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89 Anonymous

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1. Project Number and Name - (Can be found on email) *

IP2010 Laparoscopic insertion of a non-active implant for gastro-oesophageal reflux disease

Your information

2. Name: *

Tom Wiggins

3. Job title: *

Consultant Upper Gastrointestinal Surgeon

4. Organisation: *

University Hospitals Birmingham

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

AUGIS BOMSS

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

6159025

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I am planning to begin using this technology within my practice soon. I have recently been through an application for utilisation within my NHS Trust as a 'novel therapeutic intervention' which was successful. I have attended educational sessions regarding the device and watched instructional videos. I am arranging to visit an expert surgeon perform cases in person in the near future.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

I am not currently using the device but have recently received approval to do so within my NHS Trust. In the UK, the device has been already approved and used at two NHS Trusts (i.e., Imperial St Mary's London and University Hospital Southampton). Another Trust (Chelsea and Westminster) has also received approval to begin utilising the device. The technology is currently in use at more than 25 hospitals across Europe with more than 800 patients treated so far since CE mark approval in Europe.

This procedure would only be performed by specialists in Upper Gastrointestinal surgery although Gastroenterologists may be involved in patient selection and/or workup.

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

This procedure is planned to be utilised as an alternative to traditional forms of anti-reflux surgery such as fundoplication and now magnetic sphincter augmentation. Evidence suggest it may be beneficial to patients in terms of unwanted side effects particularly associated with fundoplication (particularly increased gas bloating, inability to belch and post-operative dysphagia) with a similar safety profile. It may be of particular benefit in the subset of patients who have poor oesophageal motility and currently can not be safely offered surgical treatment of gastro-oesophageal reflux.

16. Does this have a multi-indication?

No

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

The basic approach to surgery is similar to the traditional technique of anti-reflux surgery in terms of laparoscopic techniques, patient positioning and operating time. The technique is however innovative in that it allows for recreation of the natural anti-reflux mechanism at the Angle of His and then placement of the device to re-enforce this mechanism and prevent gastro-oesophageal reflux. This avoids encircling of the oesophagus and therefore has potential significant benefits in terms of unwanted side effects following surgery (such as gas bloating, inability to belch and post-operative dysphagia) which may occur after fundoplication whilst maintaining a similar safety profile in the currently available literature. It may also be of particular benefit in the subset of patients who have poor oesophageal motility and currently cannot be safely offered surgical treatment of gastro-oesophageal reflux due to significant risk of inability to swallow effectively post-operatively.

18. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- (•) The first in a new class of procedure.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

It is likely that this device will be used alongside currently available surgical procedures for gastro-oesophageal reflux including fundoplication and magnetic sphincter augmentation. In particular for those patients with poor oesophageal motility this device may well become the standard of care in this particular patient sub-group as they have a current unmet need for surgical procedures to treat gastro-oesophageal reflux due to the significant risk of post-operative dysphagia.

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No, there are no substantial modifications related to the device. The surgical technique for this procedure has been standardised by consensus of an international group of senior upper gastrointestinal surgeons.

21. Do you think guidance would be helpful on this topic?

- (•) Yes
- ( ) No

Current management

22. Please describe the current standard of care that is used in the NHS.

Current available options for surgical management of gastro-oesophageal reflux are laparoscopic fundoplication or magnetic sphincter augmentation. These procedures are both completed using laparoscopically and can be performed either as a day-case or with overnight stay. In general results are good but some patients can be significantly troubled by gas-related symptoms post-operatively (gas-bloating, inability to belch, increased flatulence) particularly following fundoplication. Patients with poor oesophageal motility are also challenging to manage surgically due to the risk of post-operative dysphagia.

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

This device differs from the currently available surgical treatment for gastro-oesophageal reflux disease particularly in relation to it's mechanism of action. This device aims to avoid encircling of the oesophagus and helps to restore the functioning of the lower oesophageal sphincter by restoring the natural anti-reflux mechanism at this point. As detailed above it may avoid certain side effects and have direct utility for a group of patients who currently may not be offered surgical treatment of gastro-oesophageal reflux disease.

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

From the currently available literature this device appears to provide very good outcomes in terms of resolution of gastro-oesophageal reflux disease whilst maintaining an equivalent safety profile to other procedures. It avoids some of the troublesome symptoms which can occur after fundoplication (gas bloating, inability to belch, increased flatulence).

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Poor oesophageal motility on pre-operative testing is currently considered a relative contra-indication to anti-reflux surgery due to the risk of post-operative dysphagia. Therefore many of these cases are not considered for surgical treatment of gastro-oesophageal reflux. As this device avoids encircling of the oesophagus the risk of such dysphagia is reduced significantly and these patients would likely be set to particularly benefit from the utilisation of this surgical technology.

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Particularly for patients with poor oesophageal motility this would likely lead to improved overall outcomes. By moving more directly to an effective surgical treatment these patients would need less clinical assessments in both primary and secondary care. Reduced long term gas-related side effects may also reduce requirements in the post-operative period.

