



**RefluxStop™ treats the cause of reflux
without compressing the food passageway**

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Gastroesophageal reflux disease

Gastroesophageal reflux disease (GERD or acid reflux) is caused by the reflux of acidic stomach fluid into the esophagus.



Figure 1

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

How acid reflux occurs

When the esophageal sphincter is too close to the diaphragm or even above the diaphragm, the sphincter cannot work properly, and acidic stomach fluid can flow back into the esophagus. While breathing, pressure variations are produced in the chest preventing the lower esophageal sphincter from functioning properly. This results in acid reflux (Figure 2).



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 esophagus I, affecting 10-20% of daily acid reflux sufferers².

Source: 1. The Karolinska Institute 2020; Cancer Research UK 2014; Lagergren et al. 1999
2. Modiano, Gerson 2007; Cossentino, Wong 2003

Typical symptoms and complications associated with reflux

- Heartburn
- Barrett's esophagus (precancerous tissue changes)
- Regurgitation (reflux of gastric fluids)
- 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 sufferers¹ 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 acid reflux operation since the 1950s, although side effects are common. In this procedure, the upper part of the stomach is wrapped around the esophagus, constricting the food passageway, which often leads to swallowing problems, gas bloating and inability to belch and vomit.



RefluxStop™ restores the natural functionality

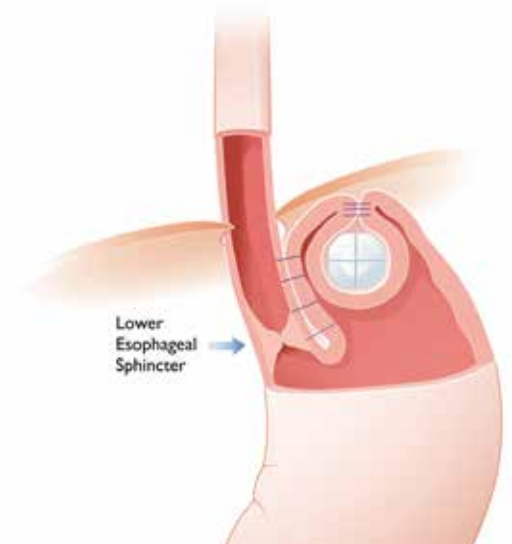
RefluxStop™ is an implantable medical device which restores the natural function of the esophageal sphincter without compressing the food passageway.

RefluxStop™ maintains the esophageal sphincter in its natural position



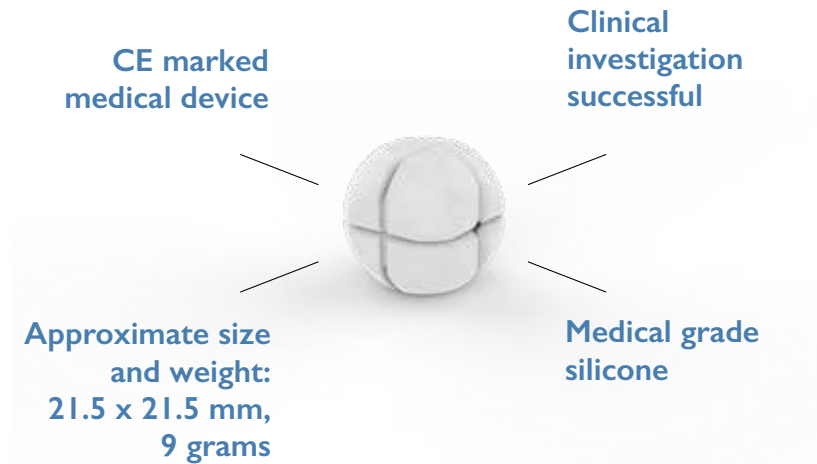
If the esophageal sphincter is temporarily or permanently above the diaphragm, it usually does not function correctly.

RefluxStop™ restores the natural anatomy by keeping the esophageal sphincter permanently in the abdomen, below the diaphragm. It is not necessary to wrap and constrict the esophageal sphincter in order to prevent reflux as this often causes unwanted side-effects.



