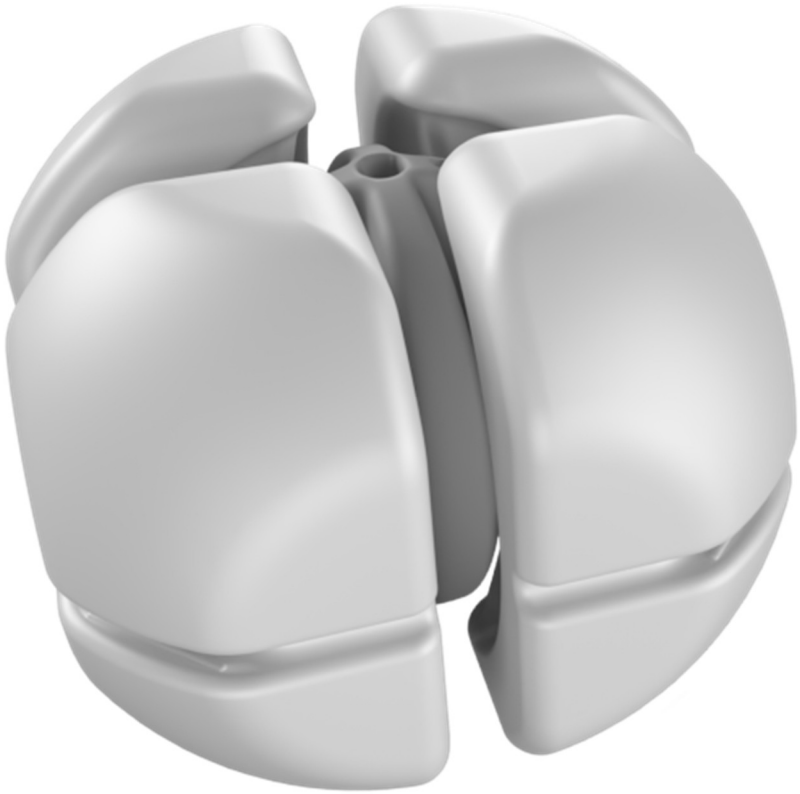
RefluxStop® BY Implantica

Patient Information



Treats Acid Reflux by Restoring and Maintaining the Body's Natural Anatomy & Physiology

RefluxStop® by Implantica
Bringing advanced technology into the body

Caution: USA Federal Law restricts this device as "prescription only."

Table of Contents

What is RefluxStop®?

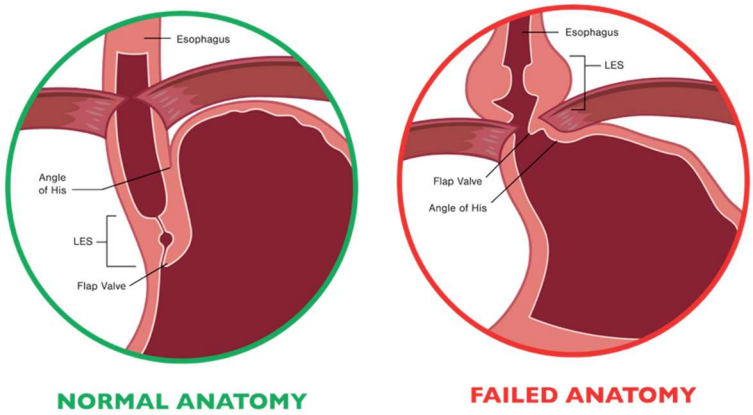
RefluxStop® is a medical device intended for patients 18 years and older. It was developed to treat acid and non-acid reflux in patients diagnosed with gastroesophageal reflux disease (GERD). The sphere shaped device is made of biocompatible medical grade silicone that is used in various medical implants. It is about the same size as a quarter, almost 1 inch in diameter (24.5 mm).

What is GERD?

GERD is a condition that occurs when the reflux of stomach contents into the esophagus causes troublesome symptoms and/or complications.[1]

The body has a natural acid reflux barrier that consists of several anatomical and physiological components that work together to prevent acid reflux.

When any of the components fail, it leads to misalignment and reflux often occurs. The more these components fail, the worse acid reflux gets.



How RefluxStop® Treats GERD

The RefluxStop® procedure restores the lower esophageal sphincter (LES) and maintains it in the correct position allowing the acid-reflux barrier (ARB)[2] to function normally by preventing stomach contents from coming back up into the esophagus.

Reposition

Reposition the lower esophageal sphincter (LES) to its natural position well below the diaphragm.