This is reflected in two recently published analyses assessing the cost-effectiveness and budget impact of RefluxStop in the UK NHS, finding it to be highly likely to be cost-effective (against PPI-based medical management, Fundoplication, and magnetic sphincter augmentation) [1] and associated with substantial reductions in post-operative complications (i.e., surgical failures, re-operations, and endoscopic oesophageal dilatations) at a marginal budget impact [2].

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

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

The clinical facilities necessary for this procedure are expected to be the already established specialised NHS centres of excellence providing standard abdominal laparoscopic operations.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

As a novel procedure, the manufacturer provides a comprehensive training programme; however, any surgeon having experience with standard laparoscopic fundoplication techniques likely has a short learning curve with implementation of this procedure.

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Given that the RefluxStop procedure does not involve encircling and putting pressure on the oesophagus, the device is designed to avoid most of the side effects that occur in other anti-reflux procedures and are burdensome for the patients, especially dysphagia, gas bloating and inability to belch and vomit. One foreseeable complication of importance is the possible migration or penetration of RefluxStop. No such complication has occurred in the CE study's both 4 and 5-year follow-up. However, both the device and procedure have been designed to mitigate potential harm caused by such complications. First of all, the device is encapsulated in the stomach wall forming a tear-drop shape formed by the encapsulated device protruding into the stomach cavity. Thereby in the unlikely event of such complications, the device will enter the stomach cavity. The RefluxStop™ device is designed in five separate pieces. The individual pieces of the device are as small as 15 mm and will easily pass through the pylorus (the opening into the intestine), the intestinal tract and out through the anus thereby avoiding re-operation measures, if such an event occurs, which is likely to occur unnoticed. Recurrence of reflux symptoms will most likely occur within a year, but no other harm is expected in a normal case. Lastly, the device is radiopaque, allowing visualization on X-ray.

In rare cases, an early penetration into the stomach cavity is caused by poor blood circulation in the stomach wall, which may be caused by a defect in patient's blood supply or too tight invagination or damaged stomach outer surface/serosa. Other general potential surgical harms (type and frequency) are equivalent to other types of laparoscopic anti-reflux surgery. According to published literature and data on file accumulated on an ongoing basis, procedure-related AEs are rare. Patients having known silicone allergy may experience hypersensitivity reactions and therefore should be avoided in patient selection for this new procedure. Since the procedure has several similarities to existing anti-reflux surgeries (e.g., fundoplication), the general procedure-related safety profile involving complications such as bleeding, infection, pulmonary or anaesthesia-related side effects are likely to be similar. Re-herniation is likely to be reduced by RefluxStop due to its principal action of acting like a mechanical stop hindering and reducing such side effects. The 4-year long-term safety outcomes data looks very promising and consistent with the real-world data presented by several anti-reflux experts in scientific meetings. Relevant literature sources pertaining to AEs are reported at the end of the document. Anecdotal AEs: N/A Theoretical AEs: silicone-induced hypersensitivity

30. Please list the key efficacy outcomes for this procedure/technology?

The key efficacy outcomes for this new technology include reduction in dysphagia and odynophagia, reduction in reflux symptoms (e.g., heartburn, regurgitation, gas bloating, ability to belch/vomit), reduction in PPI use, normalisation of 24-hour pH monitoring results, which are manifested in the improvement of the Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) score and patient satisfaction.

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

No major concerns currently identified.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

None currently considered.

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

Published abstracts:
· Harsányi L, Kincses Z, Altorjay Á. Treating acid reflux without compressing the food passageway: 3-year outcomes with the RefluxStop implant. Zeitschrift für Gastroenterologie. 2023;61(08):401. DOI: 10.1055/s-0043-1771713
· Borbély Y, Haltmeier T, Prevost GA, Dipietro Martinelli C, Kröll D. RefluxStop – A Novel Device to Address Gastroesophageal Reflux Disease in the Context of Esophageal Hypomotility. British Journal of Surgery. 2023;110(Supplement_5). DOI:10.1093/bjs/znad178.022
· Borbély Y, Kröll D, DiPietro Martinelli C, Haltmeier T, Prevost G. 442. The RefluxStop procedure as a novel surgical technique for management of gastroesophageal reflux disease: Two-year follow-up data at a hospital in Switzerland. Diseases of the Esophagus [Internet]. 2023; 36(Supplement_2). DOI: 10.1093/dote/doad052.233
· Fringeli Y, Kessler U, Linas I, Zehetner J. Laparoscopic Hiatal Hernia Repair with RefluxStop: Outcomes in 30 Patients with a Minimal Follow-Up of 12 Months. British Journal of Surgery. 2023;110(Supplement_5). DOI: 10.1097/sle.0000000000001256
· Lehmann T, Simkus M, Oehler C. Topic: Endoscopic Foregut Surgery (Including Endobariatrics) Abstract ID: 82A Retrospective Chart Review of 79 Patients Undergoing the RefluxStop Procedure to Manage Gastroesophageal Reflux Disease: Safety and Efficacy. Foregut. 2023;3(3):401. DOI: 10.1177/26345161231196002

Conference presentations

· Elshafei M, Lehmann T, editors. RefluxStop implant for gastroesophageal reflux disease: clinical outcomes at almost 2 years in a pooled cohort of 158 patients from two German hospitals. SAGES; 2024 17-20 April 2024; Cleveland Ohio.

