal Reflux Disease in the United Kingdom

Sam Harper[1*], Lukasz Grodzicki[2], Stuart Mealing[1], Elizabeth Gemmill[3], Paul Goldsmith[3], Ahmed Ahmed[4]

[1]York Health Economics Consortium, York, UK
[2]Sherwood Forest Hospitals NHS Foundation Trust, Nottingham, UK
[3]Central Manchester University Hospital NHS Foundation Trust, Manchester, UK
[4]Department of Surgery and Cancer, Imperial College London, London, UK

> "In all the country-wide analyses (UK, Switzerland, Sweden, and Norway), RefluxStop™ was determined to be a highly cost-effective treatment for GERD patients compared with the current standard care of Proton pump inhibitor-based medical management and surgical options such as Nissen fundoplication and Magnetic sphincter augmentation (LINX system)."

Analysis in the UK and Italy showed that when RefluxStop™ is used across a healthcare system, clinical outcomes are better and there is a marginal budget impact vs. other GERD treatments. This is due to cost savings associated with RefluxStop™. In all these economic analyses, country specific local cost data were used.

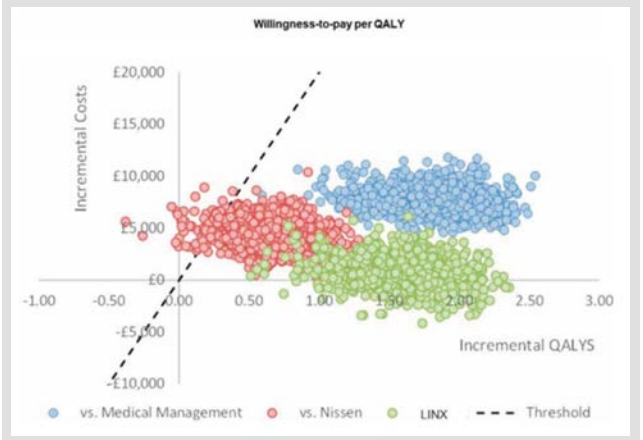
The study results have all been developed as full manuscripts in association with country specific surgical experts at several centres of excellence. The results are currently in either the submission stage or the peer review process.

Business Cases for the NHS

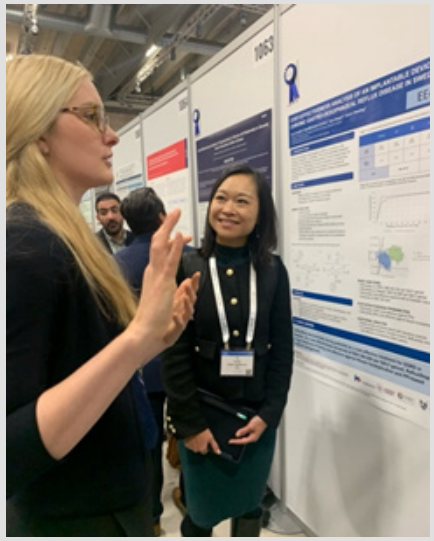
In 2023, Implantica also developed business cases showing the financial benefits of RefluxStop™ compared to other surgical options in the UK NHS. These business cases are required for inclusion in each NHS hospital trust, so they are critical to Implantica's growth. In 2023, we submitted business cases to more than five NHS hospitals.

These business cases have played a major role in offering RefluxStop™ at two NHS trusts of which one already started RefluxStop cases in late 2023 and other is scheduled to begin first cases in Q2 2024. The team continues to develop business cases as required for submission to other NHS hospital trusts.

Overall, as can be seen below in the Cost- Effectiveness plane, showing the NICE cost-effectiveness threshold of £20,000 per QALY. The results of the UK cost-effectiveness analysis show that RefluxStop is highly likely to be a cost-effective treatment option for GERD patients when compared with the management options currently available in the country.



The blue-ribbon winning poster at ISPOR, Cost-Effectiveness Analysis of an Implantable Device for Chronic Gastro-Oesophageal Reflux Disease in Sweden, earned a blue ribbon, **recognition as a top 5% poster in this major health economics conference.**



Reimbursement

On the reimbursement front, the team has had some early success to possibly enlist RefluxStop™ as an interventional procedure to be evaluated by UK NICE and eventually develop a nationwide guidance. This would be a major growth driver in RefluxStop™ adoption in the UK.

Conclusion

Throughout 2023, the Health Economics and Payer Evidence team produced, published, and presented impactful studies to highlight the economic impact of RefluxStop™ as a widely accepted surgical treatment for GERD. The country specific studies are especially influential to localized payers, which will in turn drive localized adoption of RefluxStop™

The role of payers in expanding access to RefluxStop™ cannot be underestimated. It's critical that this team keeps producing impactful studies to positively influence payer economic and budgetary evaluations. Looking to the future we plan to continue to partner with top academic institutions and build on the country specific strategy to pave the way for payer acceptance to allow more patients access to the innovative treatment they need.

References

Harper S, Grodzicki L, Mealing S, Gemmill L, Goldsmith PJ, Ahmed AR (2023). Cost-effectiveness of a novel, non-active implantable device as a treatment for refractory gastro-esophageal reflux disease. J Med Econ;26(1):603-613.
Harper S, Grodzicki L, Mealing S, Gemmill E, Goldsmith P, Ahmed A (2024). Budget Impact of RefluxStop™ as a Treatment for Patients with Refractory Gastro-oesophageal Reflux Disease in the United Kingdom. J Health Econ Outcomes Res;11(1):1-7

CLINICAL EVIDENCE TO ACHIEVE REIMBURSEMENT FOR REFLUXSTOP– DATA AT MAJOR CONFERENCES 2023

45 Conference abstracts submitted in leading conferences

29 Oral and poster presentations in leading conferences & 2 educational panels

11 Conference abstracts accepted in 2023 for 2024 leading conferences

15 Manuscripts are published or under submission

2 RCTs Comparing to Nissen and PPI

2 Registries

IIT Studies
Multiple studies

REFLUXSTOP MADE A BIG IMPACT AT BOTH EFS IN EUROPE AND AFS IN U.S. DURING 2023

RefluxStop™ Therapy Growth - Powered by Superior Scientific Evidence

For decades, the reflux treatment landscape has consisted of proton pump inhibitor (PPI)-based medical management and anti-reflux surgery, mainly with different variations of laparoscopic fundoplication. PPI therapy does not directly treat the cause of acid reflux and 40% of patients don't respond to it[4]. On the other hand, surgical treatment brings several uncomfortable adverse events like dysphagia, bloating, and painful swallowing.

Consequently, there is a huge unmet need in the management of reflux disease, where patients can have a long-term symptom-free life with the fewest possible side effects.

In addition we know untreated reflux disease is associated with significant morbidity and mortality as it can lead to precancerous Barrett's esophagus[1] which may progress to esophageal cancer.[2] 10-20% of GERD patients develop pre-cancerous changes.[3]

Therefore, to change the treatment landscape to a new more complication free surgical approach, evidence generation for the new treatment is necessary. This is key for the new treatment to be incorporated in the healthcare reimbursement system.

40% of patients don't respond to PPI therapy.[4]

SOURCE

Ref 1-4, see end of this section on page 69

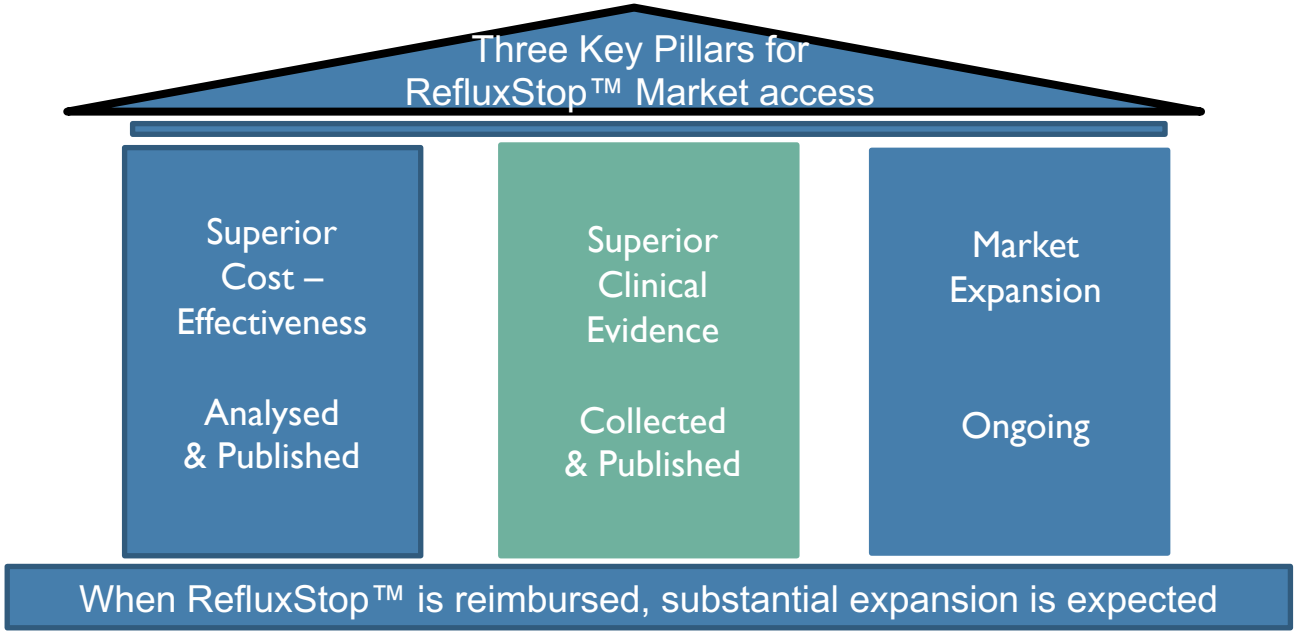
Implantica's goal is to address this enormous and urgent treatment gap for the millions of reflux patients and drive a paradigm shift in GERD disease management with RefluxStop™ therapy.

Evidence Generation Strategy

Implantica's evidence-generation strategy and publication plan support the pillars of the scientific narrative behind RefluxStop™, which is critical to securing reimbursement approval from healthcare systems while driving a paradigm shift in the way GERD is managed today.

A competitive superiority of RefluxStop™ against the standard of care and other relevant therapies needs to be established, enabling the broader payer approval success.

The payer evidence team is working with leading academic institutes and expert surgeons throughout Europe to deliver high-quality clinical data to meet the payer's and clinical community's needs, demonstrating the burden of disease and the unmet need for reflux disease. Our goal, through superior clinical data, is that the reflux treatment landscape should experience a paradigm shift.



Thorough systematic literature reviews have been conducted to establish the poor quality of life experienced by GERD patients, the insufficient clinical efficacy of Laparoscopic Nissen Fundoplication, and different endoscopic treatment alternatives.

Several manuscripts are under submission or peer review process that will present the current unmet need in this patient population. These systematic reviews provide evidence that RefluxStop™ has superior clinical and patient-centric benefits.

These results were presented at several international conferences, such as the Association of Upper Gastrointestinal Surgery of Great Britain and Ireland (AUGIS) annual meeting in the UK and Professional Society for Health Economics and Outcomes Research (ISPOR) European annual meeting.

Demonstrating Clinical Superiority through RCTs and Real-World Studies

Implantica Health Economics and Payer Evidence team aims to generate and disseminate high-quality clinical evidence solidifying RefluxStop™'s superior clinical efficacy and safety over other existing treatment options. Data will be generated from both controlled studies and open-label investigator-initiated clinical trials.

An excellent consistency has been observed in RefluxStop™ clinical data coming from its well-designed CE-mark study's long-term follow-up and real-world clinical data from independent surgeons and academic institutes. RefluxStop™ CE-mark study recently concluded its 3-year and 4-year long-term efficacy and safety follow-up that are currently under peer-review and submission process.

These long-term data showed clear and sustained improvement in both patient-centric and GERD-related objective endpoints. Patient quality of life measured through the most acceptable instrument "GERD-HRQL" questionnaire, has shown more than 90% reduction (improvement) over the 4-year period of follow-up compared to the total score at baseline.

Outcome	Baseline (n=50)	1-year follow-up (n=47)*	3-year follow-up (n=47)	4-year follow-up (n=44)**
Dysphagia *(reported as AE or with GERD-HRQL subscore >2)*	22%	2%	2%	2%
Device explantation	-	0	0	0
Device-related SAEs	-	0	0	0
AEs	-	12 AEs	2 AEs***	No new AEs since yr 3

Figure 2 Patient safety data was consistent over 4 year time period observed in RefluxStop CE mark study. (Presented at SAGES 2024 conference in Ohio, Cleveland during April 17 – 20, 2024)

AE, adverse event; GERD-HRQL, Gastroesophageal Reflux Disease Health-Related Quality of Life; PPI, proton pump inhibitor;
SAE, serious AE.
** 3 patients quit the study at 6 months (2) and 3 months (1) – none took PPI when quiting.*
*** Additional 3 patients well treated at year 3*
**** Mild dysphagia and heartburn*

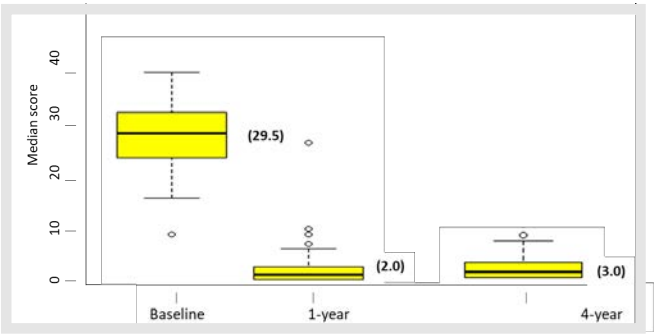


Figure 3 Improvement in patients' quality of life (measured through GERD-HRQL) was consistent over 4 year time period observed in RefluxStop CE mark study. (Presented at SAGES 2024 conference in Ohio, Cleveland during April 17–20, 2024)

Several investigator-initiated studies are in an advanced stage, and the results have already been presented at multiple global conferences in EU countries and the United States. These investigator studies (real-world data) strongly supplement RefluxStop™'s data from the CE-mark clinical study.

Recently, data were presented from two investigator-initiated studies conducted in Switzerland and Germany at the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) conference in Ohio, Cleveland, USA. Three- to five-year follow-up data from a Swiss hospital showed statistically significant improvement in GERD specific quality of life measured by GERD-HRQL instrument both in short-term and long-term follow-up.

This study reported a follow-up time of 3–5 years, where patients achieved a sustained improvement of GERD-Specific quality of life that reflects patient's overall well-being and symptom-free life. This Swiss hospital also presented excellent long-term safety data for RefluxStop™ patients over this period.

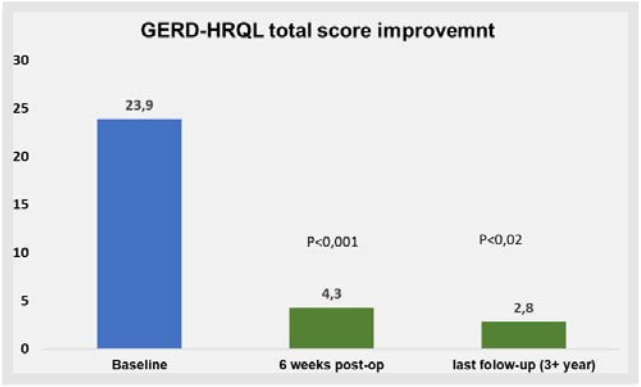


Figure 4 Investigator initiated study from a Swiss academic hospital with follow-up of 3–5 years. (Presented by Borbely et al. at SAGES 2024 conference in Ohio, Cleveland during April 17–20, 2024)

Discontinuation of PPI medication is often considered an important treatment goal in the management of GERD. Therefore, it is important to ensure that a significant number of patients are no longer using PPI and other anti-reflux medications after surgical treatment such as RefluxStop™. RefluxStop™ CE-mark study reported a significant proportion of patients were not using PPI medications at 3-year and 4-year follow-ups, while a similar trend has been observed in real-world evidence from a pooled German dataset. 5-year data has been summarized for the FDA PMA submission.

Through another investigator-initiated study, two German centers pooled their data and presented their findings at the SAGES conference in 2024 in Ohio, Cleveland, USA. In this study, a significant proportion of patients discontinued PPI medication in the follow-up period. A total of 158 patients were included in this investigator-initiated study that reported 96,4% of patients discontinued PPI use at the follow-up period; this difference compared to baseline was statistically significant (p<0,001).

In addition to Implantica-sponsored studies, a good number of investigator-initiated studies will supplement evidence generation activities that will ultimately be disseminated as peer-reviewed publications.

158

Patients included in investigator-initiated study reported that

96.4%

of patients discontinued PPI use at the follow-up period

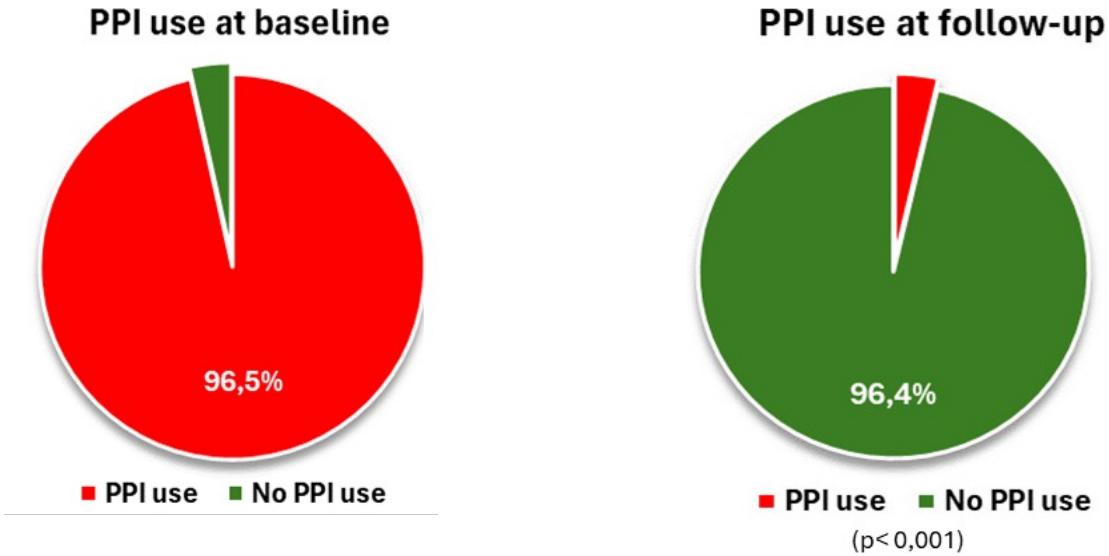


Figure 5 Investigator initiated study from two German centres with 158 patients with a mean follow-up period of almost 2-years. (Presented by Elshafei et al. at SAGES 2024 conference in Ohio, Cleveland during April 17–20, 2024)

Conclusions

Throughout 2023, the Publication and Evidence Synthesis teams generated valuable data and evidence to demonstrate the urgent need for innovation on the landscape of GERD treatment and contributed to drive for a paradigm shift in the standard treatment for GERD.

The upcoming publications based on RefluxStop™ CE-mark study long-term follow-up and several investigator-initiated studies will generate compelling evidence that will support building the scientific narrative of RefluxStop™ to distinguish its efficacy and safety from the existing treatment options.

With every attendee at a presentation, every conversation with a surgeon, and every article published online, the awareness and acceptance of RefluxStop™ scientific evidence is multiplying and establishing its unique value and tremendous potential to create a paradigm shift in GERD patient care.