Source: 1. Modiano, Gerson 2007; Cossentino, Wong 2003;
2. The Karolinska Institute 2020; Brusselsaers et al. 2018

RefluxStop™ – safe and effective

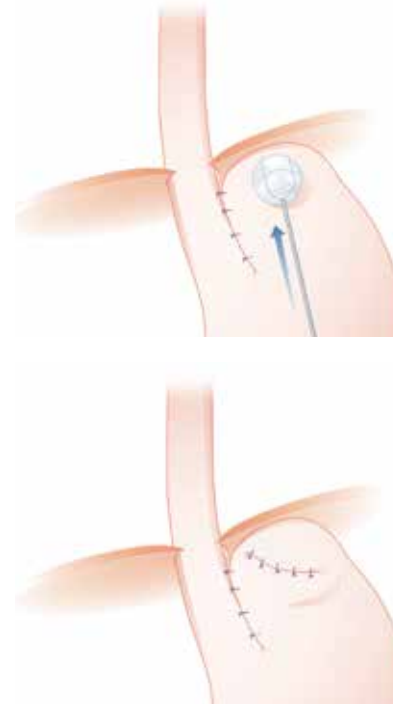


The implant consists of 5 parts for optimal flexibility and maximum safety.

- 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 called fundus is attached to the esophagus, and RefluxStop™ is placed on the outer stomach fundus wall and covered with stomach wall tissue.

Result

RefluxStop™ now 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 remains uncompressed avoiding related unpleasant side effects.

RefluxStop – 3-year results of our CE mark clinical trial

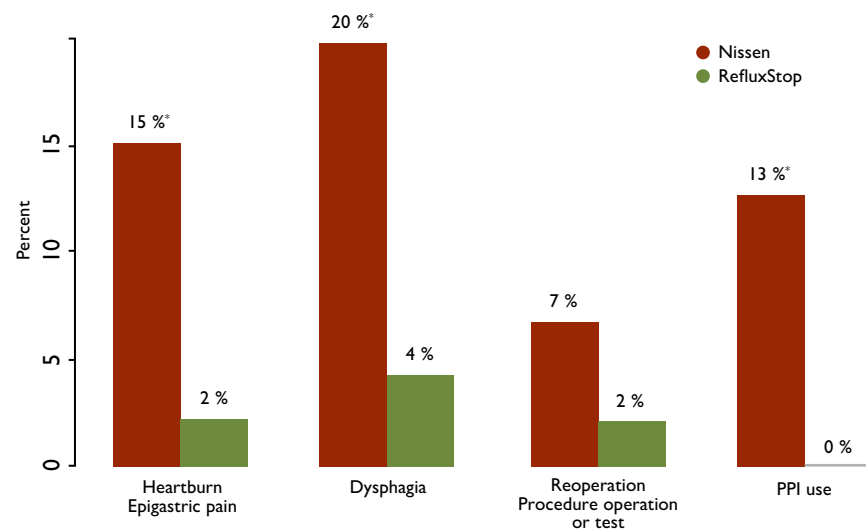
- No device was explanted
- No complication specifically related to the device

Efficacy at 3-year follow-up*

- 100% of the patients did not take regular daily PPI medication
- 98% had no acid reflux, as measured by 24-hour pH monitoring in lower esophagus
- 96% did not have any swallowing problems
- 2% of the patients were dissatisfied with the procedure

* 3 patients left the study earlier, none of them taking PPI and none of them having swallowing difficulties.

Comparison to standard of care, the Nissen fundoplication procedure



*Statistically significant improvement

Who can benefit from surgery with RefluxStop™?

People who suffer from reflux and

- who have concerns about the side effects and long-term effects of medication (PPI).
- whose symptoms cannot be completely alleviated by medication, e.g. heartburn
- who want to reduce the risks of precancerous lesions, as this risk is not reduced by PPI therapy¹
- who suffer from chronic hoarseness and/or tooth damage due to acid reflux
- who experience impairments in everyday life and work
- whose quality of life is impaired
- who have not been helped by other anti-reflux procedures
- who do not want other surgical procedures.

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



RefluxStop™ – frequently asked questions

1. Where can 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 and ask for price 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 acidic stomach fluid into the esophagus is prevented.

4. Does RefluxStop™ help against laryngopharyngeal (silent)

Reflux or only against GERD/GORD? The RefluxStop™ procedure treats all types of reflux.

5. How fast will I be back to normal life? Patients can usually leave the hospital after a few days. After one week you should be recovered.

6. When can I start eating normally? Directly after surgery you should follow a liquid diet for a short period of time. Thereafter you can eat normally again. Please follow the dietary recommendations of your surgeon.

7. Will I have difficulties swallowing? The food passageway is not affected by the RefluxStop™ procedure as is the case with existing procedures that compress the food passageway. According to the RefluxStop™ clinical trial you can even expect that swallowing problems in many instances will fade away over time even if you had difficulties swallowing before 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™? In contrast to other surgical treatment methods, the food passageway is not affected by the RefluxStop™ procedure, so 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 affected.

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™ surgery?

The results of the clinical trial 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 pass 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 MRI scan after RefluxStop™ implantation?

Yes, Magnetic Resonance Imaging is possible without any restrictions.