Repair

Repair the tear or weakness in the diaphragm often causing a hiatal hernia.

Reconstruct

Reconstruct the natural angle between the stomach and esophagus (angle of His).

Restore

Restore and maintain the body's natural anatomy and physiology that prevents reflux

Sources and References:
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Why Doctors Recommend RefluxStop®

RESTORES THE BODY'S NATURAL ANATOMY AND PHYSIOLOGY	RefluxStop® restores and maintains the body's natural anatomical structure and physiological function of the ARB that prevents GERD.
REDUCED POST-SURGICAL SIDE EFFECTS:	RefluxStop® does not encircle the esophagus thereby minimizing common side effects like swallowing problems, gas bloating, and difficulty burping and vomiting.[3, 4]
CAN BE USED IN CONJUNCTION WITH OTHER ELECTRICAL IMPLANTS:	RefluxStop® can be used in conjunction with pacemakers, implantable defibrillators, metallic or electrical implants, etc.
DOES NOT PROHIBIT IMAGING:	RefluxStop® is Magnetic Resonance Imaging (MRI) safe. There are no restrictions on imaging after the RefluxStop® procedure.
IS MINIMALLY INVASIVE:	The RefluxStop® procedure is performed under general anesthesia as a minimally invasive laparoscopic (keyhole) surgery, lasting about 1-1.5 hours on average.
IS WELL TOLERATED:	After RefluxStop® surgery, patients usually go home next day after surgery. The surgeon will advise when a normal diet can be consumed after surgery. Often lighter food is recommended during the first week after surgery.
IS REMOVABLE IF NEEDED:	As the body's anatomy is restored, and not altered, the RefluxStop® device can be removed if needed during a minimally invasive laparoscopic procedure.

Contraindications:

The RefluxStop® System is contraindicated in patients with:

- Known sensitivities or allergies to the device materials (medical grade silicone [NusilMED-4860] and barium sulphate [$BaSO_4$ powder]);
- Intraoperative findings determined by the operating surgeon that may result in unfavorable conduct of the procedure.
- Known sensitivities or allergies to the device materials (Stainless Steel AISI 316L and medical-grade silicone ML-154).

Warnings and Precautions:

- Severe retching, heaving, or vomiting immediately post-op could result in surgical failure causing a possible re-herniation. Care should be taken to discuss this matter with the anesthesiologist beforehand to take necessary precautions and medications preventing post-op retching.

- The safety and effectiveness of the RefluxStop® System have not been evaluated in a prospective study in the following patient populations or conditions

  Patients who have:
  - *A body mass index (BMI) > 35 kg/m^2.*
  - *Para-esophageal or Hiatal hernia >3 centimeters.*
  - *Known delayed gastric emptying.*
  - *History or suspicion of esophageal or gastric cancer.*
  - *Known presence of larger esophageal or gastric varices.*
  - *History of anti-reflux or bariatric procedure with extirpated fundus.*
  - *Severe stricture or stenosis of the lower esophagus.*
  - *Presence of esophagitis grade D according to the Los Angeles classification (will prolong operation time).*
  - *Who are pregnant at the time of the procedure.*
  - *Achalasia, scleroderma, and nutcracker esophagus.*
  - *Comorbidities that may not make them a good candidate for surgery.*

Risks of Having the RefluxStop® Procedure Done

Adverse events that may be related to the use of the RefluxStop® device include, but are not limited to: those commonly associated with general anesthesia, abdominal laparoscopic surgery, and the RefluxStop® device. These may be serious and could even lead to death.

Potential adverse events related to general anesthesia and abdominal surgery could include, but are not limited to: Abdominal abscess, abdominal pain, adverse reactions to anesthesia (dizziness, headache, nausea, sore throat, teeth damage, visual complications), allergic shock, anaphylactic shock, atrial arrhythmia or fibrillation, cardiac arrhythmia or arrest, fever, hemorrhage, heart attack, hypotension, hypoxemia, ileus, incisional herniation, infection (related risks which could also occur separately or in any combination including: perforation, esophageal stenting, fistulation, peritonitis, mediastinitis), pneumonia, pneumothorax, pulmonary embolism, reintervention, respiratory distress, resurgery, sepsis, septic shock, septicemia, stroke, thrombophlebitis, thrombosis, urinary retention, urinary tract infection, visceral adhesions, weight loss and wound dehiscence.