1. Oh DS, Demeester SR. Pathophysiology and treatment of Barrett's esophagus. World J Gastroenterol. 2010 Aug 14;16(30):3762-72. doi: 10.3748/wjg.v16.i30.3762. PMID: 20698038; PMCID: PMC2921087.

2. Prasad GA, Bansal A, Sharma P, Wang KK. Predictors of progression in Barrett's esophagus: current knowledge and future directions. Am J Gastroenterol. 2010 Jul;105(7):1490-1502. doi: 10.1038/ajg.2010.2. Epub 2010 Jan 26. PMID: 20104216; PMCID: PMC3408387.

3. Runge TM, Abrams JA, Shaheen NJ. Epidemiology of Barrett's Esophagus and Esophageal Adenocarcinoma. Gastroenterol Clin North Am. 2015;44(2):203-231.

4. Returra F, Bronzini F, Campigotto M, et al. Refractory Gastroesophageal Reflux Disease: A Management Update. Front Med (Lausanne) 2021;8:765061. doi: 10.3389/fmed.2021.765061.

eHealth is believed to revolutionize healthcare with more advanced treatment and smart implants

Ability to treat diseases in a way which were previously seen as untreatable

eHealth will save costs – reduced hospital stay and number of visits

eHealth will bring treatment closer to the patient – patient will be involved and more in charge

eHealth

The future of eHealth

While most development regarding eHealth is focused on gathering information from outside the patient's body, Implantica's eHealth-system is designed to monitor, deliver, and handle data as well as **treat illnesses from inside the body**. This enables a reduced cost of care and better patient outcomes.

The Implantica eHealth Platform is a digital health system to support our pipeline of smart medical implants designed for a safe and secure control and monitoring over the internet.

The Implantica eHealth Platform is designed to enable healthcare professionals to reduce unneeded or inefficient in-person visits by allowing the remote monitoring of long-term or chronic illness. Health information to be generated from the active implanted devices and collected patient feedback, integrated with data collected from the Patient's mobile health devices such as smart phones, watches, and digital scales. Designed to allow information to be collected from Remote Treatment Monitoring can be used by the Healthcare Professional to observe the state of the device and make treatment modifications over the internet.

Designed for remote treatment modifications and monitoring enable more personalized care, increase treatment quality and reduce cost. Treatment information presented to the patient through their personal smartphone or other devices is intended to keep them informed and engaged in their therapy, expected to lead to better patient compliance and outcomes.

An uncompromised commitment to the cybersecurity of the devices and system is at the center of this technology. The e-InVivo Smart Implant is designed to ensure the end-to-end integrity of all health data transmitted over the internet.

Similarly the design involves Healthcare Professional to be authorized to apply treatment changes to a particular person and device and change the treatment.

The Wireless Energizing Platform and e-InVivo Smart Implant are designed to collect anonymous real world data for performance monitoring and diagnostics. This targets the continuous improvement of the system and devices, gain insights on the devices in the field and push any needed updates and to measure the effectiveness of our treatments and support product improvements.

The data to be stored within the Implantica eHealth Platform is designed to be accessible through an Implantica-provided terminal to minimize the time to onboard a new hospital, and can optionally be integrated into an existing Hospital Information System.

Implantica has designed an eHealth platform with safety and efficiency in focus, adapted for the future of our entire pipeline portfolio of devices, designed to revolutionize healthcare and save costs for society.

An uncompromising commitment to the cybersecurity of the devices and system is at the center of the design of our eHealth platform, e-InVivo

> e-InVivo™ is aimed at treating illnesses from inside the body controlled from distance

eHealth

eHealth platform – the digitilisation of healthcare

The e-InVivo™ eHealth platform is a small, intelligent implanted device designed to allow early detection, easy monitoring and better treatment with the possibility to change treatment on distance – designed to save substantial costs for society.

The e-InVivo™ platform is designed to be used as a stand-alone implant or integrated with a multitude of Implantica's other development devices and remain in use in the body for an extended period. In combination with Implantica's wireless energising technology, the e-InVivo™ platform is designed to be charged, controlled and adjusted wirelessly through intact skin reducing or eliminating the need for additional invasive procedures.

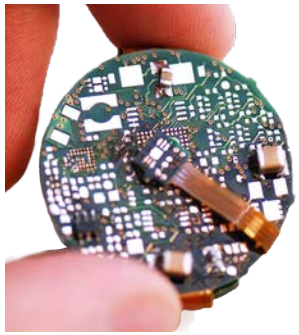
The e-InVivo™ platform is designed to collect and process information inside the body, transfer data wirelessly to healthcare providers or to the patient through an external device, such as a smart watch or smart phone. To further leverage the value of the platform, Implantica may potentially build eHealth databases of information collected from inside the body. The data would be collected solely on the basis of informed patient consent and in full compliance with applicable data protection regulation.

These databases is targeting to be an important tool in the development of eHealth-oriented healthcare, helping medical researchers and health-care providers identify treatment weaknesses and potential cost reductions.

Among other things, healthcare should be implemented closer to the patient: the treatment will come to the patient instead of as today, the patient traveling to the hospital and spending time in waiting rooms. Healthcare should be proactive, and not reactive as it is today. Although we all know that early detection is key, the healthcare sector has been incapable of providing a suitable proactive approach. Here Implantica has an important role to play.

The eHealth Platform is designed to be a landmark in the eHealth marketplace

- Monitor and take automatic action to cause desired treatment effect
- Control bodily functions
- Communicate with caregiver and patient
- Adjust treatment on distance



> e-InVivo™ is aimed at improving health and reducing costs by improving preventive and proactive healthcare on distance.

Wireless energising platform

Advanced technology into the body requires wireless power

Implants that require little energy, such as cardiac pacemakers, are so far the only active implants to achieve wide use. Historically, active implants that perform complex tasks, operate small motors and pumps and manage data input from various sensors require more current and haven't had the same success since batteries would need to be frequently replaced.

Wireless Energy

To overcome this hurdle Implantica has designed a Wireless Energising Platform. This platform is a proprietary energy transmission and control system designed to safely power implants directly or recharge them wirelessly through intact skin.

The technology also allows for the wireless control and exchange of data, enabling postoperative adjustments, continuous data feeds and greater quality and reliability of data reporting directly to both the patient and caregiver.

Bringing advanced technology into the body requires sufficient power to operate a device inside the body long-term

Wireless Energising Platform

- Miniaturized system
- Remote control
- Wireless energy supply

Urinary incontinence & UriControl®

Urinary incontinence

The most common type is called stress urinary incontinence (SUI); a leakage of urine when pressure is put on the bladder and can occur during laughter, coughing or during physical activities. It is caused by a weakened sphincter or pelvic floor muscles. For women, possible causes of SUI include changes in oestrogen levels and nerve function due to aging, pregnancy or menopause. For men, the most common cause is complications related to prostate surgery. The second most common type of incontinence is urge incontinence, characterised by a sudden and strong urge to urinate that is hard to suppress and is often intense enough to cause urine leakage.

Addressable market

More patients are turning to surgeries in an attempt to relieve their suffering. 500,000 surgeries for urinary incontinence were done in 2016 worldwide[1]. Current market for devices only is valued at USD 3.1 billion forcasted to grow by a CAGR of 9%*. UriControl® is expected to significantly improve existing treatment and radically improve quality of life for a very large number of people by providing a solution that restores their dignity and freedom.

UriControl®

Reimbursed in most countries allowing fast market introduction – older numbers from 2018**

Germany (EUR)	11,000
Switzerland (CHF)	18.600
US (USD)	13,000
Canada (CAD)	18,000

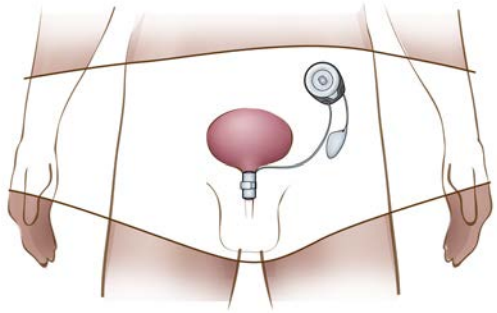
Source: ** AiM Reimursement Evaluation 2018

Urinary treatment device market:*

- Valued at USD 3.1 billion 2023
- CAGR 9% forecasted 2024 - 2032
- Forecasted USD 6.1 billion 2032

SOURCE

*Global Market Insight 2024



Remote controlled artificial urinary sphincter – recharged once per month

Adaptable intelligent closing pressure to avoid urinary leakage

200m Number of global sufferers[1-3]

10% Of all adult woman[1,2]

20% Of all prostate cancer operated men[1]

3.1 USD bn Device market only 2023*

Source:
(1) ISS 2020 supported by statistics from DRG systems;
(2) Calhoun, Nygaard & Thom 2007;
(3) Barry 2003;

UriControl®

Improving urinary control

UriControl® is designed as a remote controlled artificial urinary sphincter with an advanced pressure regulation system which works directly on the urethra.

It targets to significantly improve on existing manual pump concepts to treat urinary incontinence with the use of Implantica's wireless technology. Most importantly, it is expected to address the 10 percent of all women suffering from urinary leakage where no optimal treatment exists today.

The principle of UriControl® is well proven as the hand pumped artificial urinary sphincter device exists on the market today. UriControl® is expected to be both more convenient and hygienic to use as well as offering improved treatment functionality since it is designed to be operated by a remote-control or mobile phone. UriControl® is a smart active implant with an advanced pressure regulation system which will work directly on the urethra. It is estimated to both reduce complications and improve treatment efficiency.

UriControl® is expected to radically improve quality of life for a very large number of people by providing a solution that restores their dignity and freedom.

> UriControl® is estimated to be a ground-breaking device to treat urinary incontinence for both men and women.

Obesity & AppetiteControl™

Obesity

According to the World Health Organization, 2.5 billion adults around the world were classified as overweight in 2022, 890 million of those were obese. Obesity is a growing health problem globally. In 2021 adult obesity rates in 16 OECD countries with measured data was on average 26 percent with the US topping the scale with about 43 percent of adults being obese.

17%[1]

Average growth of number obesity surgeries between 1997-2018

9%[2]

Forecasted average growth of number obesity surgeries between 2021-2028

Target to reach a market size of USD 4.8 billion in 2028[2]

Source:

[1] *Research summarized by ISS AG 2020, including journal Obesity Surgery;*

[2] *BioSpace 2022*

Today obesity drugs, such as Ozempic and Wegovy, are very popular and the most commonly used method to lose weight. They are also quite effective in reducing weight by approximately 10%, as shown recently in randomized clinical studies. They are a bit cumbersome since they are injected in the abdominal wall or thigh. Side effects include among others, hair loss, gallstones, nausea, dehydration, changes in bowel movement, such as diarrhea or extreme constipation and the more severe pancreatitis. While obesity drugs are effective in reducing weight in overweight people, the more obese people need surgery.

Current surgical treatment of obesity usually causes irreparable damage to your stomach. Surgical procedures involve opening the food passageway, and a portion of your stomach is removed. These procedures are high risk and several complications may occur both related to surgery, and postop side effects such as dumping syndrome with a sudden fall in blood sugar.

AppetiteControl™

AppetiteControl™ is a device designed to treat obesity using a completely new treatment approach – by controlling appetite in the same way as the body itself controls appetite – without damaging your food passageway. AppetiteControl™ is designed to achieve a possible paradigm shift in obesity surgery. While maintaining complete weight control, AppetiteControl™ patients are expected to be able to enjoy food intake with full appetite and no dietary restrictions.

AppetiteControl™ is designed to be less invasive than gastric sleeve and gastric bypass and even avoids opening the food passageway and making any permanent anatomical changes; assuming clinical validation and successful market introduction it holds the promise of bringing about a paradigm shift in obesity surgery.

”

Implantica's platform e-InVivo™ is designed to monitor, deliver and handle information as well as treat from inside the body. Inside the body the possibilities of improving healthcare are much better

AppetiteControl™

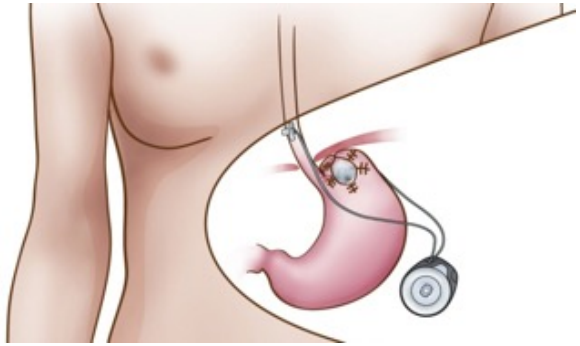
AppetiteControl™ is an implant based on our smart eHealth platform to be able to adjust treatment on distance. It is designed for inducing satiety, imitating the body's own natural functions by stretching the upper part of the stomach in the same way as when the stomach becomes full of food. When one eats and the stomach becomes full, the stomach wall starts to distend or stretch and in the upper part of the stomach, stretch receptors send a signal to the brain. The brain signals that the stomach is full and that eating should stop.

A smart food sensor system has been designed and tested on students. When food is swallowed it triggers the implanted sensor, which is designed to keep track of the eating and when enough pre-programmed food has been swallowed, designed to send an electronic signal to a control unit that starts the stretching movement which triggers nerve signals to the brain telling the person they have had enough food.

Patients should be able to eat normally to feel full after an average portion of food. Hindering overeating will result in permanent weight loss, while still allowing patients to enjoy food intake with full appetite and no dietary restrictions.

The weight of the patient and important implant parameters is sent to the caregiver and the device is designed to be reprogrammed remotely to achieve the weight agreed between the doctor and subject.

- **AppetiteControl™ imitates how fullness is achieved in real life**
- **AppetiteControl™ controls appetite without affecting the food passageway**
- **AppetiteControl™ – programmable design to target optimal weight loss**



UriRestore® & Urinary retention

100 million[1] people worldwide are not able to urinate, often paraplegic

Implantica has several products that are designed to really make a difference. People who are unable to urinate and need to insert a catheter every time have a burdensome life. Every one of these sufferers would do anything they can to be able to urinate without inserting such catheters.

1.8 percent of the US population suffer from paralysis, of which 27.3 percent is caused by spinal cord injury, resulting in an annual cost of approximately $40.5 billion in the US alone[2, 3].

Implantica has designed UriRestore® to be able to help these sufferers to urinate on command using a remote control.

An estimated 5.4 million people live with paralysis in the United States. The leading causes of paralysis are stroke, spinal cord injury, and multiple sclerosis.

PRC 2023

> UriRestore® is designed to be a groundbreaking device to treat inability to urinate so called urinary retention for both men and women.

SOURCE

[1] US figure extrapolated to estimate global sufferers

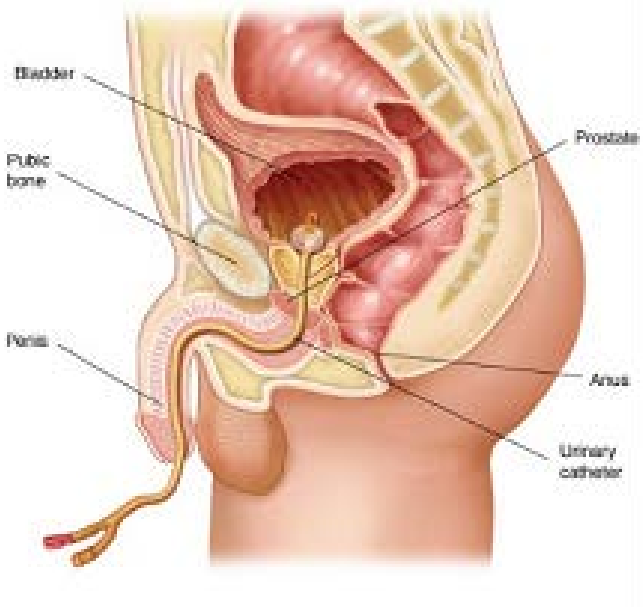
[2] Christopher & Dana Reeve Foundation, Stats about paralysis,

[3] Paralysis Resource Center (PRC)

UriRestore®

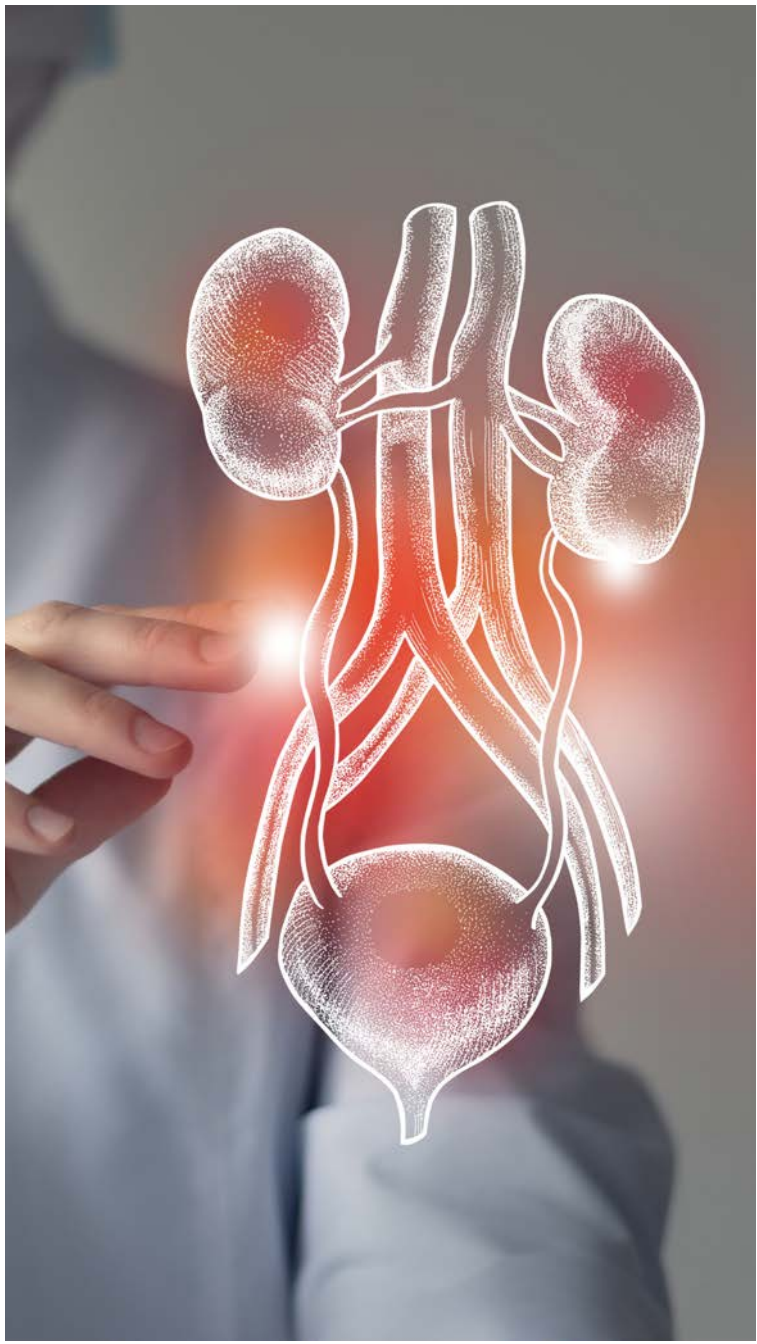
Implantica has designed UriRestore® to be able to help sufferers to urinate on command using a remote control. The only option for urinary retention sufferers currently is as mentioned above catheterization, which has a high infection risk since a new catheter must be manually inserted into the urethra each time to urinate, approximately 5 times per day and even more so if the catheter is left permanently. Inserting a catheter in your own bladder 20,000 times during a ten year period is not only severely cumbersome, but also involves lots of cost for society.