Key findings were that, after surgery, total GERD-HRQL score was reduced to median of 2 (0-4) reduced from baseline of 22 (19-31.5), representing a decrease of 90.9% ($p<0.001$). At baseline, 96.5% patients were actively using PPI medication reduced to 3.6% at follow-up. All patients with dysphagia at baseline (11.4%) had resolution at follow-up, however 5 patients (3.2%) reported de-novo mild dysphagia that resolved spontaneously without intervention. No patients needed post-operative esophageal dilatation. Two patients (1.3%) had the device penetrate early into the stomach cavity without complications (believed due to pouch being sutured too tightly), one of whom later had re-operation with Toupet fundoplication. Hiatal hernia recurred in two patients (1.3%); in both cases the hernia was repaired keeping the device intact in its invaginated fundus pouch that was repositioned.

· Elshafei M. One-year follow-up of 15 patients with gastroesophageal reflux disease managed with the novel RefluxStop device. Høstmøtet (Norwegian Surgical Society) Conference; 2023 October 26-28, 2023; Oslo, Norway.

Key findings were that, at one year, GERD-HRQL score improved 82%. Heartburn and regurgitation symptoms improved or completely resolved in all patients except one. No patient had post-operative dysphagia. No reoperation or oesophageal dilatation was required, and no readmissions within the year.

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

· NCT02759094 Evaluation of Safety and Effectiveness of the RefluxStop Device in the Management of GERD (active, not recruiting).
· NCT05870163 Post-Market Registry for the Evaluation of RefluxStop in GERD Treatment. Number of enrolled patients (91) – Germany (43), Switzerland(24), Italy(19) and Norway(5)
· RXI005 / RENEW RCT (RCT RefluxStop vs. Nissen): to be conducted in Austria (submitted to Ethical Committee and waiting for approval), Switzerland (submitted to Ethical Committee and waiting for approval), Germany (submitted to Ethical Committee and waiting for approval), Italy (under preparation), Spain (under preparation), UK (under preparation)
· RXI008 / IM REVOLUTION RCT (RCT RefluxStop vs.PPI): under preparation and to be conducted in Austria, Switzerland, Germany, Italy, Spain, and UK

36. Please list any other data (published and/or unpublished) that you would like to share.

· Bjelović M, Harsányi L, Altorjay Á, Kincses Z, Forsell P. Non-active implantable device treating acid reflux with a new dynamic treatment approach: 1-year results: RefluxStop™ device; a new method in acid reflux surgery obtaining CE mark. BMC Surg. 2020;20(1):159. DOI: 10.1186/s12893-020-00794-9.
· Harsnányi, L, et al. Treating acid reflux without compressing the food passageway: 4-year safety and clinical outcomes with the RefluxStop device in a prospective multicenter study. Surg Endo, 2024, Accepted for publication June 2024.
· Fringeli Y, Linas I, Kessler U, Zehetner J. Laparoscopic Large Hiatal Hernia Repair With RefluxStop: Outcomes of Six Months Follow-up in Thirty Patients. Surg Laparosc Endosc Percutan Tech. 2024;34(2):143-9. DOI: 10.1097/sle.0000000000001256
· Fringeli Y, Linas I, Kessler U, Zehetner J. Short-term results of laparoscopic anti-reflux surgery with the RefluxStop device in patients with gastro-esophageal reflux disease and ineffective esophageal motility. Langenbecks Arch Surg. 2024;409(1):78. DOI: 10.1007/s00423-024-03264-5
· Schoppmann SF. Multicentric short term and safety study of ineffective esophageal motility patients treated with RefluxStop device. Scientific Reports. 2024. doi:Accepted for publication June 2024.

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Hard to estimate as the most suitable cohort is a subset of refractory GORD patients, however we anticipate a few hundred patients nationally could be treated with this new procedure in the initial years. Over 9 million people in the UK suffer from GORD today, of which at least 10% do not benefit from medical treatment. Anti-reflux surgery is considered in patients with chronic GERD who experience inadequate response, are intolerant to, or do not wish to continue lifelong medical therapy (such as PPIs). Today, approximately 2000-2500 anti-reflux procedures are performed annually in the UK.

