



RefluxStop™ treats the cause of acid reflux by restoring and maintaining the natural physiological anatomy

Gastroesophageal reflux disease

Gastroesophageal reflux disease (GERD or acid reflux) is a condition that develops when the reflux of stomach contents into the esophagus causes troublesome symptoms and/or complications¹.

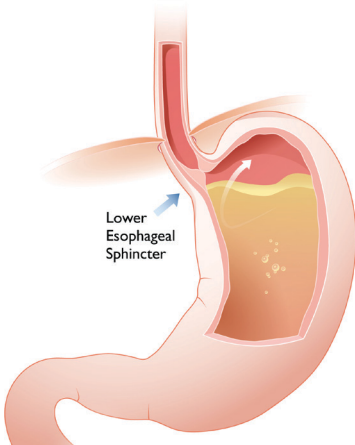


Figure 1

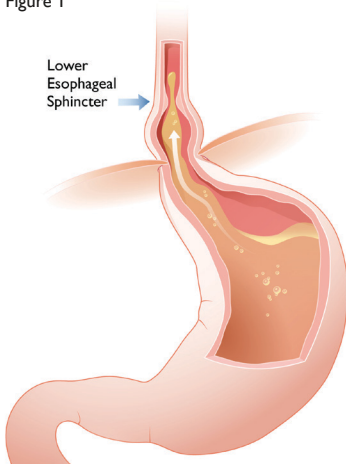


Figure 2

The Lower Esophageal Sphincter (LES) is located between the esophagus and the stomach. It allows food to pass into the stomach but prevents stomach content from flowing back into the esophagus. The esophageal sphincter functions properly when it is in its natural position below the diaphragm. (Figure 1)

How acid reflux occurs

The esophageal sphincter's natural position is compromised in those suffering from acid reflux². When the esophageal sphincter is too close to or even above the diaphragm, the pressure variations in the chest when breathing will prevent it from closing properly. This results in acid reflux (Figure 2).

Chronic reflux can lead to serious damage to the esophagus such as inflammation, ulceration and tissue changes. Such tissue changes are a precancerous condition known as Barrett's esophagus³, affecting 10-20% of daily acid reflux sufferers⁴.

Source:

1. Vakil N, van Zanten SV, Kahrilas P, et al. The Montreal definition and classification of gastroesophageal reflux disease: a global evidence-based consensus. *Am J Gastroenterol*. 2006;101:1900–20.
2. Martinucci I, de Bortoli N, Giacchino M, Bodini G, Marabotto E, Marchi S, Savarino V, Savarino E. Esophageal motility abnormalities in gastroesophageal reflux disease. *World J Gastrointest Pharmacol Ther*. 2014 May 6;5(2):86–96. doi: 10.4292/wjgpt.v5.i2.86. PMID: 24868489; PMCID: PMC4023328
3. The Karolinska Institute 2020; Cancer Research UK 2014; Lagergren et al. 1999
4. Modiano, Gerson 2007; Cossentino, Wong 2003

Typical symptoms and complications associated with reflux

- Heartburn
- Barrett's esophagus (precancerous tissue changes)
- Regurgitation (reflux of stomach content)
- Pain in the upper abdomen
- Bloating / gas bloat syndrome / Flatulence
- Difficulties swallowing
- Throat lump
- Chronic cough
- Hoarseness
- Tooth damage
- Bad breath

Treatment methods

Changing diet

Avoiding certain food and beverages that stimulate increased acid production can relieve symptoms but does not treat the cause of acid reflux.