UriRestore® is designed to be a remote-controlled device enabling those who cannot urinate, such as spinal cord injury (SCI) and multiple sclerosis (MS) patients, to urinate on demand using Implantica's wireless platform. UriRestore® designed to avoid the frequent use of catheters, which limits the infection risk of constant catheter placement. Controlled via remote, the patient initiates urination by pressing a button which mechanically acts on the bladder to empty it. UriRestore® is expected to profoundly improve patients quality of life, making an impact on humanity.



Catheterization is used for urinary retention sufferers.

Due to high infection risk, new catheter must be inserted each time to urinate, approximately 5x/day.



Intestinal Stoma & StomaRestore®

Making plastic stoma bags obsolete

Market for plastic bags collecting fecal matter alone is **> USD 2.5 billion**

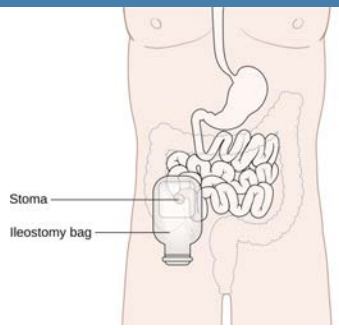
Stoma market

$3.8bn
Ostomy care market
USD estimated 3 billion in year 2022[1]

874k
Surgeries p.a. globally[2]

5%
Estimated 2022-2033 addressable market CAGR[1]

Status-quo treatment

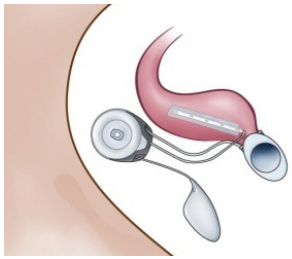


- Fecal matter passes through stoma and stored in stomy pouch.
- Stoma patients collecting fecal matter in plastic bag outside the abdominal wall.

Our solution – StomaRestore®

StomaRestore® designed with:

- Active storage of fecal matter inside the body emptied on command by electrical stimulation
- Smart unique sphincter function inside the body
- **Designed for a substantial impact on patients' lives**



- Designed to avoid stomabags with fecal matter flowing into a plastic bag attached to the skin
- Designed to restore normal anatomy by creating a reservoir and connecting to anus
- Patented sphincter allows flow control and emptying function at anus – combining electrical stimulation to train and always keep a healthy muscular intestinal wall

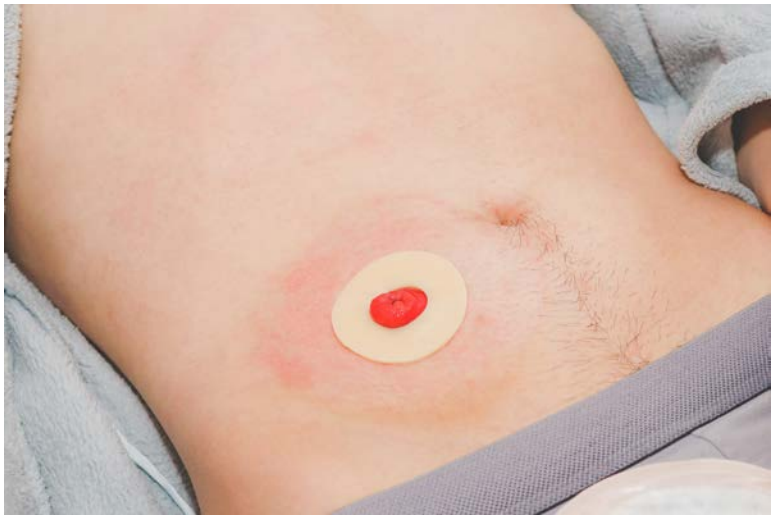
Source: (1) Future Market Insights Inc. 2022; (2) ISS 2020.

StomaRestore®

StomaRestore® is designed to free patients who need an ostomy operation or existing ostomates from using stoma bags, which targets to greatly improve their quality of life.

Ostomies are performed as part of the treatment for a wide variety of conditions including inflammatory bowel diseases such as ulcerative colitis and Crohn's disease; colorectal cancer; intra-abdominal infections; fistulas; and wounds or mechanical damage to the gastrointestinal ("GI") tract. Many patients suffering such illnesses need to remove part of their intestine and therefore receive astoma, which is when the end of the intestine protrudes through the abdominal wall. These patients use a plastic bag to collect their fecal matter outside the abdominal wall. These operations typically have a severe effect on patient quality of life and self-image. In addition, the procedure can have physical complications such as leakage from the stoma, skin irritation, allergic reactions, food blockages, leakage of mucus and bleeding, or even prolapse.

StomaRestore® is designed for the surgeon to be able to create a special reservoir of normal intestine and in most cases connect the patient's intestine to the anus. StomaRestore® represents both a remote controlled opening and closing as well as emptying function of the reservoir. The intestine would be trained everyday with peristaltic muscle contractions created by electrical stimulation to preserve a healthy muscular intestinal wall, building the platform for a successful treatment. StomaRestore® is expected to offer a completely new solution to ostomy patients and is expected to permanently free patients from using stoma bags.



PotencyFlow® – proven principle to treat impotence taken to a new level

Safe for the 50% of sufferers where drugs (Viagra type) do not work or could not be used due to complications

Impotence market

332m

- Sufferers by 2025[1]

1.7bn

- Device Market USD 2023[2]
- 2028 forecasted to USD 2.7bn

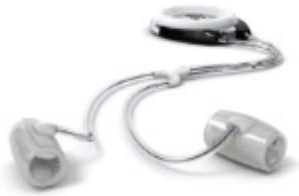
10%

- Estimated 2023-2028 addressable market CAGR[2]

Status-quo treatment

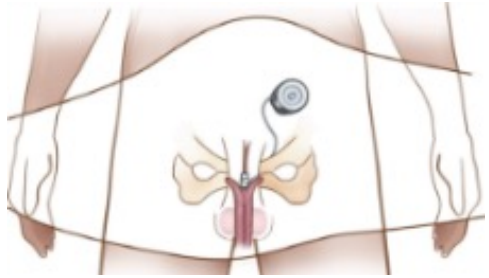
- Erection is caused by pressurized blood. Too low inflow or too high outflow of blood hinders erection
- Surgeons previously closed/ligated the large blood vessel leaving the penile tissue
- Successful outcome for a year or two, thereafter failure due to small blood vessels increasing in size
- With penile implants all normal functionality is damaged for good

Our solution – PotencyFlow®



- Urinary sphincter (UriControl®) adapted with new software to be used for impotence treatment
- PotencyFlow® designed to temporarily hinder blood leaving the penile tissue causing erected status– proven principle
- Such temporary closure will not cause smaller blood vessels to increase in size

- **Leveraging UriControl® by using the same device with new software to treat impotence**
- **The functional principle of this device is proven in literature – taken to a new level**



Source: (1) National Institute of Health (NIH) (2) MarketsandMarkets 2023.

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:

1. 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).

ISO 14001 certification in Spain and Portugal – A testament to our environmental commitment

In November 2023, Implantica's subsidiary in Spain became the first entity in the Implantica group to receive ISO 14001 certification, thus achieving certain standards in its environmental management system.

The subsidiary in Spain was established in 2023 in order for Implantica to be able to compete in public tenders in Spain and Portugal, while also enabling the company to get closer to the customer base in these markets. To be eligible to compete in the tenders, the company needed to have an ISO 14001 certification, and this was achieved in November 2023.

Juan Gómez, Director Spain & Portugal, was responsible for implementing all the necessary procedures and protocols required in the ISO 14001 framework.

"We are mainly focusing on selling RefluxStop™ to public hospitals, and this requires us to be able to compete in public tenders, and thus have this certification. There were several criteria that we had to meet to achieve this, mostly related to our day-to-day operations, processes and personnel, and not for example the manufacturing of the product, as we do not produce it here," he explains.

In addition to achieving the criteria for the first time, there is also an annual audit to make sure that the company's environmental commitment stays strong over time. This ongoing process, and thus accumulated experience, is also expected to contribute to the whole Implantica group moving further ahead in its overall environmental efforts over time.

After being able to compete in public tenders in Spain from late 2023, Implantica has already started to become successful.

"There was a tender in the Madrid region at the end of the year, and it was announced in March that it was awarded to Implantica. So, we have the first important tender win in place, and we are planning to compete in more tenders in 2024 while delivering products to the Madrid region," says Juan Gómez. Implantica's sustainability mission is complemented by measures for the company's environmental and social responsibility.

> The environmental management system ISO 14001, implemented in Spain, will support Implantica's overall sustainability progress going forward.

Board of Directors

Liselott Kilaas

Chair of the board

Born: 1959

Education: Master of Business Administration from IMD Business School in Lausanne, Switzerland; Master's Degree, Mathematics and Statistics from the University of Oslo, Norway.

Background: Liselott Kilaas has around twenty years of international management experience and a background in strategic and operational performance development across a broad spectrum of businesses. She has further extensive non-executive board and audit committee experience from the Central Bank of Norway and sectors such as Telecommunication, Media and Shipping and was awarded the Norwegian 2019 Women's Board Award.

Current positions: Board member in Orkla ASA (publ), Peab AB (publ), Avonova AB, Folketrygdfondet and Recover Nordic ASA. CEO Evidia GmbH.

Holdings in Implantica (including related parties):

Liselott Kilaas holds no SDRs or warrants in the company, however, she has a 5-year share program of 28,135 SDRs.

Johan Bojs

Vice-chair of the board

Born: 1964

Education: LL. M. University of Stockholm; Bachelor of Business University of Gothenburg; Professional Board Member Course, Michaël Berglund Institute in Stockholm.

Background: Johan Bojs is an experienced attorney specializing in tax and commercial law.

Current positions: Own law practice in Sweden. Board member in Cornerstone Group AB, Olero Invest AB and Olero Lodge AB.

Holdings in Implantica (including related parties):

Johan Bojs owns 132,362 SDRs in Implantica AG through his insurance policy.

Tomas Puusepp

Board member

Born: 1955

Education: Electrical Engineer, studies in Physics at the Royal Institute of Technology in Stockholm and at the University of Stockholm and Management (IEP) at IMD in Lausanne.

Background: Tomas Puusepp has held various positions at the Research Institute for Nuclear Physics, Scanditronix and Ericsson before being employed by Elekta in 1988.

Since then, he has held various management positions, including head of Elekta's neurosurgery operations, President of Elekta's subsidiary in North America, global head of Elekta's sales, marketing and service operations, and President and CEO of Elekta during fiscal years 2005/06 to 2013/14, and during 2015/16.

Current positions: Board member of Permobil Holding AB, Sectra AB (publ), Instoria Sweden AB, Instoria Invest AB, Elekta Foundation and board member and CEO of Investest AB.

Holdings in Implantica (including related parties):
Tomas Puusepp owns 20,000 SDRs in Implantica AG.

Board of Directors

Stephan Siegenthaler

Board member and Chief Strategy Officer

Born: 1957

Education: Studies at the Conservatory for Music, Bern (CH), Music Teacher Diploma. Studies at the Conservatory for Music in Geneva, Virtuosité, Soloist Diploma; Postgraduate Studies, Nordwestdeutsche Musikhochschule, Detmold, Germany.

Background: Stephan Siegenthaler co-developed a gastric band (SAGB) business into a multinational company, eventually commanding approximately 28 per cent of the obesity surgery market outside of the US over a six-year period which was sold to Johnson & Johnson for a significant amount. He focused primarily on building the sales organization, created an extensive and critical surgical and hospital network, recruited high-performing salespeople, and established an in-house sales force in 32 countries.

Current positions: Stephan Siegenthaler has no other ongoing assignments.

Holdings in Implantica (including related parties):
Stephan Siegenthaler owns 900,000 SDRs in Implantica AG.

Klaus Neftel

Board member

Born: 1945

Education: PhD, University of Bern, Switzerland and ECFMG Certificate (Educational Commission for Foreign Medical Graduates).

Background: Prof. Dr. Klaus Neftel is a certified haematologist and specialist in Internal Medicine. Former Chief of Internal Medicine at the Zieglerspital, Bern, Professor at the University of Bern, Founder of Medtec AG, a continuous medical education program. He has been awarded the Swiss Society for Internal Medicine 1983, 1988, 2002 and the Swiss Society for Haematology 1983.

Current positions: Independent medtech investment advisor.

Holdings in Implantica (including related parties):
Klaus Neftel owns no shares, SDRs or warrants in the company.

Management

Dr. med. Peter Forsell

*Founder and CEO since inception**

Born: 1954

Education and experience: Peter Forsell is a medical doctor educated at Karolinska Institute and specialist surgeon at Karolinska Hospital. He also has additional finance and legal education. Dr. Peter Forsell is the Co-founder of Obtech Medical AG, where he also was Executive Chairman of the Board. He developed the Swedish Gastric Band (SAGB) and turned it into an international business, capturing 28 per cent of the obesity surgery market outside of the US.

In 2002, in an early stage before US FDA approval, the business was sold to Johnson & Johnson for CHF 175m. After the sale, the total gastric band market peaked at 40 per cent of the world market. From the corporate journey with Obtech, he gained valuable experience in medical device product development, regulatory approval, and building a multinational corporation, including a sales organisation in 32 countries.

Dr. Forsell is a serial inventor and has invented RefluxStop as well as created most of Implantica's IP with many new breakthrough medical implants. His inventions are covered by an extensive patent portfolio of over one thousand patent cases including Implantica's wireless energising and eHealth platforms.

Dr. Peter Forsell funded the R&D activities of Implantica with the proceeds from the sale of Obtech Medical and has invested more than EUR 100 million in Implantica.

Holdings in Implantica (including related parties): Peter Forsell owns 21,616,770 SDRs and 1,125,000,000 class B shares in Implantica AG.

Andreas Öhrnberg

*Chief Financial Officer since 2020**

Born: 1978

Education and experience: Andreas Öhrnberg holds two master's degrees, a M.Sc. in Computer and Systems Sciences from Stockholm University and a M.Sc. in Business from Stockholm School of Economics, and is a Chartered Financial Analyst.

He has over 15 years of experience in senior finance and general management positions. Before joining Implantica in 2020, he served as Group CFO at Talkpool, a publicly listed technology group headquartered in Switzerland.

Previously, Andreas Öhrnberg was a Vice President at Swiss Re, a global Fortune 500 company.

Holdings in Implantica (including related parties): Andreas Öhrnberg owns 23,869 SDRs in Implantica AG. He has been granted an option program equaling 87,169 SDRs in total, vesting over five years, of which 23,869 options have been exercised.

Nicole Pehrsson

*Chief Corporate Affairs Officer since 2016**

Born: 1966

Education and experience: Bachelor of Arts in Economics, University of California, Los Angeles (summa cum laude). Nicole Pehrsson has strong financial experience in corporate finance and equity research. In Switzerland, Nicole worked as an equity research analyst at EFG Bank AG, Zurich, and before that as a business developer in the Corporate Finance team of JP Morgan, Zurich. In the US, she worked as an analyst in the Corporate Finance Group of Kidder, Peabody & Co. Inc. in Los Angeles and Boston. Extracurricular financial activities involved among others appointed to Investment Advisory Board of the City of Huntington Beach (CA) and the Boston Women's Fund in Boston (MA).

Holdings in Implantica (including related parties): Nicole Pehrsson owns 481,417 SDRs in Implantica AG and has a share program for 42,400 shares vesting over a five-year period.

Stephan Siegenthaler

*Chief Strategy Officer and board member since inception**

Born: 1957

Education and experience: Studies at the Conservatory for Music, Bern (CH), Music Teacher Diploma. Studies at the Conservatory for Music in Geneva, Virtuosité, Soloist Diploma; Postgraduate Studies, Nordwestdeutsche Musikhochschule, Detmold, Germany.

Stephan Siegenthaler co-developed a gastric band (SAGB) business into a multinational company, eventually commanding approximately 28 per cent of the obesity surgery market outside of the US over a six-year period and was sold to Johnson & Johnson for a significant amount. He focused primarily on building the sales organisation, created an extensive critical surgical and hospital network, recruited high-performing salespeople and established an in-house sales force in 32 countries.

Holdings in Implantica (including related parties): Stephan Siegenthaler owns 900,000 SDRs in Implantica AG.

* Executive Management

Management

Amit Kukreja

Chief Market Access & Strategy Officer since 2021

Born: 1983

Education and experience: MBA from WHU Germany and a Mechanical Engineering Degree from Manipal Institute of Technology. Amit Kukreja has 15 years of extensive global medtech industry and strategy experience. He has served in several worldwide and regional leadership and advisory roles, driving and shaping reimbursement, health economics, clinical evidence planning, payer relations and upstream marketing & communications for disruptive medtech products.

Before joining Implantica in 2021, Amit served as Vice President of Corporate Market Access at Masimo Corporation, a global leader in innovative noninvasive patient monitoring technologies. Before that, he was the Vice President of Global Marketing, Reimbursement & Patient Access at Second Sight Medical Products, a global leader in neuromodulation implant devices for blindness.

Susana Mogensen

Vice President Quality & Regulatory Affairs since 2023

Born: 1972

Education and experience: Ph.D. in Plant Biology from Brigham Young University and Master of Science degrees in Horticulture and Agriculture Engineering from the Instituto Superior de Agronomia and Brigham Young University.

Susana Mogensen has over 17 years of quality, clinical and regulatory affairs experience in start up and mid-size companies with a successful track record of bringing multiple complex PMA products to the market. Prior to Implantica Ms. Mogensen was Vice President Quality & Regulatory Affairs at Occlutech, where she was responsible for a PMA approval of a novel cardiovascular implantable device. Prior to Occlutech, she was Head of Quality, Clinical & Regulatory Affairs at Laborie Switzerland, a Global company with solutions in urology and gastroenterology where she integrated the Swiss QA & RA departments into the Global organization of Laborie. Ms. Mogensen is an expert in EU Medical Device Regulation, FDA regulations having been responsible for 510K, PMA and IDE approvals as well as CE marking certification of products under the MDR.

Corporate governance report

1 Introduction

Implantica AG is a company limited by shares in the sense of article 261ff of the Liechtenstein Persons' and Companies' Act (Personen- und Gesellschaftsrecht) (the "PGR"), incorporated in Liechtenstein and registered with the Liechtenstein Commercial Register on 7 February 2020 under the registration number FL-0002.629.889-3.

Corporate governance in the Company is governed by Liechtenstein laws and regulations and the Articles of Association of Implantica AG also taking into consideration the Swedish Corporate Governance Code. External regulations that shape the Company's corporate governance framework include the Liechtenstein PGR, the Swedish Corporate Governance Code (the "Code") and the Nasdaq First North Growth Market's Rulebook (the "Rulebook"). Internal instructions and policies of importance for corporate governance purposes include the Articles of Association, the Organizational Regulations, the Information Policy and the Insider Policy. The corporate governance of the Company is exercised by the following corporate bodies:

- General Meeting of Shareholders
- Board of Directors and Board Committees
- Chairman of the Board
- CEO and Executive Management
- Statutory Auditor

2 Corporate bodies

2.1 General Meetings of Shareholders

Shareholder influence in the company is exercised at the General Meeting of Shareholders which, in accordance with the Liechtenstein PGR, is the company's highest decision-making body.

A shareholders' meeting can take decisions about all matters in the company that do not constitute another company body's exclusive area of competence.