Possible risks associated with anti-reflux surgery in general, which may apply to the RefluxStop® surgical procedure, could include, but are not limited to: Intraoperative complications, reinterventions, respiratory complications also comprising atelectasis, pleurisy and pneumothorax, flatulence, retching, vomiting, bloating, hiccups, oral discomfort and glossodynia, reherniation also comprising fundus including the device, bleeding especially hemorrhage from the short gastric, the spleen including spleen extirpation, gastric or esophageal perforation, dysphagia including need for esophagus dilatation, odynophagia, recurrence of GERD symptoms such as heartburn/chest pain, dyspepsia, regurgitation, crus sutures damaging/cutting through the crus muscles due to retching/heaving/vomiting, sutures damaging the esophagus with retching, pain, ileus, esophageal widening, esophageal obstruction or reconstruction, narrowing or stenosis, or infection including peritonitis and abscess, gas bloating, inability to belch or vomit, diarrhea, vomiting and delayed gastric emptying, and hiatal repair performed too tightly causing dysphagia.

Observed Adverse Events

A 50 patient European, multicenter, prospective study was conducted to support approval of the RefluxStop® System. Results from this study, including major adverse events related to the RefluxStop® device, are outlined below:

Total (N=50)				
Serious procedure-related adverse event	**Outcome**	**Severity**	**Duration**	**Subjects (n)**
Foreign body– subcutaneously broken needle	RESOLVED	Mild	1 days	1
Suture rupture – re-suture	RESOLVED	Moderate	1 days	1
Infection with abscesses and empyema	RECOVERED	Severe	52 days	1
Intra-abdominal hemorrhage, drainage of hematoma	RECOVERED	Severe	1 days	1
Pleurisy	RECOVERED	Moderate	11 days	1

Non-serious adverse events*	**Outcome**	**Severity**	**Duration**	**Subjects (n)**
Dyspepsia	NOT RESOLVED	Moderate	–	1
Dysphagia	RECOVERED	Mild	3.3 years	1
Temporary intestinal paresis postoperative	RECOVERED	Mild	4 days	1
Incisional hernia with abdominal pain	UNKNOWN	Moderate	–	1
Procedural pneumothorax	RECOVERED	Mild	1 days	1
** In addition, 3 Mild incidents/adverse events in two subjects resolved during surgery: hepatic lesion and adhesiolysis with hemorrhage*				

No device-related adverse event occurred	**Outcome**	**Severity**	**Duration**
Zero device related adverse event during entire 5-year study	**0**	**0**	**0**

Possible additional risks related to the RefluxStop® device or procedure based on Real-World RefluxStop® procedure experience – may include, but are not limited to:

- Re-herniation may occur, but often the re-herniated fundus can be restored with the device intact in its fundal pouch. This risk is greater in patients with a larger hernia before surgery. This was the most common serious safety event among 602 patients from 22 centers[6]. It occurred in 1.33% of patients (8/602 cases) after 0.25 to 6.75 years (average 2 years) follow-up in patients with hiatal hernia before surgery. In standard-of-care surgery, re-herniation is a problem with an up to 15-50% reoperation rate in patients with large hernia[7]. RefluxStop is designed to reduce this problem.
- Device erosion (short-term), which may occur due to surgery-related hampered blood supply to the stomach wall or too tight of an invagination of the device in the stomach wall pouch, both possibly related to the individual patient anatomical condition. Early erosion occurred in 4/602 cases in the previously mentioned real-world study. If the stomach pouch ends up being sutured too tightly around the device, it may erode through the stomach wall into the stomach cavity where it passes through the digestive tract like food, as it was designed to do. These events were mainly asymptomatic, and no further intervention was needed at the time; however, reflux symptoms may recur at a later stage.
- Lack of treatment effect or recurrence of reflux symptoms
- Device removal or re-operation
- Mucosal ulcer could form at the device position due to a reduced blood supply, if the stomach device-pouch is performed too tightly
- Device erosion (long-term)
- If the pouch is not closed completely, device slippage may occur
- Sutures between the stomach and fundus may come loose, causing relapse of reflux symptoms.

RefluxStop® Procedure Benefits

Benefits of the RefluxStop® procedure may include:

- Restores and maintains the body's natural anatomy and physiology allowing it to function normally.
- Reduction in acid exposure to your esophagus.
- Improvement in heartburn and regurgitation symptoms.
- Reduction or elimination of GERD medications.
- Does not encircle the esophagus as is the case with fundoplication procedures, thereby minimizing common surgical side effects like swallowing problems, gas bloating, and the inability to belch and vomit.
- Performed via a minimally invasive laparoscopic keyhole procedure.
- Ability to resume a normal diet following surgery.
- Usually, discharged the next day after surgery.
- No restrictions in conjunction with other electrical implants such as pacemakers, implantable defibrillators etc. and metallic implants in the abdomen.
- There are no restrictions on Magnetic Resonance Imaging (MRI) after the RefluxStop® procedure, as with some surgical procedures.