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Efficacy outcomes:
· Symptoms relief
· 24-hour pH monitoring (not routinely performed post-operatively
· Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) score
· PPI usage
· Patient satisfaction
· Heartburn
· Regurgitation

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Safety outcomes:
· Dysphagia (reported as an AE or with GERD-HRQL dysphagia subscore >2)
· Esophagus dilatation
· Device-related SAEs
· Intra- and post-operative AEs

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

None to add

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

None

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Tom Wiggins

45. Date: *

29/06/2024

View results

Respondent

90 Anonymous

33:29
Time to complete

1. Project Number and Name - (Can be found on email) *

IP2010 Laparoscopic insertion of a non-active implant for gastro-oesophageal reflux diseas

Your information

2. Name: *

Fergus Noble

3. Job title: *

Consultant Surgeon

4. Organisation: *

University Hospital Southampton NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

AUGIS

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

6040316

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes, I am very familiar with this technology and procedure.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

I have started operating on patients under supervision of an experienced surgeon (Proctor) before performing independently soon. The procedure has several similarities to existing laparoscopic anti-reflux surgery with some specific unique steps for the implant.

The technology is currently in use at more than 25 hospitals across Europe with more than 800 patients treated so far since CE mark approval in Europe. In the UK, the device has been already approved and used at two NHS Trusts (i.e., Imperial St Mary's London and University Hospital Southampton) and additional two NHS Trusts just approved it for use (i.e., University Hospital Birmingham and Chelsea & Westminster, London) that are due to start operating with this procedure within the next 3 months or so.

No, this procedure is expected to be only used by specialist upper gastrointestinal surgeons Both gastroenterologists and upper gastrointestinal surgeons are involved in patient selection. If a patient is selected by an experienced surgeon or gastroenterologist, they are expected to receive the intended benefit from this anti-reflux procedure.

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. Does this have a multi-indication?

Yes - reflux.

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

The procedure has several similarities to the standard of care laparoscopic anti-reflux procedure in terms of safety and ease of operation. Mostly, it is a straightforward typical laparoscopic abdominal procedure with an addition of specific unique modifications and steps related to the implant placement and positioning. While there are many similarities in terms of certain steps of the procedure, overall, it is an innovative approach in anti-reflux surgery that utilises an intentional approach to restore the normal function of the anti-reflux barrier via repair of hiatal hernia, re-creation of the gastroesophageal flap valve, and stabilisation of the newly constructed anatomy.

18. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- (•) The first in a new class of procedure.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

The procedure has several similarities to the existing standard of care laparoscopic anti-reflux procedure in terms of safety and ease of operation; however, it is an innovative approach in anti-reflux surgery that utilises an intentional approach to restore the normal function of the anti-reflux barrier via repair of hiatal hernia re-creation of the gastroesophageal flap valve, and stabilisation of newly constructed anatomy.

According to the ongoing collection of evidence from clinical studies published and presented in leading scientific meetings, this procedure can be used as a surgical treatment alternative to the standard of care for general GERD patients and the results reported are very encouraging.

This new technology may fulfil an urgent unmet need for "difficult-to-treat" or "no adequate options at all" patient subgroups, such as those with concomitant ineffective oesophageal motility and large hiatal hernia where there is a dire need for an effective treatment.

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No, there are no substantial modifications related to the device. The surgical technique for this procedure has been standardised by consensus of an international group of senior upper gastrointestinal surgeons.

21. Do you think guidance would be helpful on this topic?

- ( ) Yes
- ( ) No

Current management

22. Please describe the current standard of care that is used in the NHS.

The current standard-of-care treatment options in the UK NHS is fundoplication or Linx.

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

No.

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

According to presentations at congresses from various surgeons, published clinical results and data on file accumulated on an ongoing basis, this new technology is safe in patients with refractory GERD and seems to have fewer side effects compared to alternative surgical treatments. This treatment seems to be a superior alternative for all patients. It expands the indication to patient groups that lack any good treatment today, represented in a real-world setting, such as severe cases involving: Barrett's esophagus, advanced esophagitis and difficult-to-treat comorbidities such as esophageal dysmotility and large hiatal hernia.

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Patients with esophageal dysmotility.

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Patients with poor oesophageal motility currently do not have satisfactory therapeutic options and are often sent back and forth between their GP and the local secondary care gastroenterology department. The use of this procedure would likely resolve such issues in these patients while also improving symptoms and quality of life. As a result, patients would be expected to be discharged following symptom resolution, presumably not utilising further GP and gastroenterology resources that can be allocated elsewhere.

The post-operative interventions or complications (i.e., short-term oesophageal dilatation, re-herniation, post-operative dysphagia, and re-operation) observed in existing treatment options are expected to be reduced or minimised after symptom resolution. The burden on the healthcare system could be reduced due to reduction in post-op complications, symptoms, hospital and GP visits.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

No changes required.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

As a novel procedure, the manufacturer provides a comprehensive training programme; however, any surgeon having experience with standard laparoscopic fundoplication techniques likely has a short learning curve with the implementation of this procedure.