Shareholders' meetings may be convened by the Board of Directors or, if necessary, by the Company's statutory Auditors. The Board of Directors is further required to convene an extraordinary general meeting if, so resolved by a shareholders' meeting or, if so requested by holders of shares holding in aggregate at least ten percent of the nominal share capital of the Company.

According to the Articles of Association, the General Meeting of Shareholders shall be convened by the Board of Directors of the Company at the latest twenty days before the date of the meeting. The meeting shall be convened by way of a notice appearing on the Company's website www.implantica.com.

Shareholders of the Company can be represented by proxy at shareholders' meetings by another person which does not need to be a shareholder but a representative by law or specially designated independent proxy. The General Meeting of Shareholders shall elect the independent proxy for a term of office lasting until completion of the next annual General Meeting of Shareholders. Re-election is possible.

2.2 Board of Directors

The Board of Directors is responsible for the conduct of the Company's affairs and the representation of the Company. The members of the Board of Directors are elected by the General Meeting of Shareholders.

According to the Articles of Association, the Board of Directors shall consist of a minimum of 3 and a maximum of 9 members. It is currently composed of 5 members.

Pursuant to the Articles of Association, the Board of Directors delegates, within the limits of the law and the Articles of Association, the management of the Company in whole or in part to the Executive Management.

Over 2023, the Board of Directors has combined physical meetings in Lichtenstein with video conferences.

Board of Directors

Name	Position	Board member of the Company since[1]	Independent to the Company and its management	Independent to major shareholders	Present at meetings of the Board
Liselott Kilaas	Chairman of the Board	2020	Yes	Yes	(7/7)
Johan Bojs[2]	Vice-Chairman of the Board	2020	No	Yes	(7/7)
Prof. Dr. Klaus Neftel	Board member	2020	Yes	Yes	(5/7)
Tomas Puusepp	Board member	2020	Yes	Yes	(5/7)
Stephan Siegenthaler[3]	Board member	2020	No	Yes	(7/7)

[1] Implantica AG was established in 2020.
[2] Johan Bojs is a lawyer and has provided the Company with legal advice for which the Company has paid marketable compensation.
[3] Stephan Siegenthaler is employed by Implantica AG as Chief Strategy Officer.

2.3 Chairman of the Board of Directors

The tasks of the Chairman include:

a. The coordination of the work of the Board of Directors, issue invitations to Board of Directors meetings, and draw up the agenda together with the Board of Directors Secretary;
b. Ensuring that the Board of Directors receives the Board-level information and documentation that is necessary for decision-making;
c. Leading General Meetings of Shareholders and Board of Directors meetings;
d. Coordinating the work of the committees along with the Committee Chairman and participate in committee meetings;
e. Monitoring the implementation of resolutions of the Board of Directors and the General Meeting of Shareholders;
f. On behalf of the Board of Directors, the Chairman or the Vice-Chairman shall exercise the direct supervision and control over the Executive Management.

2.4 Nomination and Remuneration Committee

The Company has established a combined Nomination and Remuneration Committee. The committee is setup as a board subcommittee, as common in continental Europe. This deviates to the Code, which foresees the Nomination and Remuneration Committee making proposals directly to the shareholder meeting.

According to the Articles of Association, the Company shall have a Nomination and Remuneration Committee that consists of a minimum of two and a maximum of three members of the Board of Directors.

The General Meeting of Shareholders in 2023 reelected Johan Bojs (Chairman) and Prof. Dr. Klaus Neftel to the Nomination and Remuneration Committee. The members of the Nomination and Remuneration Committee are elected individually by the General Meeting of Shareholders for a term of office lasting until the completion of the next annual General Meeting of Shareholders.

In accordance with the Articles of Association, the Nomination and Remuneration Committee has inter-alia the following powers:

a. Develop a remuneration strategy and submit it for approval to the Board of Directors which will receive final approval by the General Meeting of Shareholders in line with the principles described in the Articles of Association;
b. Support the Board of Directors in preparing the proposals to the General Meeting of Shareholders regarding the remuneration of the members of the Board of Directors and the Executive Management;
c. Assume other responsibilities assigned to it by law, the Articles of Association or by the Board of Directors.

2.5 Risk and Audit Committee

The Board of Directors has established a Risk and Audit committee which is equivalent to the Audit Committee according to the Swedish Corporate Governance Code. It is inter-alia responsible for oversight of the Company's financial reporting process, selection of the independent auditor and receipt of audit results.

The committee comprises two members: Liselott Kilaas (Chairman) and Johan Bojs.

The essential tasks of the Risk and Audit Committee include:

a. Examination of and the presentation of proposals to the Board of Directors concerning the organization of the accounting, financial control, and financial planning systems;
b. Critical analysis of the Company and its financial statements. Discussion of these financial statements with the CFO and the External Auditors. The presentation of proposals to the Board of Directors concerning these financial statements;
c. Assessment of the efficacy and performance of the External Auditors and their fee, as well as their independence.
d. The assessment of the reports of the External Auditors (including the audit report pursuant to Article 196 PGR) and the discussion of these reports with the External Auditors;
e. Assessment of the functional capability of the internal control system, under the inclusion of Risk Management and Compliance.

2.6 CEO and Executive Management

The CEO bears overall responsibility for the operational leadership of the Company and in this task is supported by the Executive Management. The CEO is responsible for the implementation of the overall Company strategy. The responsibility also includes the development and monitoring of good corporate governance and compliance. In consultation with the Chairman, the CEO represents the Company vis-à- vis important investors, the media, and other stakeholders, as well as with the public at large. The board is evaluating the work of the CEO continuously as well as a formal evaluation once a year.

In line with the PGR, the Board of Directors delegates, within the limits of the law and the Articles of Association, the management of the Company in whole or in part to the Executive Management. The Executive Management is the key management body of the Company. It shall support the Board of Directors in the strategy's development and is responsible for its implementation, results and supports the cooperation within the Company. The Executive Management is also responsible for the Company management and ensuring compliance with corporate governance standards.

3 Remuneration

3.1 Remuneration strategy

Implantica is committed to a Remuneration framework that is balanced and performance-oriented aligning the interests of employees and shareholders. The framework is designed to promote long-term sustainable performance for the Group and its shareholders through a mix of fixed and variable compensation components.

The Annual General Meeting sets aggregate amounts of remuneration to the Board of Directors and the Executive Management. Whereas the Remuneration Committee develops the remuneration strategy and supports the Board of Directors in preparing the proposals for the General Meeting.

3.2 Remuneration of Directors and the Executive Management

The members of the Board of Directors are entitled to cash compensation. Selected members of the Board of Directors are also eligible for the long-term share-based incentive plan. In addition, one Director, is entitled to pension contributions.

Remuneration to the Executive Management consists of a fixed salary and statutory pension. Besides the cash remuneration, selected members of the Executive Management are eligible for the long-term share-based incentive plan.

3.3 Cash and Pension Remuneration

The table below outlines Board of Directors and Executive Management cash and pension remuneration over 2023.

3.4 Long term share-based incentive plan

The call options granted under the long-term share-based incentive plan to Board of Directors and Executive Management are as follows:

Name	Call Options granted (31 Dec 2023)	Call Options exercised (31 Dec 2023)	Effective date of grant
Nicole Pehrsson	42,400	-	February 1, 2019
Andreas Öhrnberg	87,169	23,869[1]	February 1, 2020
Liselott Kilaas	28,135	-	April 1, 2020
Total	**155,704**	**23,869**	

[1] During 2023 a total of 23,869 call options were exercised by Mr. Öhrnberg.

The option grants vest annually over a five-year period. The long-term share-based incentive plan form an integral part of plan participants' total remuneration package with the option strike price being zero. Note 19 on Share-based Compensation, in the consolidated financial statements, provides more details on the share-based incentive plan.

Board of Directors and Executive Management cash and pension remuneration over 2023

In EUR	Fixed	Variable	Pension	Social Security	Total
Board of directors					
Liselott Kilaas	36,024	-	-	-	36,024
Johan Bojs	10,292	-	-	-	10,292
Tomas Puusepp	14,409	-	36,024	-	50,433
Prof. Dr. Klaus Neftel	15,439		-	-	15,439
Stephan Siegenthaler	-	-	-	-	-
Board of directors in total	**76,164**	**-**	**36,024**	**-**	**112,188**
Executive Management					
Dr. Peter Forsell (CEO)	203,791	-	-	483	204,274
Other senior executives	483,747	-	44,349	47,527	575,624
Total senior executives	**687,538**	**-**	**44,349**	**48,010**	**779,898**
Total Board of Directors and Executive Management	**763,703**	**-**	**80,373**	**48,010**	**892,086**

4 Securities and ownership

4.1 Securities

Implantica AG has two classes of shares, class A and class B. The class A shares are listed on the Nasdaq First North Premier Growth Market, through Swedish Depository Receipts ("SDRs"). One SDR represents one class A share in Implantica AG. The class B shares are not listed.

The class A and class B shares are governed by the laws of Liechtenstein and are issued in CHF. All of the underlying shares and the SDRs are freely transferable.

Each class A and class B share provides entitlement to one vote. Through a resolution passed by an absolute majority of votes present at a shareholders' meeting, class B shares may be converted into class A shares and class A shares may be converted into class B shares.

The SDRs are registered in a central securities depositary register in accordance with the Swedish Central Securities Depositories and Financial Instruments Accounts Act (1998:1479). This register is maintained by Euroclear, Box 191, 101 23 Stockholm, Sweden. The ISIN code for the Company's SDRs is SE0001234568.

4.2 Ownership

Per 31 December 2023, one shareholder held more than 10% ownership interest. Dr. Peter Forsell held 47.4 % of the capital and 96.9 % of the votes on 31 December 2023.

5 Audit and Controls

The Board of Directors is responsible for the overall supervision and control of the Group and its management. The Board of Directors in particular monitors compliance with applicable law and regulations.

5.1 Statutory auditor

The statutory external auditors are elected by the General Meeting of Shareholders on an annual basis and have the powers and duties vested in them by law. The present statutory auditor is KPMG (Liechtenstein) AG. Lars Klossack is the responsible auditor. Mr. Klossack is an authorized public accountant and a member of the Liechtenstein Association of Chartered Accountants.

If the auditors discover violations of the law or the articles of association during their audit, they must report this in writing to the Board of Directors and, in important cases, to the General Meeting of Shareholders. The auditors are subject to the duty of confidentiality except in respect of the members of the board of directors and the other auditors.

The auditors meet with the Board of Directors and the Audit Committee on at least a yearly basis.

5.2 Risk Assessment and Control

The company has established processes for risk assessment, in order to ensure that the risks the company is exposed to are handled within the risk management framework established by the Board of Directors.

An overall company-wide risk assessment is conducted at least yearly. The risks are mapped and linked to mitigating actions. Risks are monitored by the Audit and Risk Committee throughout the year.

Implantica has an internal control system in place to ensure that the financial resources of the organization are properly used, protected and recorded. The system determines, with reasonable assurance, that the financial reporting is reliable and prepared in accordance with generally accepted accounting practices, in compliance with applicable laws and regulations. The Board of Directors is ultimately responsible for internal control.

The Board of Directors has considered the need for an internal audit function but has taken the view that it is not currently warranted for Implantica. This due to the scope of the operations and because the Board of Directors' monitoring of the internal control is deemed sufficient to ensure that internal controls are effective. The Board of Directors is reviewing the need in the event of changes that may give rise to reevaluation and at least once annually.

Share information and shareholders

Implantica AG is a public company listed on Nasdaq First North Premier Growth Market through Swedish Depositary Receipts (SDRs) since 21 September 2020. One SDR represents one underlying Class A share in the company. The company has two share classes, Class A and Class B shares. The SDR is included in the following indices: First North All-Share, First North Health Care, and First North Sweden.

Share capital

The fully paid in share capital of the Group amounts to CHF 138,723 thousand (EUR 129,137 thousand) and is divided into 58,111,537 registered shares with a nominal value of CHF 2.00 each (Class A) and 1,125,000,000 with a nominal value of CHF 0.02 each (Class B).

Nasdaq First North and Certified Adviser

The Nasdaq First North Growth Market is an alternative market for Nordic growth companies designed primarily for small and medium-sized enterprises. Implantica's stock is traded in the segment Premier where requirements are higher. Among other things the company must undertake to follow the Swedish Code of Corporate Governance. First North Growth Market does not have the same legal status as a regulated market and its regulatory framework is less extensive than those applicable in the exchange's bigger markets. Every company whose stock is traded on First North Growth Market Stockholm has a Certified Adviser who monitors the company's compliance with First North's regulations for the provision of information to the market and investors. Implantica's appointed Certified Adviser FNCA Sweden AB, +46 (0)8 528 00 399, info@fnca.se.

Ticker information

Ticker: IMP A SDB
ISIN code: SE0014855029

Analyst coverage

Chien-Hsun Lee
Pareto Securities

The 10 largest shareholders as of December 31, 2023

Name	Capital (%)
Peter Forsell	47.4 %
Handelsbanken Fonder	9.3 %
EFG Bank	7.2 %
TIN Fonder	3.2 %
SIX SIS AG	2.8 %
Avanza Pension	2.8 %
SEB Life	2.1%
UBS	1.6 %
Fjärde AP-Fonden	1.3 %
Credit Suisse	1.2 %

Source: Euroclear Sweden

Consolidated financial statements

Consolidated statement of profit or loss

in thousands of EUR	Notes	Jan to Dec 2023	Jan to Dec 2022
Net Sales		1,408	842
Cost of sales			
Amortisation of capitalized development costs	14	(1,227)	(1,227)
Other cost of sales		(90)	(36)
Total cost of sales		**(1,317)**	**(1,263)**
Gross profit/(loss)		**91**	**(421)**
Other income		33	-
Research and development costs	5	(7,016)	(5,805)
General and administrative costs	5	(14,948)	(12,221)
Operating loss		**(21,840)**	**(18,447)**
Financial income	7	701	1,595
Financial expenses	7	(3,289)	(4,548)
Loss before income taxes		**(24,428)**	**(21,400)**
Income taxes	8	(74)	39
Loss for the period		**(24,502)**	**(21,361)**
Attributable to			
Owners of Implantica AG		(23,744)	(20,824)
Non-controlling interests	22	(758)	(537)
Loss for the period		**(24,502)**	**(21,361)**
Earnings per share			
Basic and diluted loss per share Class A (in EUR)	18	(0.34)	(0.30)
Basic and diluted loss per share Class B (in EUR)	18	(0.00)	(0.00)

The notes on pages 96 to 117 are an integral part of these consolidated financial statements.

Consolidated statement of profit or loss and other comprehensive income

in thousands of EUR	Notes	Jan to Dec 2023	Jan to Dec 2022
Loss for the period		**(24,502)**	**(21,361)**
Other comprehensive income			
Remeasurement of net defined benefit liability	20.3	(296)	71
Related income taxes		36	(9)
Total items that will not be reclassified to profit or loss		*(260)*	*62*
Translation differences	17.4	5,593	4,895
Total items that may be reclassified subsequently to profit or loss		*5,593*	*4,895*
Other comprehensive income for the period, net of tax		**5,333**	**4,957**
Total comprehensive income for the period		**(19,169)**	**(16,404)**
Attributable to			
Owners of Implantica AG		(18,411)	(15,868)
Non-controlling interests	22	(758)	(536)
Total comprehensive income for the period		**(19,169)**	**(16,404)**

The notes on pages 96 to 117 are an integral part of these consolidated financial statements.

Consolidated statement of financial position

in thousands of EUR	*Notes*	31 December 2023	2022
ASSETS			
Current assets			
Cash and cash equivalents	9	87,922	108,951
Accounts receivable		432	88
Other current receivables	10	989	866
Inventories	11	311	166
Total current assets		**89,654**	**110,071**
Non-current assets			
Property, plant and equipment	12	273	242
Right-of-use assets	13.1	874	1,129
Intangible assets	14	38,163	35,977
Deferred tax assets	8.3	987	988
Total non-current assets		**40,297**	**38,336**
Total assets		**129,951**	**148,407**

in thousands of EUR	*Notes*	31 December 2023	2022
LIABILITIES AND EQUITY			
Current liabilities			
Financial liabilities	15	314	328
Financial liabilities due to ultimate main shareholder	15	1	41
Other current liabilities	16	3,431	2,867
Total current liabilities		**3,746**	**3,236**
Non-current liabilities			
Financial liabilities	15	584	817
Pension liability	20	575	267
Total non-current liabilities		**1,159**	**1,084**
Total liabilities		**4,905**	**4,320**
Equity			
Share capital	17.1	129,137	129,137
Capital reserves	17.2	370,548	370,548
Treasury share reserve	17.3	(2)	-
Translation differences	17.4	15,647	10,054
Retained earnings		(388,059)	(364,185)
Total equity attributable to owners of Implantica AG		**127,271**	**145,554**
Non-controlling interests	22	(2,225)	(1,467)
Total equity		**125,046**	**144,087**
Total liabilities and equity		**129,951**	**148,407**

The notes on pages 96 to 117 are an integral part of these consolidated financial statements.

Consolidated statement of cash flows

in thousands of EUR	*Notes*	Jan to Dec 2023	2022
Loss for the period		**(24,502)**	**(21,361)**
Adjustments for			
Depreciation, amortisation and impairment	12-14	1,624	1,689
Financial income	7	(701)	(1,595)
Financial expenses	7	3,289	4,548
Income taxes	8.1	74	(39)
Share-based compensation	19	187	803
Other financial result		(45)	(29)
Change in pension liabilities		(18)	97
Other non-cash items		(84)	(90)
Changes in net working capital			
Decrease / (increase) accounts receivable		(344)	(75)
Decrease / (increase) other current receivables		(123)	(390)
Decrease / (increase) inventories		(145)	(29)
(Decrease) / increase other current liabilities		880	513
Net cash outflow from operating activities		**(19,908)**	**(15,958)**
Cash flows from investing activities			
Purchase of property, plant and equipment	12	(87)	(61)
Investment in intangible assets	14	(3,742)	(9,243)
Divestments in fixed term deposits	9	-	50,352
Interest received	7	675	38
Net cash inflow/(outflow) from investing activities		**(3,154)**	**41,086**

in thousands of EUR	*Notes*	Jan to Dec 2023	2022
Cash flows from financing activities			
Treasury shares acquired	17.3	(59)	-
Payment of lease liabilities	13.2	(305)	(413)
Interest paid	7	(27)	(300)
Repayment of financial liabilities	15	(40)	(224)
Net cash outflow from financing activities		**(431)**	**(937)**
Net increase/(decrease) in cash and cash equivalents		**(23,493)**	**24,191**
Effect of exchange rate fluctuations on cash held		2,464	427
Cash and cash equivalents at 1 January	9	108,951	84,333
Cash and cash equivalents at 31 December	**9**	**87,922**	**108,951**

The notes on pages 96 to 117 are an integral part of these consolidated financial statements.