How to Decide on This Treatment

When considering RefluxStop®, it is important to think about the following:

The device is designed to be a permanent implant and is supported by five years of clinical data. Sustainability of effect, as assessed by quality of life scores, has not been studied past 5 years, however, some patients have now had the device implanted for up to 9.5 years. As with any implant, there is a possibility that the device may need to be removed or replaced in the future (for example, after many years). If the device stops functioning as intended, your GERD symptoms may return, or you may experience unusual pain.

Safety of the RefluxStop® Procedure

In the RefluxStop® clinical study of 50 patients with 5-year follow-up[5], 11 patients reported 16 adverse events (AEs) related to the procedure, most of which (14/16) occurred prior to 1-year follow-up. Seven of those reported events by 5 patients were complications directly related to surgery, classified as serious (i.e., one patient had a single infection with three diagnoses) and all were satisfactorily resolved within 3 months after surgery. Two patients reported 2 minor procedure-related AEs between 1- and 5-year follow-up. There were no device-related AEs reported during the entire study period.

0	No deaths related to RefluxStop® and or the procedure.	0	Re-herniation on 5-year contrast swallow x-ray.	0	Adverse events related to the RefluxStop® medical device itself.
0	Device explants.	0	Device migration/erosion*	0	Device deficiencies.
0	Esophageal dilations performed.	0	Device dislocation*	2	Patients reported minor procedure-related side effects between year 1 and year 5

* Based on 5-year contrast swallow x-ray

RefluxStop® 5-Year Pivotal Clinical Trial Results[4, 5]

98% of the patients stopped taking daily PPI medication.	Quality of life score was improved by 90% at 5 years compared to before surgery
95.5% of patients showed improved or no regurgitation compared to pre-surgery. In total, 93.6% of patients reported fully resolved or minimal regurgitation at final follow-up.	100% of patients were able to belch & vomit 5 years after surgery (a common side effect in the magnitude of 40% in standard of care procedures[3]).
Quality of life score improvement from a median 29.5 (out of 50) before surgery to score 3 at 5 years post procedure.	95.5% of patients experienced non-worsening gas bloating (none, an improvement, or equal to symptoms pre-surgery) (a common side effect in the magnitude of 50% in standard of care[3]).

As every patient is different, in particular the abdominal anatomy, outcomes can vary by individual. It is possible that even after treatment you may need to continue GERD medication. If the procedure fails, your GERD symptoms may return. Please discuss your medical history with your doctor to determine if you have any conditions for which the RefluxStop® procedure is not recommended. The RefluxStop® procedure is not the only option available to you. Your doctor will discuss this option and other options available to you for your consideration.

Please note that RefluxStop® treats reflux of stomach content into the esophagus which often causes pain and damages tissue, however, RefluxStop® does not treat gastritis, an inflammation in the stomach mucosa (inner lining), or SIBO, a small intestine bacterial overgrowth. The lower acid levels in the stomach, from PPI use, allows bacteria to pass through the stomach into the small intestine with undigested food causing overgrowth and leading to SIBO.

Minimal post-surgical side effects

Excellent clinical outcomes

Restores & maintains natural anatomy & physiology

Who May Benefit From RefluxStop®?

RefluxStop® is used to treat GERD and could benefit patients if:

Their quality of life is impaired by acid reflux (everyday life and work)	They experience tooth damage due to acid reflux often identified by their dentist
Symptoms are not completely alleviated or controlled by medication, e.g., heartburn	Concerns exist about the risks of developing precancerous chronic inflammation in the lower esophagus called Barrett's esophagus (10-20% risk)
They experience side effects from PPI medications or are concerned about potential risks associated with long-term PPI use .	The effectiveness and/or food passageway related side effects of standard of care procedures that encircle the esophagus is in question or a problem
Prior anti-reflux procedures did not resolve the problem	They experience chronic coughing or hoarseness by acid reaching the vocal cords or the lungs.

What Happens Before the Treatment?

You will need to have several tests to make sure you are healthy enough for the surgery and to assess your esophagus. Your doctor will explain these tests to you.

These tests will likely include but may not be limited to:

ESOPHAGEAL pH TESTING

Tests for acid in the esophagus.

MANOMETRY / MOTILITY

Measures pressures in the esophagus and effectiveness of swallowing.