Medication

Medication is the standard therapy, particularly at initial diagnosis. The production of acid is limited by proton pump inhibitors (PPIs), the most commonly used drug. The disadvantage is that reflux is not prevented and only the symptoms are alleviated due to lower acidity in the regurgitating stomach fluid. Furthermore, the symptoms often do not completely disappear¹ and continue to affect the patient's quality of life. Lifelong drug therapy can lead to severe complications and unwanted side effects.²



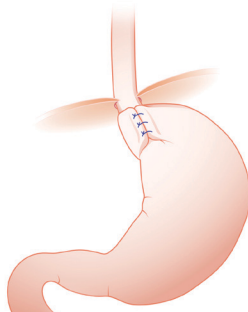
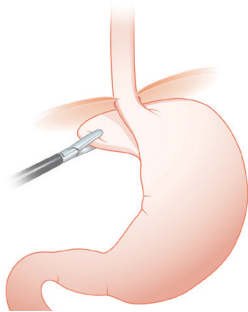
Source:

1. Raghunath AS et al. 2009

2. V. Gomm 2016; Moreira Faulhaber 2010; M. E. Grams et al. 2016; Rosch P 2010; Cheung K et al. 2017; Washio et al. 2016

Medication and cancer risk

Most alarmingly, acid reflux is associated with precancerous changes in the lower esophagus (Barrett's esophagus), which occurs in 10-20% of daily sufferers compared to 1-2% of the global population¹. There is no proof that cancer risk is prevented by drug therapy², which may be one of the reasons to choose a surgical treatment.



The cause of acid reflux can only be treated by surgery

The fundoplication procedure has been the standard anti-reflux operation since the 1950s, even though side effects are common. In this procedure, the upper part of the stomach is wrapped around the esophagus, encircling and putting pressure on the food passageway, which often leads to swallowing problems, gas bloating and inability to belch and vomit.

Source:

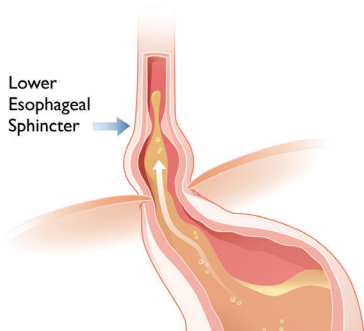
1. Modiano, Gerson 2007; Cossentino, Wong 2003;

2. The Karolinska Institute 2020; Brusselsaers et al. 2018

RefluxStop™ restores the natural functionality

RefluxStop™ is an implantable medical device which restores the natural function of the esophageal sphincter without encircling the food passageway.

RefluxStop™ maintains the esophageal sphincter in its natural position

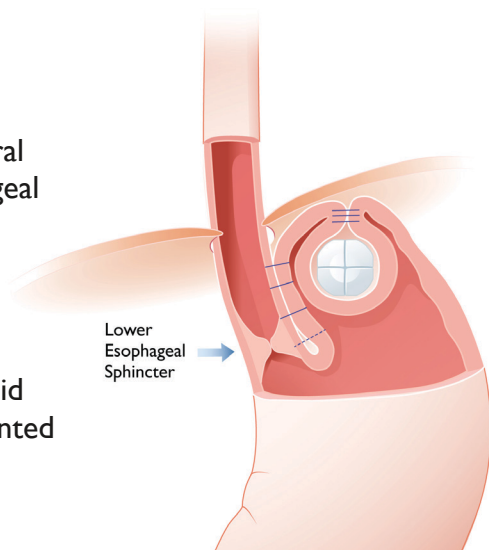


The esophageal sphincter's natural position is compromised in those suffering from acid reflux¹.

If the esophageal sphincter is temporarily or permanently above the diaphragm, it normally does not function correctly.

RefluxStop™ restores the natural anatomy by keeping the esophageal sphincter permanently in the abdomen, below the diaphragm.

It is not necessary to wrap and put pressure on the esophageal sphincter in order to prevent acid reflux as this often causes unwanted side-effects.



Source:

I. Martinucci I, de Bortoli N, Giacchino M, Bodini G, Marabotto E, Marchi S, Savarino V, Savarino E. Esophageal motility abnormalities in gastroesophageal reflux disease. World J Gastrointest Pharmacol Ther. 2014 May 6;5(2):86-96. doi: 10.4292/wjgpt.v5.i2.86. PMID: 24868489; PMCID: PMC4023328.