Consolidated statement of changes in equity

		Jan to Dec 2023							
in thousands of EUR	*Notes*	Share capital	Capital reserves	Treasury share reserve	Translation differences	Retained Earnings	Total	Non-controlling interests	Total equity
Balance at 31 December 2022		**129,137**	**370,548**	**-**	**10,054**	**(364,185)**	**145,554**	**(1,467)**	144,087
Loss for the period		-	-	-	-	(23,744)	(23,744)	(758)	(24,502)
Other comprehensive income (net)		-	-	-	5,593	(260)	5,333	-	5,333
Total comprehensive income (net)		**-**	**-**	-	**5,593**	**(24,004)**	**(18,411)**	**(758)**	**(19,169)**
Treasury shares acquired	17.3	-	-	(59)	-	-	(59)	-	(59)
Share-based compensation	19	-	-	57	-	130	187	-	187
Total transactions with shareholders		**-**	**-**	**(2)**	**-**	**130**	**128**	**-**	**128**
Balance at 31 December 2023		**129,137**	**370,548**	**(2)**	**15,647**	**(388,059)**	**127,271**	**(2,225)**	**125,046**

		Jan to Dec 2022						
in thousands of EUR	*Notes*	Share capital	Capital reserves	Translation differences	Retained Earnings	Total	Non-controlling interests	Total equity
Balance at 31 December 2021		**129,137**	**370,548**	**5,160**	**(344,226)**	**160,619**	**(931)**	159,688
Loss for the period		-	-	-	(20,824)	(20,824)	(537)	(21,361)
Other comprehensive income (net)		-	-	4,894	62	4,956	1	4,957
Total comprehensive income (net)		**-**	**-**	**4,894**	**(20,762)**	**(15,868)**	**(536)**	**(16,404)**
Share-based compensation	19	-	-	-	803	803	-	803
Total transactions with shareholders		**-**	**-**	**-**	**803**	**803**	**-**	**803**
Balance at 31 December 2022		**129,137**	**370,548**	**10,054**	**(364,185)**	**145,554**	**(1,467)**	**144,087**

The notes on pages 96 to 117 are an integral part of these consolidated financial statements.

Notes Consolidated Financial Statements

NOTE 1 General information

Implantica AG (the 'Company') is domiciled at Aeulestrasse 45, 9490 Vaduz, Liechtenstein. These consolidated financial statements ('financial statements') as at and for the year ended 31 December 2023 comprise the Company and its subsidiaries (together referred to as the 'Group'). The Group is primarily involved in the research and distribution of medical implants. Implantica AG was admitted to trading on the Nasdaq First North Premier Growth Market in Stockholm in September 2020. Implantica AG is ultimately controlled by the Implantica Founder, Dr. Peter Forsell.

These financial statements were authorised for issue by the Company's Board of Directors on 25 April 2024. As of this date, no material events after the reporting date have occurred. The consolidated financial statements will be submitted for approval to the Annual General Meeting of Shareholders of Implantica AG, to be held on 22 May 2024.

NOTE 2 Basis of accounting

2.1 Basis of preparation

These financial statements have been prepared in accordance with IFRS Accounting Standards as adopted by the European Union (EU) as at 31 December 2023 and Liechtenstein Law.

For the preparation of these financial statements the historical cost basis except for all those assets and liabilities measured at fair value has been applied. All amounts are presented in EUR, and are rounded to the nearest thousand of EUR with the consequence that the rounded amounts may not add to the rounded total in all cases. All ratios and variances are calculated using the underlying amounts rather than the rounded amounts.

2.2 Going concern

These financial statements have been prepared on the going concern basis which assumes that the Group will continue in existence in the foreseeable future.

2.3 Basis of consolidation

Subsidiaries (Note 21) are all companies over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Intercompany balances, transactions and resulting unrealised income are eliminated in full except for foreign currency transaction gains or losses.

Non-controlling interests are measured initially at their proportionate share of the acquiree's identifiable net assets at the date of acquisition. Changes in the Group's interest in a subsidiary that do not result in a loss of control are accounted for as equity transactions.

2.4 Critical accounting estimates and judgements

The preparation of these financial statements requires management to make assumptions and estimates that affect the reported amounts of expenses, assets and liabilities at the date of the financial statements. If in the future such assumptions and estimates deviate from the actual circumstances, the original assumptions and estimates will be modified as appropriate in the year in which the circumstances change. The valuation of the following material positions is based on the critical accounting estimates and judgements.

Intangible assets – capitalised costs

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortisation and accumulated impairment losses. Amortisation of the asset begins when development is complete and the asset is available for use (i.e., when market launch has occurred).

It is amortised over the expected useful life. During the development phase, the intangible asset is tested for impairment annually.

There can be no guarantee that such products will complete the development phase or will be commercialised or that market conditions will not change in the future. Hence a revision of management's assessment of future cash flows related to those products may be required. Specifically, management is required to make estimates and judgements in the area of developing and financing the intangible assets not yet in use. As such, the Group faces development risks in terms of finalising the development and launch of its products. Development risk includes the risk that the product does not obtain regulatory approval and therefore technical feasibility is not given.

2.5 Changes in accounting policies

The accounting policies applied in these financial statements are the same as those applied in the Group's consolidated financial statements as at and for the year ended 31 December 2022 (i.e. previous financial year) except the changes of the following amended standards, that the Group applies as of 1 January 2023. However, the application of these amendments did not have a material impact on the Group's consolidated financial statements:

- Amendments to IAS 1 – Disclosure of accounting policies
- Amendments to IAS 8 – Definition of accounting estimates
- Amendments to IAS 12 – Deferred tax related to assets and liabilities arising from a single transaction

NOTE 3 Published financial reporting standards not yet applied

Several new accounting standards and interpretations have been published that are not mandatory for reporting periods ending 31 December 2023 and have not been early adopted by the Group. These standards are not expected to have a material impact on the Group in the current or future reporting periods and on foreseeable future transactions.

NOTE 4 Material accounting policies

4.1 Foreign currencies

Transactions in foreign currencies

Transactions in foreign currencies are converted to the functional currency of each reporting unit using the foreign exchange rate applicable at the transaction date. Assets and liabilities in foreign currencies are remeasured at each reporting date using the foreign exchange rate applicable at that date. Any foreign exchange rate differences are recognised in the consolidated statement of profit or loss.

Functional and presentation currency

The functional currency of a reporting unit is the currency of the primary economic environment in which the reporting unit operates. The functional currency of Implantica AG is Swiss franc (CHF). The consolidated financial statements are presented in EUR. The financial information of reporting units that have a functional currency different from the presentation currency (foreign operations) are translated to EUR as follows:

- assets and liabilities using the rate applicable at each balance sheet date (closing rate); and
- income and expenses using the average rate of the period (average rate).

Foreign exchange gains or losses resulting from the translation of financial statements of foreign operations are recognised in other comprehensive income and presented separately in equity as "Translation differences".

Exchange rates applied to key foreign currencies:

		31 Dec		Jan to Dec	
Currency	Unit	2023	2022	2023	2022
		Closing rates	*Closing rates*	*Average rates*	*Average rates*
CHF	1	1.080	1.015	1.029	0.996
USD	1	0.905	0.937	0.925	0.951
SEK	100	9.012	8.991	8.722	9.414

4.2 Cash and cash equivalents

Cash and cash equivalents comprise cash balances at financial institutions and cash on hand.

4.3 Accounts receivable

Accounts receivable without a significant financing component are initially measured at the transaction price, and subsequently measured at amortised cost using the effective interest method less expected credit losses. The Group analyses the expected credit losses incurred in the past and estimates anticipated credit losses based on forward looking indicators.

4.4 Inventories

Inventories are measured at the lower of costs and net realisable value and consist of RefluxStop™ and deployment tools. Costs comprise costs of purchase plus any directly attributable costs. Costs are assigned to individual items of inventory on the basis of weighted average costs. Costs of purchased inventory are determined after the deduction of rebates and discounts. Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs necessary for the sale. Inventories are written-down to the net realisable value in the period in which the write-down occurs (e.g. due to low turnover).

4.5 Property, plant and equipment

Property, plant and equipment are measured at cost less accumulated depreciation and impairment losses. Depreciation expenses utilise the straight-line method over the estimated useful life of the assets. Assets are depreciated to their residual value. The following table summarises the respective useful lives used by the Group:

Asset category	Number of years
Furniture	8
Vehicles/Tools	5
IT/Hardware	5

The residual values and useful lives are reviewed at the end of each reporting period and adjusted if necessary. An asset's carrying amount is impaired to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount. Gains and losses on disposals are determined by comparing proceeds with the carrying amount. These are included in the consolidated statement of profit or loss.

4.6 Right-of-use assets and lease liability

The Group recognises a right-of-use asset (i.e. leased buildings) and a lease liability at the lease commencement date. The right-of-use asset is initially measured at the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred. The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the earlier of the useful life of the right-of-use asset or the end of the lease term. In addition, the right-of-use assets are periodically reduced by impairment losses, if any. The lease liabilities are initially measured at the present value of the future lease payments (incl. extension options reasonably certain to be exercised, if any), discounted using the incremental borrowing rate as the discount rate unless the rate implicit in the lease is readily determinable.

The Group applies the short-term lease recognition exemption to its short-term leases (i.e. those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases that are considered to be low value. Lease payments on short-term leases and leases of low-value assets are recognised as expense on a straight-line basis over the lease term.

4.7 Intangible assets

Development costs

Development activities involve a plan or design for the production of new or substantially improved products and processes. The development expenditure is capitalised only if development costs can be measured reliably, the product is technically and commercially feasible, future economic benefits are probable, and the Group intends to and has sufficient resources to complete development and to use or sell the assets. Development expenditure capitalised includes the cost of materials, external services, personnel and temporary employees. Furthermore, patent costs are capitalised and include legal fees in filing of new applications and prosecuting applications. Renewable patent fees are capitalised until finalisation of the development process. Other development expenditure is recognised in profit or loss as incurred. Subsequent to initial recognition, development expenditure is measured at cost less accumulated amortisation and any accumulated impairment losses.

Software

Expenditure on the implementation of software, including licenses and external consulting fees, which are directly attributable to the design and testing of identifiable and unique software products controlled by the Group are recognised as intangible assets. Costs associated with maintaining software programmes are recognised as an expense as incurred.

Amortisation and impairments

Amortisation is applied using the straight-line method over the estimated useful life of the intangible asset. Amortisation begins when the asset is available for use and for each period the amortisation is recognised in profit or loss. The following table summarises the respective useful lives used by the Group:

Asset category	Number of years
Software	3
Development costs	10

Amortisation methods, useful lives and residual values are reviewed at the end of each reporting period and adjusted if necessary. Intangible assets not yet available for use (i.e. development costs) are tested for impairment at least annually and upon the occurrence of an indication of impairment.

Impairment charges of development costs not yet available for use are recognised within "Research and development costs" while amortisation charges of intangible assets available for use are recognised within "Cost of sales" in the consolidated statement of profit or loss.

4.8 Research costs

Expenditure on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is recognised in profit or loss as incurred.

4.9 Income tax

Income tax on the profit or loss for the period comprises current and deferred tax. Current and deferred tax is charged or credited to profit or loss, except when it relates to items charged or credited directly to other comprehensive income or to equity, in which case it is recognised in these positions, as appropriate. Current income tax is based on the taxable result for the period and any adjustment to tax payable in respect of previous periods. The taxable result for the period differs from the result as reported in profit or loss because it excludes items which are non-assessable or disallowed and it further excludes items that are taxable or deductible in other periods. It is calculated using tax rates that have been enacted or substantively enacted by the end of the financial period.

Deferred tax is accounted for using the balance sheet liability method in respect of temporary differences arising from differences between the carrying amount of assets and liabilities in the financial statements and the corresponding tax bases used in the computation of taxable profit. Deferred tax is not recognised for temporary differences on the initial recognition of assets and liabilities in a transaction that at the time of the transactions affects neither accounting nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences.

Deferred tax liabilities are generally recognised for all taxable temporary differences, and deferred tax assets are recognised to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilized. Deferred tax is calculated at the tax rates that are expected to apply to the period when the asset is realized or the liability is settled, based on tax rates that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax assets and liabilities are offset when the Company has a legally enforceable right to set off its current tax assets and liabilities, and the deferred tax assets and liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realize the assets and settle the liabilities simultaneously in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

4.10 Provisions

The Group recognises a provision if it has a present legal or constructive obligation to transfer economic benefits as a result of past events and if a reasonable estimate of the obligation can be made and an outflow of resources is probable.

4.11 Revenue recognition

Revenue is recognised at an amount that reflects the consideration to which the Group expects to be entitled in exchange for transferring goods or services. The Group mainly focuses on the sale of RefluxStop™, a medical device treating acid reflux. The products are sold to hospitals. Revenue is recognised at a point in time once the customer obtains control over the product (according to the different terms of delivery). Invoices are usually payable within 90 days.

4.12 Trade and other payables

These amounts represent liabilities for goods and services provided to the Group prior to the end of the financial year which are unpaid. The amounts are unsecured and are usually paid within 30 days of the recognition. Trade and other payables are presented as current liabilities unless payment is not due within 12 months after the reporting period. They are recorded initially at their fair value and subsequently measured at amortised cost using the effective interest method.

4.13 Employee benefits – retirement and long-service leave benefit plans (IAS 19)

The Implantica Group joined a collective pension plan operated by an insurance company which covers the employees of Implantica Management AG, Zug, Switzerland, of Implantica Trading AG, Zug, Switzerland, as well as of Implantica AG, Vaduz, Liechtenstein. Both the Company and the participants provide monthly contributions to the pension plan which are based on the covered salary. The respective saving parts of premium are credited to employees' accounts. In addition, interest is credited to employees' accounts at the rate provided in the plan. The pension plan provides for retirement benefits as well as benefits on long-term disability and death. The pension plan qualifies as a defined benefit plan in accordance with IFRS. The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method.

Remeasurements, comprising actuarial gains and losses, the effect of the asset ceiling (excluding net interest) and the return on plan assets (excluding net interest), are recognised immediately in the statement of financial position with a corresponding debit or credit to retained earnings through OCI in the period in which they occur. Remeasurements are not reclassified to the income statement in subsequent periods.

Actuarial Valuation Method: To determine the present value of the defined benefit obligation and the related current service cost and, where applicable, past service cost, the Projected Unit Credit Method has been used. This method is based on the amount of working years at the date of the actuarial valuation and considers the future by including:

- a discount rates
- the salary development and leaving probability up to the beginning of the benefit payment
- inflation adjustments for the years after the first payment for recurring benefits

The liability recognised in the balance sheet in regard to defined benefit retirement benefit plans is the present value of the defined benefit obligation at the end of the reporting period less the fair value of plan assets for funded plans. The defined benefit obligation (DBO) is calculated annually by independent actuaries using the Projected Unit Credit Method, considering possible risk sharing rules stated in IAS 19. When the calculation results in a benefit to the Implantica Group, the recognised asset is limited to the present value of economic benefits available in the form of any future refunds from the plan or reductions in future contributions to the plan. The components of defined benefit costs are as follows:

- Service costs, which are recognised in the consolidated statement of profit or loss within operating result
- Interest expense or income on net liability or asset, which is recognised in the consolidated statement of profit or loss within financial result
- Remeasurements, which are recognised in the consolidated statement of other comprehensive income

Service costs include current service costs, past service costs and gains or losses on plan curtailments and settlements. When the benefits of a plan are changed, or when a plan is curtailed or settled, the portion of the changed benefits related to employee service in prior periods (past service costs), or the gains or losses on curtailments and settlements, are recognised immediately in profit or loss when the plan amendments or curtailments and settlements occur. Interest expense or income is calculated by applying the discount rate to the net defined benefit liability or asset, considering any changes in the net defined benefit liability or asset during the period as a result of contribution and benefit payments.

4.14 Share-based payment arrangements

The grant date fair value of equity-settled share-based payment arrangements granted to employees is recognised as an expense, with a corresponding increase in equity, over the vesting period of the awards. Service and non-market performance conditions are not considered when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. The amount recognised as an expense is therefore adjusted to reflect the number of awards for which the related service and non-market performance conditions are expected to be met.

"Grant date" is the date at which the entity and the employee agree to a share-based payment arrangement, and requires that the entity and the employee have a shared understanding of the terms and conditions of the arrangement.

4.15 Segment Reporting

The Group focuses on the discovery, development and prospective commercialization of medical products and implants that are intended for use in different treatment fields like in the area of gastrointestinal surgery and urology. However, there is only one segment reported in a manner consistent with management reporting to the CEO, which is the chief operating decision-maker. All revenues recorded by the Group during the years ended 31 December 2023 and 2022 have been generated with RefluxStop™ in Switzerland.

NOTE 5 Operating expenses by nature

		Jan to Dec	
in thousands of EUR	*Notes*	2023	2022
Personnel expenses	6	7,273	7,111
Consulting expenses		11,412	8,459
Audit and accounting services[1]		540	535
Communication & IT		884	534
Marketing		939	529
Depreciation and amortisation		1,624	1,689
Insurance, charges & capital taxes		145	193
Other operating expenses		464	239
Total operating expenses		**23,281**	**19,289**

NOTE 6 Personnel expenses

		Jan to Dec	
in thousands of EUR	*Notes*	2023	2022
Salaries and wages		5,066	4,411
Social security contributions		540	448
Pension defined benefits plans	20	140	235
Share-based compensation	19	187	802
Other personnel expenses		1,340	1,215
Total personnel expenses		**7,273**	**7,111**
Average number of employees		49	38
Average number of contract staff with employee like terms		29	29

[1] *Group auditor fees related to the audit of the consolidated financial statements for the year ended 31 December 2023 amounted to approximately CHF 160 thousand. In addition, the group auditor performed other audit-related services during the financial year 2023 amounting to approximately CHF 42 thousand.*

NOTE 7 Financial income and expenses

in thousands of EUR	*Notes*	Jan to Dec 2023	Jan to Dec 2022
Interest income		675	38
Foreign exchange gains		26	1,557
Total financial income		**701**	**1,595**
Interest expense		-	300
Bank charges		45	29
Interest expense on lease liabilities	13	27	35
Foreign exchange losses		3,217	4,184
Total financial expenses		**3,289**	**4,548**

NOTE 8 Income taxes

8.1 Income taxes in statement of profit or loss

in thousands of EUR	Jan to Dec 2023	Jan to Dec 2022
Current income tax expense (income)	24	(27)
Deferred income tax expense (income) from changes of temporary differences	50	(12)
Total income tax expense (income)	**74**	**(39)**

8.2 Reconciliation of effective tax rate

in thousands of EUR	Jan to Dec 2023	Jan to Dec 2022
Loss before taxes	(24,428)	(21,400)
Group's weighted average tax rate	28.1%	25.1%
Income taxes at group's weighted average tax rate	**(6,856)**	**(5,362)**
Tax losses not capitalized	6,856	5,362
Capitalisation of previously unrecognised deferred tax assets	-	(10)
Derecognition of previously recognised deferred tax assets	50	(2)
Other	24	(27)
Income taxes reported	**74**	**(39)**
Effective tax rate	-0.3%	0.2%

The tax rate of the Group is the weighted average tax rate obtained by applying the currently expected rate for each individual jurisdiction to its respective profit or loss before taxes. As a result of changes in the country mix of the profit before taxes, the Group's weighted average tax rate changed from 25.1% for the year ended 31 December 2022 to 28.1% for the year ended 31 December 2023.