ENDOSCOPY

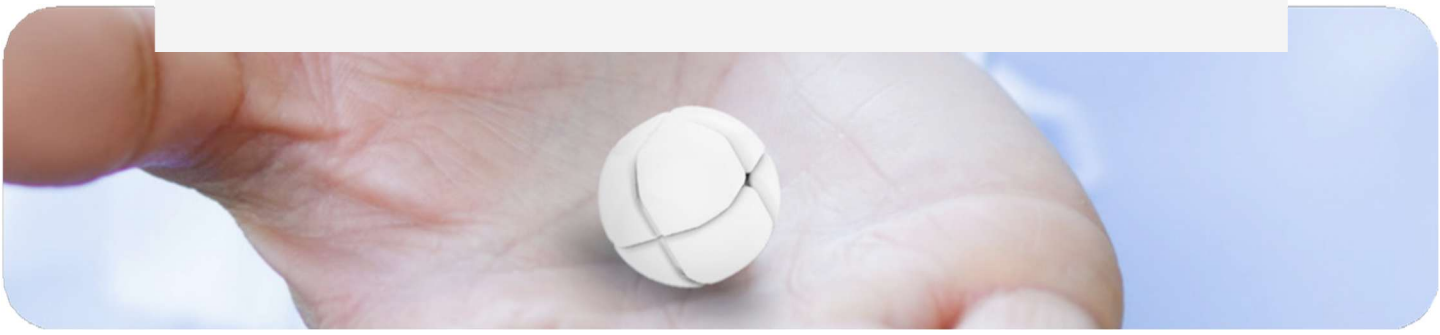
A visual examination of your esophagus using an endoscope.

BARIUM ESOPHAGRAM

X- ray to examine the esophagus. The x-ray is performed while you drink a chalky substance called contrast.

What Happens During The Treatment?

A RefluxStop® qualified surgeon will perform the RefluxStop® procedure. It is a minimally invasive laparoscopic procedure that lasts about 1-1.5 hours on average and is performed under general anesthesia.



During the procedure the natural anatomy is restored. The RefluxStop® is gently placed and covered in a pocket formed from outer stomach wall to support and maintain the position of the components of the anti-reflux barrier.

Treatment Effect

RefluxStop® prevents acid reflux by maintaining the natural anatomy and natural position of the lower esophageal sphincter by keeping it in place.

The esophagus is not encircled and therefore unpleasant side effects associated with standard-of-care anti-reflux procedures are kept to a minimum.

What Happens After The Treatment?

Recovery

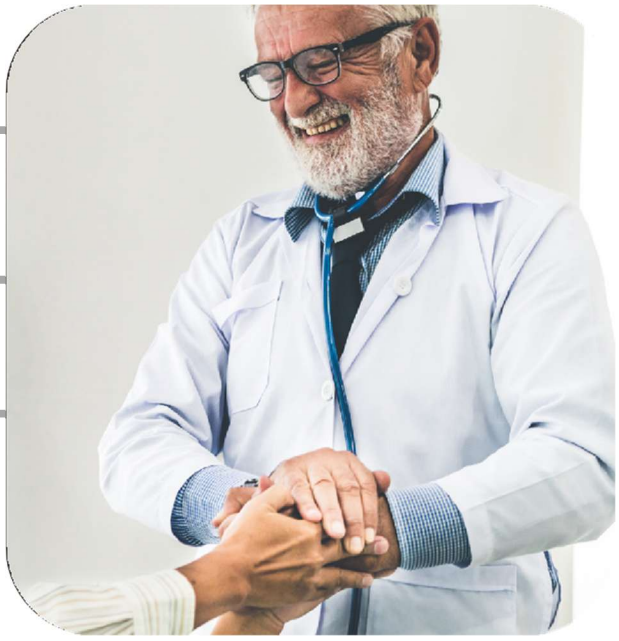
Even though this is a minimally invasive procedure, it is important to remember that your body needs time to recover.

It is very important to follow your surgeon's discharge instructions (diet, exercise, driving, returning to work).

Typically, you will be released from the hospital the same day, next day, or within a few days after the procedure.

A contrast swallow x-ray will be performed to confirm a good post-operative result.

You've come this far - don't forget to complete all your post-operative care visits with your surgeon.



Return to a Normal Diet

You should be able to return to a normal diet as soon as tolerated after the surgery following your surgeon's instructions.

Return to Normal Activity

Please follow your physicians' instructions carefully on returning to normal activities including, but not limited to return to work, driving, and exercising.

Will I have difficulty swallowing?