RefluxStop™ – safe and effective

CE marked
medical device

Clinical
investigation
successful



Approximate size and weight:
21.5 x 21.5 mm, 9 grams

Medical grade
silicone

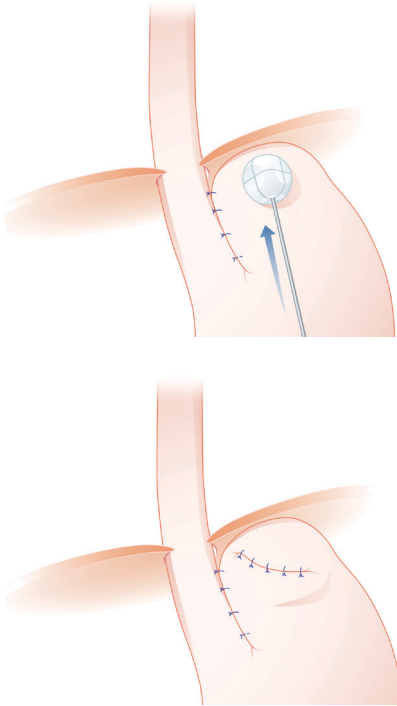


**The implant consists of
5 parts for optimal flexibility
and maximum safety.**

- Safe material with high biological compatibility
- Suitable for MRI without any restrictions
- Decades of clinical experience demonstrate the safety of medical grade silicone
- The RefluxStop™ is visible on X-rays
- Flexible rounded material

The RefluxStop™ surgery

- The surgery is performed as a minimally invasive procedure (keyhole surgery).
- The surgery typically lasts about an hour on average and is performed under general anesthesia.



The procedure

- Any hiatal hernia that may be present is repaired.
- The lower part of the esophagus with the sphincter is placed in its natural position below the diaphragm.
- The upper stomach (fundus) is attached to the esophagus, and RefluxStop™ is gently placed in a pocket of outer stomach wall and tissue fully covered with stomach wall.

Result

- RefluxStop™ prevents the sphincter from gliding up into the chest, preventing acid reflux by maintaining the natural anatomy and natural position of the lower esophageal sphincter.
- The food passageway is not encircled therefore unpleasant side effects associated with other anti-reflux procedures are kept to a minimum.

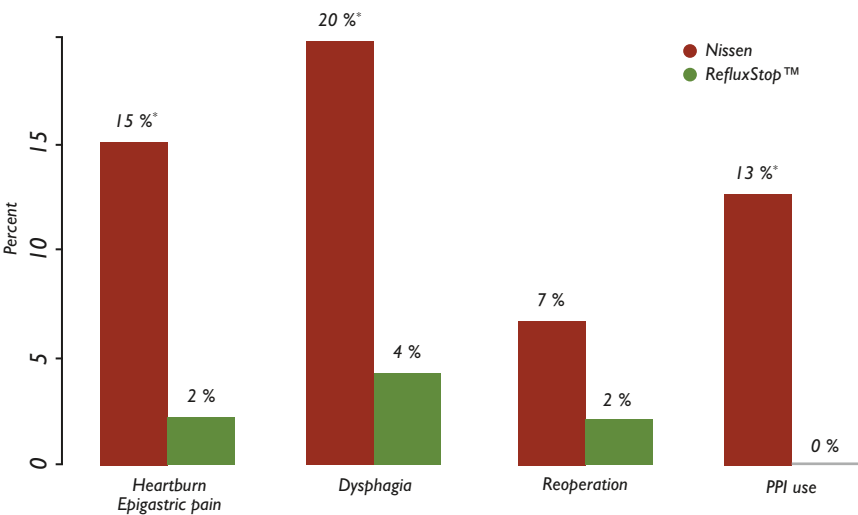
RefluxStop™ 3-year CE mark clinical trial results

Effectiveness at 3-year follow-up*

- 100% of the patients stopped taking regular daily PPI medication
- 98% had no acid reflux, as measured by 24-hour pH monitoring in the lower esophagus at 6 months
- 96% did not have any swallowing problems
- High patient satisfaction, with only 1 patient dissatisfied with the outcome (2%)
- No device was explanted
- No device specific complications

* 3 patients withdrew from the study, none of them taking PPIs at the time of withdrawal

RefluxStop™ in comparison to standard of care, the Nissen fundoplication procedure



*Statistically significant improvement

Who can benefit from surgery with RefluxStop™?