8.3 Deferred income taxes

Deferred tax assets and liabilities are attributable to the following items:

	Jan to Dec 2023					
in thousands of EUR	Balance at 1 January	Recognised in P&L	Recognised in OCI	Recognised in Equity	Translation differences	Balance at 31 December
Intangible assets	988	(1)	-	-	-	987
Share-based compensation	-	(10)	-	-	10	-
Pension defined benefits plans	-	(39)	36	-	3	-
Total deferred tax assets	**988**	**(50)**	**36**	**-**	**13**	**987**

	Jan to Dec 2022					
in thousands of EUR	Balance at 1 January	Recognised in P&L	Recognised in OCI	Recognised in Equity	Translation differences	Balance at 31 December
Intangible assets	978	10	-	-	-	988
Share-based compensation	-	(5)	-	-	5	-
Pension defined benefits plans	-	7	(9)	-	2	-
Total deferred tax assets	**978**	**12**	**(9)**	**-**	**7**	**988**

8.4 Tax loss carry-forward

	31 December			
	2023	2022	2023	2022
in thousands of EUR	Gross value		Potential tax benefits	
Tax loss carry-forward capitalised	**-**	**-**	**-**	**-**
Expiring in:				
1st to 3rd year	3,807	9	457	1
4th to 5th year	1,798	3,941	216	473
6th to 7th year	11,757	-	1,411	-
Unlimited	46,817	57,078	3,775	5,645
Tax loss carry-forward not capitalised	**64,179**	**61,028**	**5,859**	**6,119**
Total tax loss carry-forward	**64,179**	**61,028**	**5,859**	**6,119**

The tax loss carry-forward not capitalised refers to the losses in the Liechtenstein, the Malta entities as well as to the losses within the Swiss Companies. Losses carry forward in Liechtenstein and Malta could – according to local carry forward rules - be utilized for an unlimited time. Losses carry forward in Switzerland can be utilized up to seven years following the realization of the respective tax loss for corporate income tax purposes.

NOTE 9 Cash and cash equivalents and current financial assets

	31 December	
in thousands of EUR	2023	2022
Cash on hand	13	14
Cash at bank	87,909	108,937
Total cash and cash equivalents	**87,922**	**108,951**

NOTE 10 Other current receivables

	31 December	
in thousands of EUR	2023	2022
Current account due to shareholder	26	15
VAT and other tax receivables	320	207
Prepaid expenses and accrued income	643	644
Total other current receivables	**989**	**866**

NOTE 11 Inventories

	31 December	
in thousands of EUR	2023	2022
Semi-finished goods	111	46
Finished goods	200	120
Total inventories	**311**	**166**

NOTE 12 Property, plant and equipment

	Jan to Dec 2023			
in thousands of EUR	Furniture	IT Hardware	Vehicles & Tools	Total
At cost				
Balance at 31 December 2022	**177**	**278**	**30**	**485**
Additions	12	72	3	87
Translation differences	10	12	-	22
Balance at 31 December 2023	**199**	**362**	**33**	**594**
Accumulated depreciation				
Balance at 31 December 2022	**(63)**	**(150)**	**(30)**	**(243)**
Depreciation charge for the period	(23)	(44)	(1)	(68)
Translation differences	(4)	(6)	-	(10)
Balance at 31 December 2023	**(90)**	**(200)**	**(31)**	**(321)**
Net carrying amount				
Balance at 31 December 2022	**114**	**128**	**-**	**242**
Balance at 31 December 2023	**109**	**162**	**2**	**273**

	Jan to Dec 2022			
in thousands of EUR	Furniture	IT Hardware	Vehicles & Tools	Total
At cost				
Balance at 31 December 2021	**167**	**214**	**30**	**411**
Additions	3	58	-	61
Translation differences	7	6	-	13
Balance at 31 December 2022	**177**	**278**	**30**	**485**
Accumulated depreciation				
Balance at 31 December 2021	**(39)**	**(113)**	**(26)**	**(178)**
Depreciation charge for the period	(22)	(35)	(4)	(61)
Translation differences	(2)	(2)	-	(4)
Balance at 31 December 2022	**(63)**	**(150)**	**(30)**	**(243)**
Net carrying amount				
Balance at 31 December 2021	**128**	**101**	**4**	**233**
Balance at 31 December 2022	**114**	**128**	**-**	**242**

NOTE 13 Leases

13.1 Right-of-use assets

The Company leases three office buildings in Liechtenstein, Switzerland and Malta of which the one in Liechtenstein is considered to be a short-term lease.

	Jan to Dec	
in thousands of EUR	2023	2022
At cost		
Balance at 1 January	**1,687**	**253**
Additions	-	1,367
Derecognitions	(253)	-
Translation differences	90	67
Balance at 31 December	**1,524**	**1,687**
Accumulated depreciation		
Balance at 1 January	**(558)**	**(162)**
Depreciation charge for the period	(312)	(391)
Derecognitions	253	-
Translation differences	(33)	(5)
Balance at 31 December	**(650)**	**(558)**
Net carrying amount		
Balance at 1 January	**1,129**	**91**
Balance at 31 December	**874**	**1,129**

13.2 Lease liabilities

		Jan to Dec	
in thousands of EUR	*Notes*	2023	2022
Balance at 1 January		**1,145**	**92**
Lease payments (including accrued interest)		(332)	(413)
Additions		-	1,367
Accrued interest		27	35
Translation differences		58	64
Balance at 31 December		**898**	**1,145**
thereof included in current financial liabilities	*15*	314	328
thereof included in non-current financial liabilities	*15*	584	817

The lease liabilities are measured at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate as at the inception of the lease. The weighted average incremental borrowing rate applied as at 31 December 2023 is 2.76% (2022: 2.76%).

13.3 Amounts recognised in profit or loss and total cash outflows

	Jan to Dec	
in thousands of EUR	2023	2022
Depreciation of right-of-use assets	312	391
Interest on lease liabilities	27	35
Expense relating to short-term leases	99	17
Total amount recognised in profit or loss	**438**	**443**

The Group had total cash outflows for leases of EUR 431 thousand during the year ended 31 December 2023 (2022: EUR 430 thousand).

NOTE 14 Intangible assets

The intangible assets consist of two categories including software and development cost for medical devices. Software is amortised over its useful life. RefluxStop™ became available for use in 2019 when the amortisation over its useful life started. All other products are not yet available for use and therefore not amortised but tested for impairment annually.

	Jan to Dec 2023		
in thousands of EUR	Development cost	Software	Total
At cost			
Balance at 31 December 2022	**40,871**	**223**	**41,094**
Additions	3,335	91	3,426
Translation differences	-	17	17
Balance at 31 December 2023	**44,206**	**331**	**44,537**
Accumulated depreciation			
Balance at 31 December 2022	(4,908)	(209)	(5,117)
Amortisation charge for the period	(1,227)	(17)	(1,244)
Translation differences	-	(13)	(13)
Balance at 31 December 2023	**(6,135)**	**(239)**	**(6,374)**
Net carrying amount			
Balance at 31 December 2022	**35,963**	**14**	**35,977**
Balance at 31 December 2023	**38,071**	**92**	**38,163**

	Jan to Dec 2022		
in thousands of EUR	Development cost	Software	Total
At cost			
Balance at 31 December 2021	**32,123**	**214**	**32,337**
Additions	8,748	-	8,748
Translation differences	-	9	9
Balance at 31 December 2022	**40,871**	**223**	**41,094**
Accumulated depreciation			
Balance at 31 December 2021	**(3,681)**	**(189)**	**(3,870)**
Amortisation charge for the period	(1,227)	(10)	(1,237)
Translation differences	-	(10)	(10)
Balance at 31 December 2022	**(4,908)**	**(209)**	**(5,117)**
Net carrying amount			
Balance at 31 December 2021	**28,442**	**25**	**28,467**
Balance at 31 December 2022	**35,963**	**14**	**35,977**

Allocation of development cost to specific products:

	31 December	
in thousands of EUR	2023	2022
RefluxStop™	6,135	7,362
Other products not yet available for use	31,936	28,601
Total development costs	**38,071**	**35,963**

The annual impairment test is performed by comparing the carrying value of each cash-generating unit (CGU) containing development cost of products not yet available for use with their recoverable amount.

Implantica determines the recoverable amount by applying a value in use calculation. An impairment will be recorded if the carrying value of the cash-generating units exceeds its value in use. The valuation is carried out on the basis of projected future free cash flows from cash-generation using the discounted cash flow (DCF) method. The values assigned to the key assumptions outlined further below represent management's assessment of the core product's commercialisation potential as well as future trends in the relevant industry and have been based on historical data from both external and internal sources.

The projected cash flows are derived from the business plan of Implantica considering the development status of each product. The applied (post-tax) weighted average cost of capital (WACC) is 12.34% (2022: 10.52%), which has been derived by using market data from peer group companies. The terminal growth rate is assumed to be 1.1%. The value in use derived in the annual impairment test for the year ended 31 December 2023 exceeds the respective book value for all CGUs and therefore no impairment was recognised.

NOTE 15 Financial liabilities

		31 December	
in thousands of EUR	*Notes*	2023	2022
Lease liabilities	13.2	314	328
Total current financial liabilities		**314**	**328**
Current account due to founder (ultimate main shareholder)		1	41
Total current financial liabilities due to ultimate main shareholder		**1**	**41**
Lease liabilities	13.2	584	817
Total non-current financial liabilities		**584**	**817**

	Jan to Dec	
in thousands of EUR	2023	2022
At amortized cost		
Balance at 1 January	41	273
Cash flow effective		
Repayments	(40)	(224)
Total cash flow effective	**(40)**	**(224)**
Non-cash flow effective		
Translation differences	-	(8)
Total non-cash flow effective	**-**	**(8)**
Balance at 31 December	**1**	**41**

NOTE 16 Other current liabilities

	31 December	
in thousands of EUR	2023	2022
Liabilities due to related parties	11	3
Accounts payable	2,110	1,666
VAT and other tax payables	59	144
Accrued expenses and employee related accruals	1,183	1,021
Other current liabilities	68	33
Total other current liabilities	**3,431**	**2,867**

NOTE 17 Equity

17.1 Share capital

The fully paid in share capital of the Group amounts to CHF 138,723 thousand (EUR 129,137 thousand) and is divided into 58,111,537 registered shares with a nominal value of CHF 2.00 each (Class A) and 1,125,000,000 with a nominal value of CHF 0.02 each (Class B).
During the periods presented the number of shares remained unchanged.

Authorized capital
The Board of Directors is authorised to increase the share capital at any time before 16 April 2026 by a maximum amount of CHF 15,985 thousand by issuing a maximum number of 7,992,307 fully paid in Class A shares with a nominal value of CHF 2.00 each. Increases of the share capital in partial amounts is permitted.

Conditional capital for financing purposes
The share capital may be increased by a maximum amount of CHF 13,500 thousand by issuing a maximum number of 6,750,000 fully paid in Class A shares with a nominal value of CHF 2.00 each upon exercise conversion rights or options in relation with convertible debt instruments, loans and similar forms of financing the Group. The conditions for granting the option and conversion rights shall be determined by the Board of Directors.

Conditional capital for employee share option plans
The share capital may be increased by a maximum amount of CHF 2,700,000 by issuing a maximum number of 1,350,000 fully paid in Class A shares with a nominal value of CHF 2.00 each upon exercise of employee share options issued to employees (Note 19).

17.2 Capital reserves

Capital increase 2021
On 27 April 2021 Implantica AG increased the share capital through a private placement from EUR 120,187 thousand to EUR 129,137 thousand by issuing 4,900,000 Class A shares with a nominal value of CHF 2.00 each. The difference of EUR 47,226 thousand between the gross proceeds of EUR 59,075 thousand less transaction costs of EUR 2,899 thousand and the nominal amount of EUR 8,950 thousand (CHF 9,800 thousand) is recognised in capital reserves.

17.3 Treasury shares

The reserve for the Group's treasury shares comprises the cost of the Company's shares held by the Group. At 31 December 2023, the Group held 1,305 (31 December 2022: NIL). The treasury shares reserve is measured applying the "first in first out" (FIFO) method.

		Jan to Dec			
		2023	2022	2023	2022
in number of shares / thousands of EUR	*Notes*	Number of Class A shares		Treasury shares reserve	
Held by the Group at 1 January		**-**	**-**	**-**	**-**
Acquisition of own shares		30,000	-	59	-
Settlement of vested share based payment plans	19	(28,708)	-	(57)	-
Other		13	-	-	
Held by the Group at 31 December		**1,305**	-	**2**	**-**

17.4 Translation difference

During the year ended 31 December 2023 the EUR/CHF exchange rate increased from 1.015 to 1.080 (2022: from 0.968 to 1.015). As a result, the group recognised a total profit of EUR 5,593 thousand in other comprehensive income related to the translation of financial statements of foreign operations and net investments in foreign operations (Note 4.1) (2022: 4,894 thousand).

NOTE 18 Earnings per share

	Jan to Dec	
in thousands of EUR	2023	2022
Loss for the period attributable to owners of Implantica AG	**(23,744)**	**(20,824)**
Weighted average % of Class A share capital in total share capital	83.8%	83.8%
Weighted average % of Class B share capital in total share capital	16.2%	16.2%
Class A shares		
Loss for the period attributable to Class A shareholders	(19,892)	(17,446)
Weighted average number of outstanding Class A shares	58,090,580	58,111,537
Basic and diluted (loss) per share Class A (in EUR)	**(0.34)**	**(0.30)**
Class B shares		
Loss for the period attributable to Class B shareholders	(3,852)	(3,378)
Weighted average number of Class B shares	1,125,000,000	1,125,000,000
Basic and diluted (loss) per share Class B (in EUR)	**(0.00)**	**(0.00)**

Earnings per category of shares

Earnings per class of shares (Note 17) are calculated on the basis of the net loss attributable to the shareholders of Implantica AG based on their portion of the share capital and the average number of outstanding shares (i.e. excluding treasury shares held by the Group).

Anti-dilutive effect of potential outstanding shares

The impact of share-based payments arrangements (Note 19) was not considered in the diluted earnings per share calculation for Class A shares because due to the net loss for these periods their effect would have been anti-dilutive. Class B shares are not affected since based on the employee share option plan shares shall be made available and issued only through Class A shares.

NOTE 19 Share-based compensation

The Group has committed to equity settled share-based compensation plans to members of the Board of Directors and employees who distinguished themselves by a particular strong commitment to the Group. The total share-based payment expense recognised by the Group is EUR 187 thousand for the year ended 31 December 2023 (2022: EUR 803 thousand).

Share options plans

Grant date	Number of share options	Vesting conditions	Contractual life of options	Fair value at grant date
Members of the BoD				
1 Apr 2020	36,175	5 years' service from grant date (annual vesting of 7,235 share options)	Expire on 1 Apr 2025	CHF 6.30
Executive management				
1 Jan 2019	29,000	5 years' service from grant date (annual vesting of 5,800 share options)	Expire on 31 Jan 2025	CHF 5.00
1 Feb 2020	75,000	5 years' service from grant date (annual vesting of 15,000 share options)	Expire on 1 Feb 2025	CHF 6.30
31 Jul 2020	13,375	0 to 4 years' service from grant date (annual vesting of 2,771 share options)	Expire on 1 Feb 2025	CHF 6.30
Total share options	**153,550**			

The key terms and conditions related to these grants are as follows:

- all options are settled by delivery of fully paid in Class A Implantica AG shares
- the shares are delivered free of charge (i.e. exercise price CHF 0)

All of the above Class A share options are outstanding as at 31 December 2023 (2022: all), of which 97,971 are exercisable (2022: 132,159).

Other share based payment plans

Grant date	Description	Vesting conditions	Granted number of shares	Granted amounts in thousands[1)]
Other employees				
2022	Fixed number of shares with a fair value of EUR 6.34 each vesting over a period of time.	5 years' service from grant date with annually vesting one fifth of the granted number of shares	63,811	CHF 418
2022	Number of share options issued annually calculated by USD 100 thousand divided by the average share closing price over a 15-day period immediately prior to the annual vesting date, which is also the strike price of the options. The options have a lifetime of 6 to 10 years after vesting date.	5 years' service from grant date with annually vesting shares with a fair value of USD 100 thousand	N/A	USD 131
2022	Number of shares to be issued annually are calculated by dividing one fifth of the granted amount by the average share closing price over a 15-day period immediately prior to the annual vesting date.	5 years' service from grant date with annually vesting one fifth of the granted amount	N/A	EUR 75 CHF 150
2023	Number of shares to be issued annually are calculated by dividing one fifth of the granted amount by the average share closing price over a 15-day period immediately prior to the annual vesting date.	5 years' service from grant date with annually vesting one fifth of the granted amount	N/A	EUR 50 USD 160

[1)] *Outstanding amounts (i.e. for which shares or options have not yet been issued).*

Measurement of fair values

All equity-settled transactions are measured at fair value at grant date and recognised as expense over the vesting period. For the estimated fair value calculation at grant date for all options listed above an expected dividend, a risk-free interest rate and an exercise price of zero was used.

NOTE 20 Retirement benefit assets and liabilities

Pension plans and their benefits are governed in Switzerland by the Swiss Federal Law on Occupational Retirement, Survivors' and Disability Pension Plans (BVG), which stipulates that pension plans are to be managed by independent, legally autonomous units. Pension plans are regulated by a state supervisory body. A pension plan's most senior governing body (Board of Trustees) must be composed of equal numbers of employee and employer representatives.

The employer has to arrange for an affiliation contract with a pension fund to comply with legal requirements.

Although, the insurance plan is contribution-based, the plan contains a cash balance benefit formula. Under Swiss law, the collective foundation guarantees the vested benefit amount as confirmed annually to members. Interest may be added to member balances at the discretion of the collective foundation. At the retirement date, members have the right to take their retirement benefit as a lump sum, an annuity or part as a lump sum with the balance converted to a fixed annuity at the rates defined in the rules of the collective foundation.

As the pension plan qualifies as a defined benefit plan under IAS 19, the Group engaged an independent actuary to prepare the actuarial measurements required for financial reporting purposes. The actuarial measurement method calculates the liabilities based on the projected unit credit method whereas the plan assets are measured at fair value.

20.1 Amounts recognised in statement of financial position

	31 December	
in thousands of EUR	2023	2022
Defined benefit obligation	2,779	1,722
Fair value of plan (assets)	(2,204)	(1,455)
Net defined benefit obligation	**575**	**267**

The expected employer contributions to the defined benefit plan within the next 12 months is EUR 173 thousand (2022: EUR 136 thousand). The weighted average duration of the defined benefit plan obligation as of 31 December 2023 is 16.3 years (2022: 14.3 years).

20.2 Amounts recognised in profit or loss

	Jan to Dec	
in thousands of EUR	2023	2022
Current service cost	154	187
Past service cost	(21)	46
Interest expense on defined benefit obligation	46	4
Interest (income) on plan assets	(40)	(3)
Administration cost excl. cost for managing plan assets	1	1
Total expense of defined benefit plans recognised in profit or loss	**140**	**235**
thereof service cost and administration cost	134	234
thereof net interest on the net defined benefit liability (asset)	6	1

20.3 Amounts recognised in other comprehensive income

	Jan to Dec	
in thousands of EUR	2023	2022
Actuarial (gain)/loss from:		
Changes in financial assumptions	190	(307)
Changes in demographic assumptions	(2)	-
Experience adjustments to defined benefit obligation	129	64
Total actuarial (gain)/loss	**317**	**(243)**
Return on plan assets (excluding amount recognised in profit or loss)	(21)	172
Total expense/(income) of defined benefit plans recognised in other comprehensive income	**296**	**(71)**

20.4 Changes in the present value of the defined benefit obligations

	Jan to Dec	
in thousands of EUR	2023	2022
Defined benefit obligation at 1 January	**1,722**	**1,270**
Interest expense on defined benefit obligation	46	4
Current service cost	154	187
Past service cost	(21)	46
Contributions by plan participants	158	138
Benefits (paid) / deposited	247	249
Administration cost (excl. cost for managing plan assets)	1	1
Actuarial (gain) / loss	317	(243)
Translation differences	155	70
Defined benefit obligation at 31 December	**2,779**	**1,722**

20.5 Changes in the fair value of plan assets

	Jan to Dec	
in thousands of EUR	2023	2022
Fair value of plan assets at 1 January	**1,455**	**1,041**
Interest income on plan assets	40	3
Contributions by the employer	158	138
Contributions by plan participants	158	138
Benefits (paid) / deposited	247	249
Return on plan assets excl. interest income	21	(172)
Translation differences	125	58
Fair value of plan assets at 31 December	**2,204**	**1,455**

The insurance company bearing the investment risk is also making these investments on behalf of the foundation. As a result, the assets of the Swiss plan consist of a receivable from the insurance policy.