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Given that the RefluxStop procedure does not involve encircling and putting pressure on the oesophagus, the device is designed to avoid most of the side effects that occur in other anti-reflux procedures and are burdensome for the patients, especially dysphagia, gas bloating and inability to belch and vomit.

One foreseeable complication of importance is the possible migration or penetration of RefluxStop. No such complication has occurred in the CE study's both 4 and 5-year follow-up. However, both the device and procedure have been designed to mitigate potential harm caused by such complications. First of all, the device is encapsulated in the stomach wall forming a tear-drop shape formed by the encapsulated device protruding into the stomach cavity. Thereby in the unlikely event of such complications, the device will enter the stomach cavity. The RefluxStop™ device is designed in five separate pieces. The individual pieces of the device are as small as 15 mm and will easily pass through the pylorus (the opening into the intestine), the intestinal tract and out through the anus thereby avoiding re-operation measures, if such an event occurs, which is likely to occur unnoticed. Recurrence of reflux symptoms will most likely occur within a year, but no other harm is expected in a normal case. Lastly, the device is radiopaque, allowing visualization on X-ray. In rare cases, an early penetration into the stomach cavity is caused by poor blood circulation in the stomach wall, which may be caused by a defect in patient's blood supply or too tight invagination or damaged stomach outer surface/serosa.

Other general potential surgical harms (type and frequency) are equivalent to other types of laparoscopic anti-reflux surgery.

Patients having known silicone allergy may experience hypersensitivity reactions and therefore should be avoided in patient selection for this new procedure.

Since the procedure has several similarities to existing anti-reflux surgeries (e.g., fundoplication), the general procedure-related safety profile involving complications such as bleeding, infection, pulmonary or anaesthesia-related side effects are likely to be similar.

Re-herniation is likely to be reduced by RefluxStop due to its principal action of acting like a mechanical stop hindering and reducing such side effects. The 4-year long-term safety outcomes data looks very promising and consistent with the real-world data presented by several anti-reflux experts in scientific meetings.

30. Please list the key efficacy outcomes for this procedure/technology?

The key efficacy outcomes for this new technology include reduction in dysphagia and odynophagia, reduction in reflux symptoms (e.g., heartburn, regurgitation, gas bloating, ability to belch/vomit), reduction in PPI use, normalisation of 24-hour pH monitoring results, which are manifested in the improvement of the Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) score and patient satisfaction.

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

The procedure seems to be quite safe and effective. No major concerns.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Not currently known or reported.

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

Harsányi L, Kincses Z, Altorjay Á. Treating acid reflux without compressing the food passageway: 3-year outcomes with the RefluxStop implant. Zeitschrift für Gastroenterologie. 2023;61(08):401. DOI: 10.1055/s-0043-1771713 ·

Borbély Y, Haltmeier T, Prevost GA, Dipietro Martinelli C, Kröll D. RefluxStop – A Novel Device to Address Gastroesophageal Reflux Disease in the Context of Esophageal Hypomotility. British Journal of Surgery. 2023;110(Supplement_5). DOI:10.1093/bjs/znad178.022 ·

Borbély Y, Kröll D, DiPietro Martinelli C, Haltmeier T, Prevost G. 442. The RefluxStop procedure as a novel surgical technique for management of gastroesophageal reflux disease: Two-year follow-up data at a hospital in Switzerland. Diseases of the Esophagus [Internet]. 2023; 36(Supplement_2). DOI: 10.1093/dote/doad052.233 ·

Fringeli Y, Kessler U, Linas I, Zehetner J. Laparoscopic Hiatal Hernia Repair with RefluxStop: Outcomes in 30 Patients with a Minimal Follow-Up of 12 Months. British Journal of Surgery. 2023;110(Supplement_5). DOI: 10.1097/sle.0000000000001256 ·

Lehmann T, Simkus M, Oehler C. Topic: Endoscopic Foregut Surgery (Including Endobariatrics) Abstract ID: 82A Retrospectivehe RefluxStop Procedure to Manage Gastroesophageal Reflux Disease: Safety and Efficacy. Foregut. 2023;3(3):401. DOI: 10.1177/26345161231196002 Conference presentations ·

Elshafei M, Lehmann T, editors. RefluxStop implant for gastroesophageal reflux disease: clinical outcomes at almost 2 years in a pooled cohort of 158 patients from two German hospitals. SAGES; 2024 17-20 April 2024; Cleveland Ohio. Key findings were that, after surgery, total GERD-HRQL score was reduced to median of 2 (0-4) reduced from baseline of 22 (19-31.5), representing a decrease of 90.9% ($p<0.001$). At baseline, 96.5% patients were actively using PPI medication reduced to 3.6% at follow-up. All patients with dysphagia at baseline (11.4%) had resolution at follow-up, however 5 patients (3.2%) reported de-novo mild dysphagia that resolved spontaneously without intervention. No patients needed post-operative esophageal dilatation. Two patients (1.3%) had the device penetrate early into the stomach cavity without complications (believed due to pouch being sutured too tightly), one of whom later had re-operation with Toupet fundoplication. Hiatal hernia recurred in two patients (1.3%); in both cases the hernia was repaired keeping the device intact in its invaginated fundus pouch that was repositioned. ·

Elshafei M. One-year follow-up of 15 patients with gastroesophageal reflux disease managed with the novel RefluxStop device. Høstmøtet (Norwegian Surgical Society) Conference; 2023 October 26-28, 2023; Oslo, Norway. Key findings were that, at one year, GERD-HRQL score improved 82%. Heartburn and regurgitation symptoms improved or completely resolved in all patients except one. No patient had post-operative dysphagia. No reoperation or oesophageal dilatation was required, and no readmissions within the year.