RefluxStop® does not encircle the esophagus as in standard-of-care anti-reflux procedures. According to the RefluxStop® clinical trial, swallowing difficulties experienced prior to surgery in many instances improve or often even disappear post-surgery. If the esophagus is too damaged from refluxing acid, swallowing difficulties may remain, however, this can often be resolved by an endoscopic balloon dilatation.

Implant Card

Following your surgery, you will receive a RefluxStop® Implant Card. Carry your RefluxStop® Implant Card with you to notify care providers that you have received a RefluxStop®. If you lose this card, please contact your doctor's office to receive a replacement card.

Travel

Your doctor will advise when you are ready to travel. RefluxStop® will not interfere with airport security. You should carry your implant card when traveling so others will know you have an implanted device in case of an emergency.

MedicAlert

It is recommended that you register the device with MedicAlert Foundation (www.medicalert.org) or a similar organization.

Do I have to present an implant identification card at the airport security control?

This is not necessary as the implant is not made of metal or electronic components – in contrast to, for example, pacemakers which can cause problems at security controls.

When To Call Your Doctor

Upon discharge, your physician will supply you with post-surgical care instructions. Follow these carefully. Included will be a list of symptoms that, when experienced, will require you to contact the physician's office. Some of these may include, but are not limited to the following:

- Fever over 100.4 degrees or signs of infection
- Retching, heaving, or vomiting
- Difficulty swallowing or inability to swallow
- Painful swallowing
- Increased abdominal pain
- Nausea or vomiting
- Cough or difficulty breathing

What Studies Show

Clinical data on the RefluxStop® procedure includes but is not limited to a study of 50 patients* that have been followed for at least 5 years.

As RefluxStop® was available in Europe first, many independent studies representing real world patient data are available. 1,500+ RefluxStop® surgeries have been performed. Numerous articles (33) have been published on the investigator initiated studies from various hospitals in Europe. A pan-European registry is also in effect.

1,500+ RefluxStop® surgeries have been performed

The pivotal study of 50 patients has been followed for 5 years with key results summarized below.

Safety

From RefluxStop® implantation until the 5-year follow-up visit:

No complications related to the RefluxStop® device occurred during the entire study period.	No device deficiencies.	No deaths related to RefluxStop® and its procedure.
No device explants.	No device migration/erosion.	No esophageal dilation required.

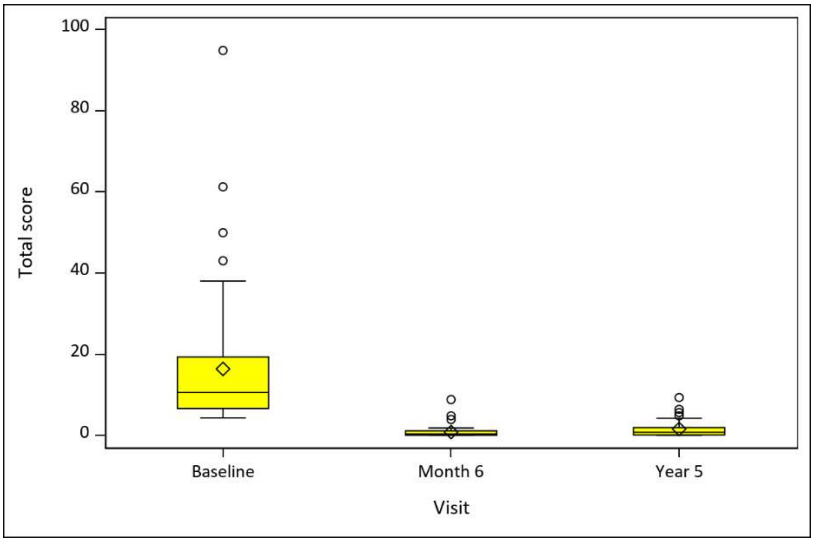
** 50 patients were included in the study and 44 of them participated in the five-year follow-up (3 subjects lost to COVID and 3 terminated the study early).*

Effectiveness

pH Testing (for Acid in the lower Esophagus)