20.6 Key actuarial assumptions

	31 December	
in thousands of EUR	2023	2022
Discount rate	1.40%	2.30%
Interest rate on retirement savings capital	1.40%	2.30%
Expected rate of salary increases	2.00%	2.00%
Mortality tables used	BVG2020 GT	BVG2020 GT

20.7 Sensitivity analysis

Changes of significant assumptions would have the following impact on the defined benefit obligation:

	31 December	
in thousands of EUR	2023	2022
Discount rate decrease by 25 bps	115	62
Discount rate increase by 25 bps	(108)	(59)
Expected rate of salary increase decreases by 25 bps	(21)	(10)
Expected rate of salary increase increases by 25 bps	21	7
Life expectancy increase by 1 year	32	17
Life expectancy decrease by 1 year	(33)	(18)

NOTE 21 List of consolidated subsidiaries

				31 December	
Registered name	Country of incorporation	Principal activities[1]	Share capital in thousand	2023	2022
Implantica Group Holding Ltd.	Malta	Holding	EUR 790,000	100%	100%
Implantica CE Reflux Ltd.	Malta	R&D	EUR 1.2	100%	100%
Implantica CE UriControl Ltd.	Malta	R&D	EUR 1.2	100%	100%
Implantica Marketing Ltd.	Malta	D&M	EUR 1.2	100%	100%
Implantica Patent Ltd.	Malta	Patent	EUR 1.2	100%	100%
Implantica Management AG	Switzerland	Management	CHF 100	100%	100%
Implantica Trading AG	Switzerland	D&M	CHF 100	100%	100%
Implantica Inc.	USA	D&M	USD 1	100%	100%
MedicalTree Swiss AG	Liechtenstein	Holding	CHF 79,500	51%	51%
MedicalTree Group Holding Ltd.	Malta	Holding	EUR 265,001.2	51%	51%
MedicalTree Patents Ltd.	Malta	Patent	EUR 1.2	51%	51%
MedicalTree CE & Production Ltd.	Malta	R&D	EUR 1.2	51%	51%
MedicalTree Distribution Ltd.	Malta	D&M	EUR 1.2	51%	51%
MedicalTree Marketing Ltd.	Malta	D&M	EUR 1.2	51%	51%
Implantica Iberia SLU [2]	Spain	D&M	EUR 3.1	100%	-

[1] R&D = Research and development; D&M = Distribution and marketing

[2] The Group incorporated in April 2023 the new distribution and marketing subsidiary Implantica Iberia SLU in Spain

NOTE 22 Non-controlling interests

The Group's non-controlling interests relate to 49% of the capital and voting rights of the Medical-Tree Swiss AG Group (refer to list of companies in Note 21). The following table summarises the financial information of the MedicalTree Swiss AG Group:

	31 December	
in thousands of EUR	2023	2022
Net assets attributable to non-controlling interests		
Current assets	96	3,477
Non-current assets	7,123	7,127
Current liabilities	(210)	(3,086)
Non-current liabilities	(11,550)	(10,512)
Net assets	**(4,541)**	**(2,994)**
Net assets attributable to non-controlling interests	*(2,225)*	*(1,467)*
Total comprehensive income allocated to non-controlling interests		
Operating result	(1,103)	(662)
Financial result	(441)	(430)
Loss for the year and total comprehensive income	**(1,544)**	**(1,092)**
Loss for the year and total comprehensive income allocated to non-controlling interests	*(758)*	*(536)*
Cash flows allocated to non-controlling interests		
Cash flows from operating activities	(531)	(659)
Cash flows from investing activities	(1)	(480)
Cash flows from financing activities	(40)	(224)
Net increase (decrease) in cash and cash equivalents	**(572)**	**(1,363)**

NOTE 23 Related parties

23.1 Transactions and balances

	31 December	
in thousands of EUR	2023	2022
Other current receivables due to founder (ultimate main shareholder)	26	15
Current financial liabilities due to founder (ultimate main shareholder)	(1)	(41)
Other current liabilities due to companies controlled by members of the BoD	(8)	(3)
Other current liabilities due to members of the BoD	(3)	-
Total net receivables due from/ (liabilities) due to related parties	**14**	**(29)**

Other current liabilities due to companies controlled by members of the Board of Directors (BoD) relate to legal counselling as well as to administrative work in relation to the development activities of the Group. The services purchased from related parties amounted to EUR 68 thousand for the year ended 31 December 2023 (2022: EUR 66 thousand).

23.2 Key management compensation

	Jan to Dec	
in thousands of EUR	2023	2022
Short-term benefits	138	126
Share-based compensation	25	31
Total compensation to members of the Board of Directors (BoD)	**163**	**157**
Short-term benefits	780	751
Share-based compensation	57	101
Total compensation to members of the Group Executive Board	**837**	**852**
Total compensation to members of the BoD and the Group Executive Board	**1,000**	**1,009**

NOTE 24 Financial risk management

24.1 Credit risk

Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial asset fails to meet its contractual obligations, and arises principally from the Group's receivables from customers, cash at bank and fixed term deposits.

The Group mitigates the credit risk by assessing the credit risk of counter parties for material transactions.

The carrying amounts of cash at bank and other financial assets (excluding prepaid expenses and tax balances) exposed to credit risk:

	31 December	
in thousands of EUR	2023	2022
Cash at bank	87,909	108,937
Accounts receivable	432	88
Other current receivables	26	15
Total carrying amount of financial assets	**88,367**	**109,040**

The Standard & Poor's credit rating of the counterparties is as follows:

	31 December	
in thousands of EUR	2023	2022
A- to A+	87,699	108,833
Without rating	668	207
Total carrying amount of financial assets	**88,367**	**109,040**

24.2 Liquidity risk

Liquidity risk is the risk that the Group will encounter difficulty in meeting the obligations associated with its financial liabilities that are settled by delivery of cash or another financial asset. The Group's approach to managing liquidity is to ensure, as far as possible, that it will always have sufficient liquidity to meet its liabilities when due, without incurring unacceptable losses or risking damage to the Group's reputation. The expected cash outflows of the Group's financial liabilities is outlined in the following tables.

	As at 31 December 2023			
	Maturities			
in thousands of EUR	Up to 1 year	From 1 to 2 years	Maturities From 2 to 5 years	Carrying amount
Other current liabilities	3,177	-	-	3,177
Current account due to founder	1	-	-	1
Lease liabilities	314	310	310	898
Total financial liabilities	**3,492**	**310**	**310**	**4,076**

	As at 31 December 2022			
	Maturities			
in thousands of EUR	Up to 1 year	From 1 to 2 years	Maturities From 2 to 5 years	Carrying amount
Other current liabilities	2,723	-	-	2,723
Current account due to founder	41	-	-	41
Lease liabilities	328	295	584	1,145
Total financial liabilities	**3,092**	**295**	**584**	**3,909**

24.3 Market risk

Foreign exchange risk

The following exposure to foreign currency risks existed as of 31 December 2023 and 2022 in relation to financial instruments:

	31 December 2023				
in thousands of EUR	EUR	CHF	SEK	Other	Total
Financial assets					
Cash at bank	63,802	23	14,602	70	78,497
Accounts receivables	-	52	-	118	170
Total financial assets	**63,802**	**75**	**14,602**	**188**	**78,667**
Financial liabilities					
Other current liabilities	6	525	595	185	1,311
Total financial liabilities	**6**	**525**	**595**	**185**	**1,311**

	31 December 2022				
in thousands of EUR	EUR	CHF	SEK	Other	Total
Financial assets					
Cash at bank	4,993	86	16,558	9	21,646
Accounts receivables	-	30	-	33	63
Total financial assets	**4,993**	**116**	**16,558**	**42**	**21,709**
Financial liabilities					
Other current liabilities	9	485	503	89	1,086
Total financial liabilities	**9**	**485**	**503**	**89**	**1,086**

The following sensitivity analysis presents the profit or loss impact of a reasonably possible change of foreign exchange rates used for the measurement of financial instruments denominated in a foreign currency. This analysis assumes that all other variables, particularly the interest rate level, remain constant.

	Jan to Dec	
in thousands of EUR	2023	2022
CHF (strengthening by 5%)	(3,212)	(282)
CHF (weakening by 5%)	3,212	255
SEK (strengthening by 5%)	700	845
SEK (weakening by 5%)	(700)	(765)

Interest rate risk

The Group is as of 31 December 2023 not exposed to negative interest rates charged on cash at bank and does not have any interest-bearing liabilities outstanding. A reasonable possible change of 50 basis points in interest rates at the reporting date would have increased/(decreased) loss by EUR 440 thousand (2022: EUR 545 thousand).

24.4 Capital management

The directors aim to maintain a strong capital base to sustain future development of the business. The directors monitor the return on capital, which the Group defines as result from operating activities divided by total shareholders' equity. There were no changes in the Group's approach to capital management during the period. The Group is not subject to externally imposed capital requirements. The equity ratio as of 31 December 2023 is 96.2% (2022: 97.1%).

NOTE 25 Financial assets and financial liabilities

The following table shows the classification and carrying amounts of financial instruments held:

	31 December	
in thousands of EUR	2023	2022
Financial assets measured at amortised cost		
Cash at bank	87,909	108,937
Accounts receivables	432	88
Other current receivables	26	15
Total financial assets	**88,367**	**109,040**
Financial liabilities measured at amortised cost		
Financial liabilities	899	1,186
Other current liabilities	3,177	1,702
Total financial liabilities	**4,076**	**2,888**

The fair value of the financial assets and liabilities is the amount at which the instrument could be exchanged in a current transaction between willing parties other than in a forced or liquidation sale. At 31 December 2023 and 31 December 2022, the carrying amounts of financial assets and liabilities equal its fair values based on their nature and maturity or due date.

The Group has no financial assets or liabilities valued at fair value other than those quoted or with prices in active markets. Therefore, no other techniques have been applied by the Group. The company has no financial assets or liabilities that are measured at fair value through profit or loss or at fair value through other comprehensive income.

Auditors report

Independent Auditor's Report

To the Board of Directors on the Consolidated Financial Statements of Implantica AG, Vaduz

Opinion

We have audited the consolidated financial statements of Implantica AG and its subsidiaries (the Group), which comprise the consolidated statement of financial position as at 31 December 2023 and the consolidated statement of profit or loss, consolidated statement of profit or loss and other comprehensive income, consolidated statement of cash flows and consolidated statement of changes in equity for the year then ended, and notes to the consolidated financial statements, including material accounting policy information.

In our opinion the consolidated financial statements (pages 92 to 117) give a true and fair view of the consolidated financial position of the Group as at 31 December 2023, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with IFRS Accounting Standards as adopted by the European Union (EU) and the provisions of Liechtenstein law.

Basis for Opinion

We conducted our audit in accordance with Liechtenstein law and International Standards on Auditing (ISAs). Our responsibilities under those provisions and standards are further described in the "Auditor's Responsibilities for the Audit of the Consolidated Financial Statements" section of our report.

We are independent of the Company in accordance with the provisions of Liechtenstein law and the requirements of the audit profession, as well as the International Code of Ethics for Professional Accountants (including International Independence Standards) of the International Ethics Standards Board for Accountants (IESBA Code) and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Key Audit Matters

VALUATION OF CAPITALIZED DEVELOPMENT COSTS

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

KPMG (Liechtenstein) AG
Vaduz, 25 April 2024

VALUATION OF CAPITALIZED DEVELOPMENT COSTS

Key Audit Matter

Capitalized development costs amounted to EUR 38.1 million (prior year: EUR 36.0 million) as of 31 December 2023, and include costs of both on-going and completed product developments. An impairment assessment is carried out for all development costs when there is any indication of possible impairment, with capitalized costs related to on-going product developments being tested for impairment at least annually. The impairment assessment requires management to make key assumptions such as forecasts of cash flows, growth rates and discount rates.

Our response

Our audit procedures included, among others, challenging the reasonableness of key assumptions made by management, including forecasts of cash flows, growth rates and discount rates. We compared management's assumptions with external data where it was available and performed retrospective reviews to assess the accuracy of previous projections. We also interviewed senior management in order to understand and challenge the key assumptions. We used our valuation specialists to assist us in evaluating certain assumptions including discount rates and in testing the arithmetic accuracy of the valuation model. They also supported us in performing sensitivity analysis to assess the level of sensitivity to certain key assumptions, so that we could particularly focus on those areas and assess management's allowance for risk.

For further information on the valuation of capitalized development costs refer to the following:

- Note 2.4 Critical accounting estimates and judgements
- Note 4.7 Material accounting policies
- Note 14 Intangible assets

Other Information in the Annual Report

The Board of Directors is responsible for the other information in the annual report. The other information comprises that information included in the annual report, but does not include the consolidated financial statements, the stand-alone financial statements of the company and our auditor's reports thereon.

Our opinion on the consolidated financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit, we have the responsibility to read the other information and to consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

If, on the basis of our work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Directors for the Consolidated Financial Statements

The Board of Directors is responsible for the preparation of the consolidated financial statements that give a true and fair view in accordance with IFRS Accounting Standards as adopted by the EU and the provisions of Liechtenstein law, and for such internal control as the Board of Directors determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the Board of Directors is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Board of Directors either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

Auditors report

Auditor's Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made.
- Conclude on the appropriateness of the Board of Directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the Group audit. We remain solely responsible for our audit opinion.

We communicate with the Board of Directors or the Risk & Audit Committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Board of Directors or the Risk & Audit Committee with a statement that we have complied with relevant ethical requirements regarding independence, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied.

From the matters communicated with the Board of Directors or the Risk & Audit Committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report, unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

KPMG (Liechtenstein) AG

Lars Klossack
Chartered Accountant

Bruno Casutt
Chartered Accountant

Vaduz, 25 April 2024

Implantica AG (Parent Company)

Financial statements

Balance sheet

in CHF	Notes	31 December 2023	2022
ASSETS			
A. Non-current assets			
I. Tangible assets		4,301	4,205
II. Financial assets	3		
1. Shares in affiliated companies		56,911,094	71,838,108
2. Loans to affiliated companies		1	71,632,082
Total financial assets		56,911,095	143,470,190
Total non-current assets		**56,915,396**	**143,474,395**
B. Current assets			
I. Receivables			
1. Receivables from affiliated companies		1,578,657	1,578,256
2. Other receivables		156,138	99,452
Total receivables		*1,734,795*	*1,677,708*
II. Securities			
1. Treasury shares	4	*2,432*	*0*
III. Cash at bank		*79,806,726*	*99,134,064*
Total current assets		**81,543,953**	**100,811,772**
C. Prepaid expenses and accrued income		**52,931**	**59,880**
Total assets		**138,512,280**	**244,346,047**

in CHF	Notes	31 December 2023	2022
EQUITY AND LIABILITIES			
A. Equity			
I. Share capital	5.1	*138,723,074*	*138,723,074*
II. Capital reserves		*407,505,509*	*407,505,509*
III. Loss carried forward		*-302,048,981*	*-91,859,643*
IV. Loss for the period		*-105,834,756*	*-210,189,338*
Total equity		**138,344,846**	**244,179,602**
B. Provisions			
1. Tax provisions		1,800	1,800
Total provisions		**1,800**	**1,800**
C. Payables			
1. Trade accounts payable		118,426	155,386
2. Payables to affiliated companies		789	0
3. Other payables		8,219	6,982
Total payables		**127,434**	**162,368**
(of which with a remaining term < 1 year)		*127,434*	*162,368*
D. Accrued expenses		**38,200**	**2,277**
Total equity and liabilities		**138,512,280**	**244,346,047**

Implantica AG (Parent Company)

Financial statements

Income statement

in CHF	*Notes*	01.01.2023 – 31.12.2023	01.01.2022 – 31.12.2022
1. Other operating income	6	2,218,292	1,419,797
2. Personnel expenses			
a) Wages and salaries		-482,629	-447,943
b) Social security and pension expenses		-54,202	-58,183
(thereof pension expenses)		*(-13,207)*	*(-19,779)*
3. Other operating expenses	7	-6,134,276	-6,012,048
4. Interest income from affiliated companies		1,740,835	1,065,802
5. Impairment losses on financial assets and securities	3	-103,120,976	-206,154,963
6. Loss before taxes		**-105,832,956**	**-210,187,538**
7. Income taxes		-1,800	-1,800
8. Loss for the period		**-105,834,756**	**-210,189,338**

Implantica AG (Parent Company)

Notes to the financial statements

NOTE 1 General information

Implantica AG (the "Company") is domiciled at Aeulestrasse 45, 9490 Vaduz.

NOTE 2 Summary of significant accounting policies

2.1 Basis of preparation

The financial statements have been prepared in accordance with the provisions of the Liechtenstein Persons and Companies Act ("PGR").

2.2 Foreign currency

Monetary current assets and liabilities denominated in foreign currencies are translated into CHF at the exchange rate at the balance sheet date. Monetary non-current assets in foreign currencies are measured at the exchange rate at the date of the transaction or at the exchange rate at the balance sheet date if lower.

2.3 Financial assets

In accordance with the principle of individual valuation, shares in affiliated companies and loans to affiliated companies are carried at cost. In case of an impairment, the impairment loss based on the estimated fair value is recognized. If the reason for the impairment no longer exists in subsequent years, the impairment is reversed up to an amount that may not exceed the acquisition cost.

2.4 Receivables and cash at bank

These are generally carried at nominal value. For general credit risks, appropriate valuation allowances are recognized.

NOTE 3 Loans to and shares in affiliated companies

The Company directly holds the following investments:

Company	Country	Share in capital and voting rights	Carrying amount at 31 December 2023	Carrying amount at 31 December 2022
Implantica Group Holding Limited	Malta	100%	227,411,274	227,411,274
Implantica Management AG	Switzerland	100%	69,000	69,000
MedicalTree Swiss AG	Liechtenstein	51%	127,651,470	127,651,470
Subtotal			**355,131,744**	**355,131,744**
Accumulated Impairment			-298,220,650	-283,293,635
			56,911,094	**71,838,108**

Impairment of loans to and shares in affiliated companies.

In 2023, Implantica AG recognized an impairment of its loans to and shares in affiliated companies. The impairment of CHF 103,120,976 was allocated to the loan to affiliated companies with a total of CHF 88,193,962 while the remaining amount of CHF 14,927,014 was allocated to the shares in affiliated companies. The impairment reflects the lower market capitalization of the Implantica AG Swedish Depositary Receipts (SDRs), that are listed on the Nasdaq First North Premier Growth Market. Per year end 2023 the market capitalization was CHF 138,344,846.