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

NCT02759094 Evaluation of Safety and Effectiveness of the RefluxStop Device in the Management of GERD (active, not recruiting). · NCT05870163 Post-Market Registry for the Evaluation of RefluxStop in GERD Treatment. Number of enrolled patients (91) – Germany (43), Switzerland(24), Italy(19) and Norway(5) ·

RXI005 / RENEW RCT (RCT RefluxStop vs. Nissen): to be conducted in o Austria (submitted to Ethical Committee and waiting for approval)
o Switzerland (submitted to Ethical Committee and waiting for approval) o Germany (submitted to Ethical Committee and waiting for approval) o Italy (under preparation) o Spain (under preparation)
o UK (under preparation)

RXI008 / IM REVOLUTION RCT (RCT RefluxStop vs.PPI): under preparation and to be conducted in Austria, Switzerland, Germany, Italy, Spain, and UK

36. Please list any other data (published and/or unpublished) that you would like to share.

Bjelović M, Harsányi L, Altorjay Á, Kincses Z, Forsell P. Non-active implantable device treating acid reflux with a new dynamic treatment approach: 1-year results: RefluxStop™ device; a new method in acid reflux surgery obtaining CE mark. BMC Surg. 2020;20(1):159. DOI: 10.1186/s12893-020-00794-9.

Harsnányi, L, et al. Treating acid reflux without compressing the food passageway: 4-year safety and clinical outcomes with the RefluxStop device in a prospective multicenter study. Surg Endo, 2024, Accepted for publication June 2024.

Fringeli Y, Linas I, Kessler U, Zehetner J. Laparoscopic Large Hiatal Hernia Repair With RefluxStop: Outcomes of Six Months Follow-up in Thirty Patients. Surg Laparosc Endosc Percutan Tech. 2024;34(2):143-9. DOI: 10.1097/sle.0000000000001256

Fringeli Y, Linas I, Kessler U, Zehetner J. Short-term results of laparoscopic anti-reflux surgery with the RefluxStop device in patients with gastro-esophageal reflux disease and ineffective esophageal motility. Langenbecks Arch Surg. 2024;409(1):78. DOI: 10.1007/s00423-024-03264-5

Schoppmann SF. Multicentric short term and safety study of ineffective esophageal motility patients treated with RefluxStop device. Scientific Reports. 2024. doi:Accepted for publication June 2024.

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Hard to estimate as the most suitable cohort is a subset of refractory GORD patients, however we anticipate a few hundred patients nationally could be treated with this new procedure in the initial years.

Over 9 million people in the UK suffer from GORD today, of which at least 10% do not benefit from medical treatment. Anti-reflux surgery is considered in patients with chronic GERD who experience inadequate response, are intolerant to, or do not wish to continue lifelong medical therapy (such as PPIs). Today, approximately 2000-2500 anti-reflux procedures are performed annually in the UK

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Efficacy outcomes: · Symptoms relief · 24-hour pH monitoring · Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) score · PPI usage · Patient satisfaction · Heartburn · Regurgitation

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Safety outcomes: · Dysphagia (reported as an AE or with GERD-HRQL dysphagia subscore >2) · Esophagus dilatation · Device-related SAEs · Intra- and post-operative AEs

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

nil

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

Nil

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Fergus Noble

45. Date: *

01/07/2024

View results

Respondent

88 Anonymous

213:51
Time to complete

1. Project Number and Name - (Can be found on email) *

IP2010 Laparoscopic insertion of a non-active implant for gastro-oesophageal reflux disease

Your information

2. Name: *

Naim Fakih Gomez

3. Job title: *

Consultant Upper GI and Bariatric Surgery

4. Organisation: *

Chelsea and Westminster NHS trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

7481642

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I am familiar with the procedure and have observed several cases. I am looking at starting performing this procedure in September 2024.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

I have not used it as of today. I have observed several cases abroad and in NHS trust (St Mary's Hospital - Imperial college london trust). I am aware another NHS Trust (Southampton) has implemented this.
-This is done only by Upper GI surgeons.
-We usually would receive these patients from Gastroenterology colleagues.

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes.