People who suffer from reflux who:

- have concerns about the side and long-term effects of medication (PPI).
- have symptoms not completely alleviated by medication, e.g. heartburn
- have concerns about the risks of precancerous esophageal lesions, as this risk is not reduced by PPI therapy¹
- experience chronic hoarseness and/or tooth damage due to acid reflux
- whose quality of life is impaired (everyday life and work)
- other anti-reflux procedures did not resolve the issue
- have concerns about the side effects and effectiveness of other surgical procedures that encircle the food passageway.

Source: 1.The Karolinska Institute 2020; Brusselsaers et al. 2018



RefluxStop™ – frequently asked questions

1. How do I find a RefluxStop™ surgeon in my area?

Please contact our customer service at info@implantica.com

2. What does the procedure cost and will it be covered by my insurance?

In most countries, health insurance will cover the costs. However, it varies from region to region. Please contact your physician for pricing and conditions.

3. How will the procedure impact acid reflux?

RefluxStop™ restores the natural position of the lower esophageal sphincter. Thereby the back flow of stomach content into the esophagus is prevented.

4. Does RefluxStop™ prevent laryngopharyngeal (silent) Reflux or only against GERD/GORD?

The RefluxStop™ procedure treats all types of reflux.

5. How fast can I return to normal activity?

Patients can usually leave the hospital the next day or up to a few days after the procedure. Typically, you will need a period of two to three weeks off work and you should not perform strenuous exercise or heavy lifting for the first six weeks. Please follow the recommendations of your surgeon.

6. When can I start eating normally?

Directly after surgery a liquid diet is recommended for a short period of time as your body is still healing. Thereafter you will be able to return to a normal diet. Please follow the dietary recommendations of your surgeon.

7. Will I have difficulties swallowing?

RefluxStop™ does not encircle and put pressure on the food passageway as is the case with existing procedures. According to the RefluxStop™ clinical trial you can even expect that swallowing problems experienced prior to surgery, in many instances will improve over time after surgery.

8. I have heard that belching is not possible anymore after other types of anti-reflux surgeries, and that gas bloating can occur.

Would such problems also be associated with RefluxStop™?

Since the RefluxStop™ procedure, does not encircle and put pressure on the food passageway belching should normally be possible.

Gas bloating is not associated with RefluxStop™ and may be reduced or disappear compared to before surgery.

9. Can I vomit after RefluxStop™ surgery? The ability to vomit is normally not affected by the RefluxStop™ procedure, as the food passageway is not encircled.

10. Will RefluxStop™ reduce my stomach capacity and thereby my appetite? The reduction of stomach volume following the RefluxStop™ procedure is minimal and should not affect your appetite.

11. What is the treatment success of the RefluxStop™ procedure? The clinical trial results are excellent compared to existing methods, however, as with any type of surgery, there is always a risk that the treatment will not meet the expected results.

12. Is the silicone material harmless and biocompatible? RefluxStop™ is made of tested biocompatible medical grade silicone, which has been used for decades in various medical implants.

13. What is the lifetime of the implant? RefluxStop™ is made of solid medical grade silicone and is therefore expected to last a lifetime.

14. RefluxStop™ shall remain implanted for the rest of my life. What if I need a re-operation? This would normally be possible as the RefluxStop™ procedure does not irreversibly change the anatomy.

15. Can I feel the implant in my daily life?
No, you will not feel the implant.

16. After I recovered from surgery, can I do what I did before?
Yes, normally there are no restrictions. Please ask your surgeon for details.

17. Do I have to present an implant card at the airport security control? This is not necessary as the implant is free of metal or electronics – in contrast to, for example, pacemakers which can cause problems at security controls.

18. Can I go for an MRI scan after a RefluxStop™ implantation? Yes, Magnetic Resonance Imaging is possible without any restrictions.

www.RefluxStop.com

Implantica CE Reflux Ltd
Sir Temi Zammit Buildings
Malta Life Sciences Park
San Gwann SGN 3000
Malta
info@RefluxStop.com



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