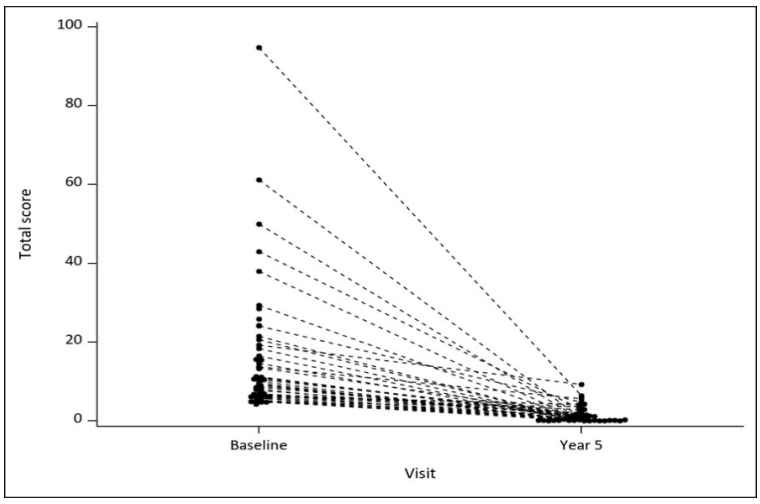
- The mean total time pH <4 was reduced by 90.4% from mean 16.35% before the procedure to 1.57% at 5-year follow-up.
- This positive pH result with patients experiencing a substantial and prolonged decrease in acid reflux duration throughout the post-procedure follow-up period is best presented in the two graphs below.
  - The first graph (Fig. 1) presents a mean successful pH value close to zero confirming very limited acid regurgitation into the esophagus and presenting similar outcomes both at 6 months and 5 years. This confirms long-term sustained treatment with the mean pH value at 5 years about one-third of the upper limit of the normal value range.
  - The second graph (Fig. 2) presents all individual results, showing substantial improvement in all patients with the majority scoring close to zero. These results further highlight the excellent, sustained and stable therapeutic efficacy of the device long-term.

Figure 1. 24-hour pH Monitoring Comparing Baseline, 6-month, and 5-year Values



NOTE: The central line within the box indicates the median score, while the diamond symbol represents the mean score. The boundaries of the box correspond to the 25th (bottom) and 75th (top) percentiles, and the whiskers extend to the range of non-outlier values. Circles beyond the whiskers denote outlier values.

Figure 2. 24-hour pH Monitoring Comparing Individual's Acid Exposure at Baseline and 5-year Values



NOTE: Each dashed line represents an individual subject's acid exposure at baseline and Year 5.

Quality of life score

Figure 3, Quality of life questionnaire score improved by 90%

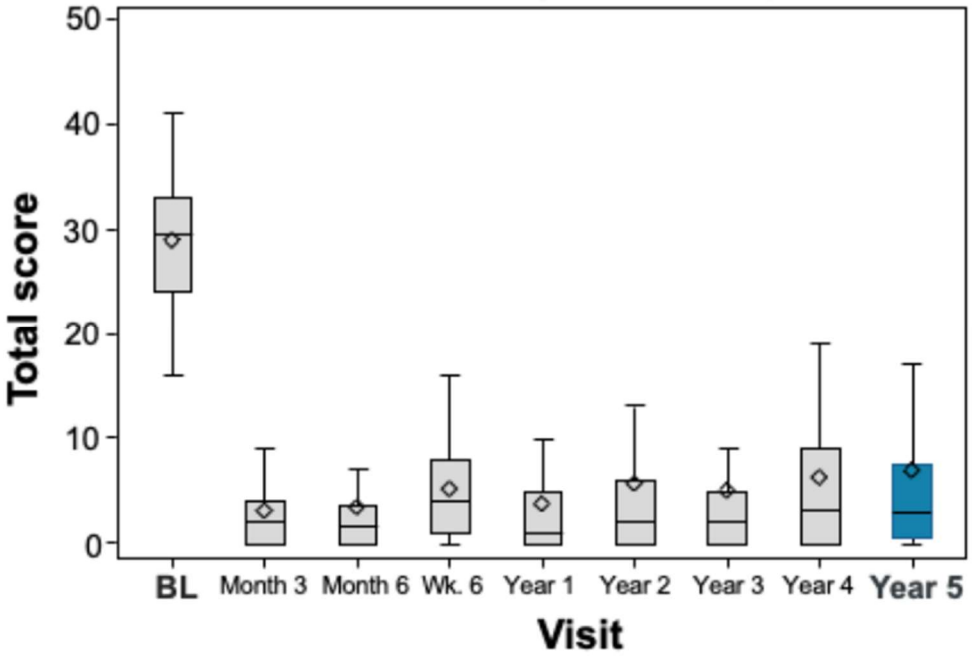


Fig. 3 Quality of life score improved from median 29.5 before surgery to 3.0 at 5 years follow-up – a 90% improvement

Gas bloating

Gas bloating is a side effect of both acid reflux and existing surgical standard of care procedures that substantially improved after the RefluxStop procedure

95.5% of subjects reported either no gas bloating, an improvement, or equal to baseline at the 5-year mark. In standard of care approximately 50% have this complication[3]

Post-procedure GERD Medication (PPI) Use

In this study:

100% of patients used Proton Pump Inhibitors (PPIs) daily prior to surgery.