Implantica AG (Parent Company)

Notes to the financial statements

NOTE 4 Treasury Shares

	Number of treasury shares	Transaction price in CHF	Par value in CHF	Share in capital
Balance as of 31 January 2023	**-**	**-**	**-**	**-**
Purchase 30.03.2023	7,500	1.94	2.00	0.01%
Purchase 31.03.2023	2,500	1.98	2.00	0.00%
Purchase 03.04.2023	2,500	2.08	2.00	0.00%
Purchase 04.04.2023	2,500	2.03	2.00	0.00%
Purchase 05.04.2023	2,500	1.98	2.00	0.00%
Purchase 06.04.2023	2,500	1.92	2.00	0.00%
Purchase 11.04.2023	2,500	1.92	2.00	0.00%
Purchase 12.04.2023	2,500	1.91	2.00	0.00%
Purchase 13.04.2023	2,500	1.90	2.00	0.00%
Purchase 14.04.2023	2,500	1.86	2.00	0.00%
Other	13	-	-	-
Settlement of vested share based payment plans 21.12.2023	-28,708	1.59	2.00	-0.04%
Balance as of 31 December 2023	**1,305**	**-**	**2.00**	**0.00%**

The shares bought and held by the Company serve the purpose of settling any vested share based payment plans.

NOTE 5 Equity

5.1 Share capital

At 31 December 2023 the share capital amounts to CHF 138,723,074 and is divided into 58,111,537 registered shares with a nominal value of CHF 2.00 each (Class A) and 1,125,000,000 with a nominal value of CHF 0.02 each (Class B).

Authorized capital

The Board of Directors is authorized to increase the share capital at any time before 16 April 2026 by a maximum amount of CHF 15,984,614 by issuing a maximum number of 7,992,307 fully paid in Class A shares with a nominal value of CHF 2.00 each. Increases of the share capital in partial amounts is permitted.

Conditional capital for financing purposes

The share capital may be increased by a maximum amount of CHF 13,500,000 by issuing a maximum number of 6,750,000 fully paid in Class A shares with a nominal value of CHF 2.00 each upon exercise conversion rights or options in relation with convertible debt instruments, loans and similar forms of financing the Company. The conditions for granting the option and conversion rights shall be determined by the Board of Directors.

Conditional capital for employee share option plans

The share capital may be increased by a maximum amount of CHF 2,700,000 by issuing a maximum number of 1,350,000 fully paid in Class A shares with a nominal value of CHF 2.00 each upon exercise of employee share options issued to employees.

5.2 Proposed appropriation of available earnings

The Board of Directors proposes to carry forward the loss for the period to the next financial year.

NOTE 6 Other operating income

Other operating income comprises mainly foreign exchange differences on cash at bank.

NOTE 7 Other operating expenses

in CHF	01.01.2023 – 31.12.2023	01.01.2022 – 31.12.2022
Consulting costs	-45,806	-61,531
Management fees	-641,463	-1,025,839
Foreign exchanges losses	-4,581,239	-3,878,923
Miscellaneous	-865,768	-1,045,755
Total other operating expenses	**-6,134,276**	**-6,012,048**

NOTE 8 Average number of employees

In 2023 Implantica AG employed 3.68 FTEs in average compared 2.52 FTEs in 2022.

Auditors report

Statutory Auditor's Report

to the General Meeting of Implantica AG, Vaduz

Report on the Audit of the Financial Statements

Opinion

We have audited the financial statements of Implantica AG (Company), which comprise the balance sheet as at 31 December 2023, the income statement for the year then ended, and the notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the financial statements (pages 120 to 124) give a true and fair view of the financial position of the Company as at 31 December 2023 and its financial performance for the year then ended in accordance with Liechtenstein law.

Basis for Opinion

We conducted our audit in accordance with Liechtenstein law and International Standards on Auditing (ISAs). Our responsibilities under those provisions and standards are further described in the "Auditor's Responsibilities for the Audit of the Financial Statements" section of our report.

We are independent of the Company in accordance with the provisions of Liechtenstein law and the requirements of the audit profession, as well as the International Code of Ethics for Professional Accountants (including International Independence Standards) of the International Ethics Standards Board for Accountants (IESBA Code) and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Key Audit Matters

VALUATION OF LOANS TO AND SHARES IN AFFILIATED COMPANIES

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current period. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

KPMG (Liechtenstein) AG
Vaduz, 25 April 2024

VALUATION OF LOANS TO AND SHARES IN AFFILIATED COMPANIES

Key Audit Matter	Our response
As at 31 December 2023 the Company had loans to affiliated companies in the carrying amount of CHF 0 million (prior year: CHF 72 million) and held shares in affiliated companies in the carrying amount of CHF 57 million (prior year: CHF 72 million). These financial assets are stated at cost less necessary impairment losses. During 2023 the market capitalization of the Company significantly decreased. Based on this impairment indicator management performed an impairment test which bases on the Company's market capitalization and recognized an impairment loss of CHF 103 million, whereby loans to affiliated companies were fully impaired by CHF 88 million and the remaining impairment loss of CHF 15 million was allocated to shares in affiliated companies. Due to the inherent uncertainty involved in the impairment assessment and the size of these financial assets, this is a key area of our audit.	Our audit procedures included, among other, assessing the reasonability of the impairment test model used by management. We did that with the support of our valuation specialists. We further assessed the reasonability of the implied enterprise value used in the impairment calculation considering the Company's market capitalization on 31 December 2023. We tested the arithmetic accuracy of the calculations performed by management.

For further information on the valuation of loans to and shares in affiliated companies refer to:

Note 2.3 Financial assets

Note 3 Loans to and shares in affiliated companies

Other Information in the Annual Report

The Board of Directors is responsible for the other information in the annual report. The other information comprises that information included in the annual report, but does not include the consolidated financial statements, the stand-alone financial statements and our auditor's report thereon.

Our opinion on the financial statements does not cover the other information, and we do not express any form of assurance conclusion thereon.

In connection with our audit, we have the responsibility to read the other information and to consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

If, on the basis of our work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Directors for the Financial Statements

The Board of Directors is responsible for the preparation of the financial statements that give a true and fair view in accordance with Liechtenstein law, and for such internal control as the Board of Directors determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditors report

In preparing the financial statements, the Board of Directors is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Board of Directors either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Liechtenstein law and ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with Liechtenstein law and ISAs, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made.
- Conclude on the appropriateness of the Board of Directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the Board of Directors or the Risk & Audit Committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Board of Directors or the Risk & Audit Committee with a statement that we have complied with relevant ethical requirements regarding independence, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied .

From the matters communicated with the Board of Directors or the Risk & Audit Committee, we determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on Other Legal and Regulatory Requirements

We further confirm that the financial statements comply with Liechtenstein law and the articles of incorporation. We recommend that the financial statements submitted to you be approved.

KPMG (Liechtenstein) AG

Lars Klossack
Chartered Accountant
Auditor in Charge

Bruno Casutt
Chartered Accountant

Vaduz, 25 April 2024

KPMG (Liechtenstein) AG, Aeulestrasse 2, LI-9490 Vaduz

Risk Factors 1/3

Risks relating to the Company's operations and its industry

The Company is an early-stage commercial company that has incurred losses since its inception and expects to continue incurring losses and negative cash flows and may not be able to achieve or maintain profitability. The only product approved to be sold is RefluxStop™ where commercialization began with a pre-launch phase in June 2018. Over the near to medium term, the Company expects that any revenue generated will be derived entirely from sales of RefluxStop™. Therefore, the Company will depend heavily on the success of RefluxStop™ to generate revenue and enable financing of operations and further growth.

Many of Implantica's products use novel concepts and treatment methods. If the products or treatment methods turn out to be ineffective in the long term or cause serious side effects, the Company's reputation could suffer, and revenue and profitability could decline. Furthermore, the Company could incur significant civil liabilities, and in many jurisdictions, claims for bodily harm that the users of the products may suffer are not subject to a statute of limitations. Shortcomings and adverse events may also cause a less favorable re-assessment of risks and benefits of the Company's products by the regulatory authorities. Product replacements leading even to removal of an implant by explantation are inherently costly in the case of implants. The Company may also be required to withdraw a product altogether from the market.

Once a CE mark or other relevant regulatory approvals or clearances have been obtained, the Company needs to adhere to specific regulations on quality systems, notably to ISO standards regarding quality systems applicable for example in the EEA and Switzerland and or the Quality System Regulation ("QSR") and Current Good Manufacturing Practices for Medical Devices (CGMP) applicable in the United States. These regulations are comprehensive and complex and apply to the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of the Company's products. Failures in handling of the Company's quality system may lead to delays in production, significant expenses and/or cause the relevant regulatory authorities to withdraw the CE mark and other clearances and approvals. Serious incidents could lead to product recalls or may force the Company to replace or withdraw products.

The Company may encounter significant obstacles in the process of obtaining CE marks, product approvals and recertifications for its development devices and designs, in particular in relation to the relevant EU notified body. Compliance with certain regulatory requirements is a prerequisite to be able to affix the CE mark to a product, without which a product cannot be marketed or sold in the EEA. The numerous obstacles in the CE marking and approval process may result in denial or delay on the part of the notified body to accept evidence or test results presented to underpin the safety and performance of the Company's development devices, and the relevant notified body can cancel or refuse to renew certifications.

The Company may not be able to obtain FDA or Institutional Review Board (IRB) clearance/approval to undertake clinical trials for any new devices the Company intends to market in the United States. Such trials are typically significantly more extensive and costly than trials for CE marking. In addition, if the clinical study involves a "significant risk" (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval/clearance of an Investigational Device Exemption, or IDE, application. The Company's development devices are likely to be considered a significant risk device requiring IDE approval prior to investigational use. Failure to obtain such relevant approvals or to comply with regulations could have a material adverse effect on the Company's business, financial condition and results of operations. It is uncertain whether clinical trials will meet desired endpoints, produce meaningful or useful data and be free of unexpected adverse effects, or that the FDA will accept the validity of foreign clinical study data, and such uncertainty could preclude or delay market clearance or authorizations resulting in significant financial costs and reduced revenue.

The Company is commercializing RefluxStop™ and, if the Company receives the respective regulatory approvals, other development devices in different jurisdictions. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Regulatory requirements can vary widely from jurisdiction to jurisdiction and could delay or prevent the introduction of development devices in those countries.

The Company's ability to commercialize RefluxStop™ and the Company's development devices depends heavily on the extent of insurance coverage and reimbursement provided by third-party payers such as public healthcare systems and private insurers. Hospitals and other healthcare providers that purchase medical devices such as the ones Implantica produce or are developing generally rely on third-party payers to pay for all or part of the costs and fees associated with the procedures performed with these devices. If Implantica's products are not granted adequate insurance coverage and/or fail to become subject to reimbursement policies, it may have a material adverse effect on the demand for, or the price of, any of the Company's products and development devices. It is uncertain if at all, when, and with what eventual outcome any of the heavily regulated procedures and processes leading to reimbursements of any of the Company's development devices will be completed. In particular regarding novel technologies, reimbursements may take many years to accomplish, or may even never be achieved.

The Company's business success depends on its ability to maintain a strong reputation among and relationships with healthcare professionals. Surgeons play a significant role in determining the course of treatment and, ultimately, the type of product that will be used to treat a patient, so the Company relies on effective communication to them. An important part of the sales process includes the education of surgeons, key opinion leaders and their respective support staff responsible for implanting the Company's products, on the safe and effective use of its products. Acceptance of the Company's innovative products depends on educating surgeons and key opinion leaders as to the distinctive characteristics, perceived benefits, safety and cost-effectiveness of the products as compared to competitors' products. If Implantica fails in convincing surgeons of the merits of its products or educating them on the use of its products, they may not use such products and the Company may be unable to establish and sustain growth or profitability.

The Company relies heavily on patents and other intellectual property rights as well as trade secret protection and confidentiality agreements to protect its products and development devices and designs. The patent applications that the Company owns may fail to result in issued patents. Even if patents are successfully issued, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. If the Company's intellectual property relating to its products is not adequate, it may not be able to compete effectively. Furthermore, the Company may be unable to protect its intellectual property and contractual rights from infringement by others. The Company may also be subject to claims that former owners or leased employees, collaborators or other third parties have an interest in the Company's owned patent rights, trade secrets, or other intellectual property as an owner, inventor or co-inventor.

Riskfactors (2/3)

The Company's products are designed to be used in surgery and to be implanted into and remain in the human body. Component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information or non-compliance with the required surgical procedures could result in unsafe conditions or injuries to, or the death of, patients and trigger product liability lawsuits, recalls and claims. The Company may fail to successfully defend itself against any alleged claims that the development devices or products cause injuries.

The Company has in the past outsourced clinical trials and research activities to several third-party clinical research organizations (CROs) and intends to continue to do so. As a result, the Company relies on CROs and clinical study sites to ensure that its clinical studies are conducted properly and on time. The Company and the CROs are required to comply with the relevant regulatory body's requirements and applicable standards for conducting, recording and reporting the results of pre-trial studies and clinical trial studies. Accordingly, if the CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, the Company may be required to repeat such clinical studies, which would delay the regulatory approval process. Accordingly, the Company is also dependent on third parties in bringing development devices and in starting and completing the regulatory approval process for its development devices. If third-party suppliers and service providers do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data the CROs obtain is compromised due to the failure to adhere to the Company's clinical protocols or regulatory requirements, or for any other reasons, the Company's product development and clinical studies may be extended, delayed or terminated, and Implantica may not be able to obtain regulatory approval for, or successfully commercialize its development devices.

The Company has no own manufacturing facilities or manufacturing experience. The Company has therefore outsourced the manufacture of working prototype of its development devices and the manufacture of its first product RefluxStop™ and intends to continue to do so. The Company is currently cooperating with the Freudenberg Group for the manufacture of RefluxStop™ and its prototypes. If Freudenberg becomes unable or unwilling to continue to manufacture RefluxStop™ at the current conditions or at all, the Company may not be able to enter into an agreement with an alternate supplier at similar conditions, which means that the Company may encounter significant delays, production shortages and additional costs. If there is a shortage of silicone in general, or if Freudenberg is unable or unwilling to manufacture the required quality and/or quantity of silicone at the current conditions, the Company's production could experience significant delays. In some of the Company's target markets, products will be sold through independent distributors and/or agents. In these countries, the loss of indirect distributors or agents could seriously harm the Company's business and operating results if a new distributor could not be found on a timely basis in the relevant geographic market. To the extent that the Company relies on sales through independent distributors or agents, any revenues received will depend primarily on the efforts of these parties.

The medical technology industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. The Company's only currently marketed product RefluxStop™ is, and any future commercialized development devices may be, subject to intense competition. Many of the Company's current and potential competitors are major medical technology companies that have substantially greater financial, technical and marketing resources than the Company has, and they may succeed in developing products that could render the Company's products obsolete or non-competitive. The Company's ability to compete successfully will depend on its ability to develop proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement from third party payers, and are safer, less invasive and more effective than alternatives available for similar purposes. Because of the size of the potential market, the Company anticipates that companies will dedicate significant resources to developing competing products. If alternative treatments are, or are perceived to be, superior to the Company's implants market products, or if competing products can be offered at a lower price, sales of the Company's products could be negatively affected and the results of operations could suffer.

The medical device industry is characterized by intellectual property litigation. The Company may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of the Company's products. The Company may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate its patents, which would be costly, time-consuming and, if successfully asserted, delay or prevent the development and commercialization of its products. As a result of patent infringement claims, or in order to avoid potential claims, the Company may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if the Company was able to obtain a license, the rights may be nonexclusive, which would give competitors access to the same intellectual property.

Riskfactors (3/3)

As part of Implantica's ordinary business, the Company collects, stores and processes personal data relating to employees and customers and patients, the latter mainly consisting of health-related information and is thus in itself of sensitive nature. In addition to data processed and stored in the ordinary course of business, the Company plans to compile a large database of patient data through the use of the Company's e-InVivo™ eHealth Platform, which is intended to be used for commercialization purposes in various ways. The Company's precautions to protect employee, customer and patient data in accordance with the privacy requirements provided under applicable laws may be ineffective, and such data may be leaked as a result of human error or technological failure or otherwise be used inappropriately. Since the Company works with third-party suppliers, manufacturers, distributors and service providers, the risk of human error, technological failure or otherwise undue disclosure is also extended to such parties' processing of the personal data and thus outside the Company's control. Non-compliance with GDPR (including the implementing rules of the EU member states) or other applicable data protection laws in other jurisdictions may in lead to fines, reputational harm and customer losses.

The Company relies on well-functioning and available IT systems. In relation to its IT systems, Implantica is exposed and vulnerable to risk relating to break-ins, piracy and similar disruptive actions. The IT systems may be interrupted by technical faults, malfunctions, network overload, maintenance work, the malicious blocking of electronic access by third parties and illegal interventions such as cyber-attacks attempting to gain unauthorized access to the Company's products, systems or confidential information (including, but not limited to, intellectual property and personal information). Some of the IT systems used by the Company are provided by external software providers and such providers could cease to provide updates or support for software programs relevant for the Company. These and other disruptions may jeopardize the security of information stored in and transmitted through the computer systems.

Until start of the pre-launch phase of the Company's first product RefluxStop™ in June 2018, the Company has had no significant operational activities except for product development. Accordingly, the Company is exposed to risks and difficulties frequently encountered by relatively young companies in new and rapidly evolving markets, particularly companies engaged in the development and sales of medical devices. These risks include, without limitation, the Company's potential inability to manage rapidly changing and expanding operations; establish and increase awareness of brands and strengthen the loyalty of key opinion leaders and customers; grow the Company's direct salesforce and increase the number of independent distributors to expand sales Europe and in targeted international markets; continue to develop and enhance the products, development devices and designs; obtain regulatory clearance or approval to commercialize new products and enhance existing product; and perform clinical research and trials on current and future development devices.

The Company relies on the continued availability to key personnel and their competence and experience. The Company is especially dependent on its board and management members, especially the CEO Dr. Peter Forsell. There is a risk that the Company in the future may seek capital to finance its operations. Such fundraising initiatives may be carried out either through new issues of shares or other financial instruments in the Company or by way of taking bank or other loans. The availability of new capital could be affected by disruptions of the capital and credit markets and borrowings will negatively affect the Company's indebtedness level. The need for additional capital will increase if earnings from the sale of RefluxStop™ are lower than expected. The ability to raise additional funds depends on financial, economic and other factors, many of which are beyond the Company's control.

The Group consists of companies domiciled in various jurisdictions. The legal structure of the Group requires Implantica to assess and evaluate possible tax consequences in relation to operating in, entering into an effectively function as a Group, in various jurisdictions, including assessments on transfer pricing issues and the fact that the Company historically has reported losses. The Company cannot be certain that its assessments and the assessment of its tax advisers regarding various tax matters are identical to the assessment of the relevant authorities. Therefore, the final assessment of tax authorities could be materially different from what the Company expect and have expected.

Legal uncertainty resulting from political instability and protectionist tendencies could adversely affect the Company in various ways and expose the Company to a number of risks. These risks include, but are not limited to rapid changes to laws and regulations; increased trade restrictions such as anti-dumping/anti-subsidy tariffs, export restrictions, embargos, import taxes, special monitoring measures, and economic sanctions against certain countries, persons, businesses and organizations, as well as other protectionist or politically motivated restraints. These and other effects of political instability and protectionism could have material adverse effects on the demand for the Company's products, on supply chain, business operations and ability to market and distribute the Company's products in relevant customer markets.

Risks related to the shares and the corporate structure

The Company's largest shareholder Dr. Peter Forsell owns approx. 47% of the Company, and the following top ten shareholders own approx. 32% of the capital rights of the Company. The share capital of the Company consists of class A shares on the one hand and class B shares on the other hand. While each share carries one vote, regardless of whether it is a class A share or a class B share, with 1 Class A share having a nominal value of CHF 2 and 1 Class B share having a nominal value of CHF 0.02.

All class B shares are currently held by the principal shareholder. Other shareholders in the Company will thus not be able to exert significant influence over matters that are decided by the Company's shareholders.

Implantica

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