16. Does this have a multi-indication?

not that I am aware of

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is a novel approach, but in accordance of the concept of enhancing the lower oesophageal sphincter. Other procedure including an implant with magnetic beads enhances and augments the sphincter function as well. It does though have a different mode of action in comparison to other surgical options as it does not involve encircling the oesophagus. This approach appears to cause much less post-operative dysphagia.

18. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- (•) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

This would be an option in the surgical armamentarium for GORD.

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

As far as I am aware, there has been no major modifications in the technique (just minor ones optimising the positioning of the implant)

21. Do you think guidance would be helpful on this topic?

- (•) Yes
- ( ) No

Current management

22. Please describe the current standard of care that is used in the NHS.

Currently the standard of care is medical treatment and surgical including fundoplication (full wrap vs partial). There is a cohort of patients with significant dysmotility which we would not particularly encourage surgery or offer surgery , and who will likely benefit from this procedure.

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

The alternative would be a magnetic beads ring (Linx) which has the downside that is contraindicated in patients with dysmotility whereas this wouldn't.

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

The main benefits is the potential to reduce the risk of postoperative dysphagia.

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Mainly the patients with oesophageal dysmotility who currently have no option with good outcomes.

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes, for patients with oesophageal dysmotility and preoperative dysphagia who would have better outcomes related to postoperative dysphagia and thus reducing readmission rates and the requirement for postoperative endoscopic dilatation.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

None.
Would just need the implant and the introduction kit.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

The training is mainly from a surgical technique prespective.
Other specialities like radiology / gastroenterology /emergency department have to be introduced to the implant as they might see them during their practice. (Xrays, endoscopy,etc...)

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

The risks are the same as for existing anti-reflux procedures. In the CE mark study (Bjelović et al. BMC Surgery (2020) 20:159) there were no serious adverse events related to the implant, no device failures and no removals.

A 4 year follow up study presented in SAGES 2024 , there were no device-related adverse events, oesophageal dilatations, migrations or explants during the entire study period. One procedure-related adverse event (AE) occurred between 1– 4 years: heartburn with a pathologic pH-result; contrast swallow directly post-surgery showed the device positioned too low. Only one dysphagia AE was recorded, though the score for dysphagia in this patient actually decreased from baseline score 5 to score 2. Two patients were dissatisfied, though with normal 24-h pH monitoring, whereof 1 had confirmed gastritis, indicating dissatisfaction for reasons other than acid reflux (data on file).

-Theoretically there might be an erosion into the abdominal cavity, for which the device would disassemble into 5 pieces which could be excreted through the digestive tract.
A potential risk of intrabdominal migration, which theoretically should not cause any issues. The parts of the implant can be extracted laparoscopically if so, and are radioopaque on Xray , so can be detected easily intraoperatively.

30. Please list the key efficacy outcomes for this procedure/technology?

In a presentation in SAGES 2024 the results were of median 90% reduction in GERD-HRQL score from baseline, with only 2/47 patients taking regular daily proton pump inhibitors (PPIs), though with normal 24-h pH

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

THe main uncertainity is the outcomes over the long term more than 10 years. The alternative fundoplication has high reflux recurrence rates of more than 60%. Anything below that number is a better option. As the alternatives are not great, on a risk benefit balance, I do not think these uncertainties are concerning.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

I do not think so.

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

Borbély Y, Haltmeier T, Prevost GA, Dipietro Martinelli C, Kröll D. RefluxStop – A Novel Device to Address Gastroesophageal Reflux Disease in the Context of Esophageal Hypomotility. British Journal of Surgery. 2023;110(Supplement_5) https://doi.org/10.1093/bjs/znad178.022.[4]
• Borbély Y, Kröll D, DiPietro Martinelli C, Haltmeier T, Prevost G. 442. The RefluxStop procedure as a novel surgical technique for management of gastroesophageal reflux disease: Two-year follow-up data at a hospital in Switzerland. Diseases of the Esophagus [Internet]. 2023; 36(Supplement_2). https://doi.org/10.1093/dote/doad052.233.[5]
• Harsányi L, Kincses Z, Altorhay Á. Treating acid reflux without compressing the food passageway: 3-year outcomes with the RefluxStop implant. Zeitschrift für Gastroenterologie. 2023;61(08):401 https://doi.org/10.1055/s-0043-1771713. [3]
• Lehmann T, Simkus M, Oehler C. Topic: Endoscopic Foregut Surgery (Including Endobariatrics)Abstract ID: 82A Retrospective Chart Review of 79 Patients 5

Undergoing the RefluxStopTM Procedure to Manage Gastroesophageal Reflux Disease: Safety and Efficacy. Foregut. 2023;3(3):401- https://doi.org/10.1177/26345161231196002 [6]
Published review
A technical review article by Professor Stefan has also been published, which provides a high-level expert overview of the technology [7]. It is available here: https://pubmed.ncbi.nlm.nih.gov/36255718/.
Published economic data
Two publications providing detailed economic evaluation are available.
A cost-effectiveness analysis [8], available at https://doi.org/10.1080/13696998.2023.2201063, comparing RefluxStopTM to PPI- based medical management, Nissen fundoplication, and the LINX reflux management system, using a UK National Health Service (NHS) perspective, concluded that RefluxStopTM was highly likely to be a cost-effective treatment for GORD when a patient's lifetime is considered.
A budget impact analysis [9], available at https://doi.org/10.36469%2F001c.90924, assessed the impact associated with introducing RefluxStopTM as a treatment option in the NHS in England and Wales.