98% of patients no longer required daily GERD medication at 6 months.

98% of patients no longer required daily GERD medication at 5 years.

Find Out More About the ARB and GERD

Anti-Reflux Barrier (ARB) also known as the gastroesophageal junction (GEJ):
This barrier prevents reflux of stomach content into the esophagus. Consisting of the crura muscle, the flap valve on the Angle of His, and the lower esophageal sphincter (LES).

Additional information can be found here: http://www.nlm.nih.gov/medlineplus/gerd.html

Find out more about RefluxStop®

The RefluxStop® procedure restores the ARB so the body can function normally.

Additional information about RefluxStop® can be found at: https://www.implantica.com/im-refluxstop/

Glossary

The Angle of His – is an acute angle between the great curvature of the stomach and the esophagus, and acts as an anti-reflux barrier by functioning like a valve. During gastric inflation, the gastroesophageal flap valve (GEFV) provides a pressure gradient against the reflux of stomach contents.

Anti-Reflux Barrier (ARB) prevents reflux of stomach content into the esophagus. Consisting of the crura muscle, the flap valve on the Angle of His, and the lower esophageal sphincter (LES).

Barium Esophagram or swallow x-ray – is used as an initial diagnostic test for several esophageal conditions such as a hiatal hernia, dysphagia (difficulty swallowing) as well as complications such as stricture, obstruction, narrowing, ulcers and tumors. During this procedure, the patient swallows barium, a white, chalky substance, which can then be viewed via x-ray. Using this procedure, the physician can view many abnormalities associated with the esophagus.

Barrett's esophagus – is a pre-cancerous disorder in which the lining of the lower esophagus (the tube that carries food from the throat to the stomach) is damaged by stomach acid.

Crura Muscle – has two functions, ventilator and "sphincter-like action on the esophagus."

Diaphragm – A dome-shaped muscular partition separating the thorax from the abdomen. It plays a major role in breathing, as its contraction increases the volume of the thorax and thus inflates the lungs.

Endoscopy – is a procedure where a doctor is able to see the inside lining of your digestive tract. This examination is performed using an endoscope (a flexible fiberoptic tube with a tiny camera at the end). The camera is connected to either an eyepiece for direct viewing or a video screen that displays the images on a color monitor. The endoscope allows diagnosis of gastrointestinal (GI) disease, esophagitis, and Barrett's esophagus.

Esophagus – is the tube that carries food, liquids and saliva from your mouth to the stomach.

Esophageal Manometry – is a test to measure the pressure inside the lower part of the esophagus. During the test, a thin, pressure-sensitive tube is passed through your mouth or nose into your stomach. Once in place, the tube is pulled slowly back into your esophagus.

Esophageal pH monitoring – is a test that measures how often and for how long stomach acid enters the food tube (esophagus) that leads from the mouth to the stomach. Often a wireless capsule is placed in lower esophagus, which wirelessly sends information.

Gastroesophageal Junction (GEJ) is the area of connection between esophagus and the stomach involving the sphincter (LES), flapvalve and angle of His.

Gastroesophageal Reflux Disease (GERD) – is a condition in which the stomach contents (food or liquid) pushes up backwards from the stomach into the esophagus (the tube from the mouth to the stomach). This action can irritate the esophagus, causing heartburn and other symptoms.

Glossary (continued)

Hiatal hernia – is the protrusion (bulging) of the upper part of the stomach into the chest through a tear or weakness in the diaphragm (crura muscle).

Laparoscopic surgery (keyhole) – is a modern minimally invasive surgical technique in which operations in the abdomen are performed through small incisions as opposed to the larger incisions needed in laparotomy surgery where a large incision is made.

Lower esophageal sphincter (LES) – is a ring of muscle that forms a valve at the lower end of the esophagus, where it joins the stomach. It's primary function is the protection of the esophagus from highly acidic stomach secretions.

Magnetic resonance imaging (MRI) – is a test that uses a magnetic field and pulses of radio wave energy to create pictures of organs and structures inside the body. In many cases MRIs give different information about these structures than what can be seen with an x-ray, ultrasound, or computed tomography (CT) scan. MRIs may also show problems that cannot be seen with other imaging methods.

Proton-pump inhibitors (PPIs) – are a group of drugs whose main action is to stop the production of stomach acid.

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