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

There are two trials registered on ClinicalTrials.gov:
1) NCT02759094 Evaluation of Safety and Effectiveness of the RefluxStop Device in the Management of GERD (active, not recruiting)
2) NCT05870163 Post-Market Registry for the Evaluation of RefluxStop in GERD Treatment (recruiting).
3) Planning of two additional European RCTs is at an advanced stage, both of which will recruit UK patients.

36. Please list any other data (published and/or unpublished) that you would like to share.

nad

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

10-15 patients in my practice

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

reduction in GERD-HRQL.
improvement in symptoms and requirement for additional pH testing and contrast swallow imaging.

Satisfaction rate, daily PPI usage, reported regurgitation.

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

device- or procedure-related serious adverse events
device migration
dysphagia/odynophagia scores.

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

Clinical trials which are in the planning stages

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

Sponsored travel to see cases in Switzerland (4-5 april 2023) by manufacturer (Implantica).

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (•) I agree
- ( ) I disagree

Signature

44. Name: *

Naim Fakih Gomez

45. Date: *

28/06/2024

View results

Respondent

3 Anonymous

12:29
Time to complete

1. Project Number and Name - (Can be found on email) *

IP2010 laparoscopic insertion of a non-active implant for gastro-oesophageal reflux disease

Your information

2. Name: *

Christopher Peters

3. Job title: *

Clinical Senior Lecturer and Consultant Upper GI Surgeon

4. Organisation: *

Imperial College London

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

RCSEng, GMC

7. Nominated/ratified by (if applicable):

BSG Oesophageal Committee

8. Registration number (e.g. GMC, NMC, HCPC) *

6050491

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

10. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I assume this is the Reflux Stop device as it is not clear- if so I am aware of the principles of how it works and how this differs from Lynx- which is in a significant way.

11. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

This device is not currently widely used at all, I know of a handful of surgeons who are placing it. It should only be placed by specialist Upper GI Surgeons who are selecting patients for it. I am not using it.

12. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

Yes

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Innovative and a completely novel approach that differs significantly from the Linx device.

16. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- (•) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

In addition as not going to help patients with large hiatus hernias for example.

Current management

18. Please describe the current standard of care that is used in the NHS.

Laparoscopic fundoplication- various types.

19. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

    The Linx device has already been assessed and is another novel alternative to the historical surgery but this works as a ring of magnetic beads. Also there are various endoscopic techniques being commercialised.

Potential patient benefits and impact on the health system

20. What do you consider to be the potential benefits to patients from using this procedure/technology?

    Good reflux control with less side effects. Quick less risky surgery.

21. Are there any groups of patients who would particularly benefit from using this procedure/technology?

    Simple reflux with good oesophageal motility.

22. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    Could lead to quicker surgery and therefore more patients treated. I am unsure if it will lead to improved outcomes.

23. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    None apart from the availability of the device.

24. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    Yes need to be trained to place it.

Safety and efficacy of the procedure/technology

25. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    Foreign body reaction. Erosion

26. Please list the key efficacy outcomes for this procedure/technology?

Treatment of symptomatic reflux, QoL.

27. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Efficacy of the treatment and longevity.

28. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Efficacy.

29. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

30. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

None specific

31. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

Not that I can find

32. Please list any other data (published and/or unpublished) that you would like to share.

None

Other considerations

33. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Very difficult to predict. Maybe 30% of patient with reflux would be suitable.

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Reduction in Deemester score.
Validated Reflux QoL scores.
Symptom control at 5 years.
PPI use at 5 years.

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Dysphagia
Excess gass / inability to belch.
Erosion.

Further comments

36. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

None

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

37. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

38. Description of interests, including relevant dates of when the interest arose and ceased. *

N/A

39. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

    Please note, all declarations of interest will be made publicly available on the NICE website. *

    - (●) I agree
    - ( ) I disagree

Signature

40. Name: *

    Christopher Peters

41. Date: *

    15/05/2023

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP2010 Laparoscopic insertion of a non-active implant for gastro-oesophageal reflux disease

Your information

Name:	Mr Ahmed Ahmed
Job title:	*Consultant Upper GI and Bariatric Surgeon*
Organisation:	*St Mary's Hospital, Imperial College Healthcare*
Email address:	[redacted]
Professional organisation or society membership/affiliation:	FRCS
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4305462

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	**Yes, I am very familiar with this technology and procedure.** **Option 1**- I am an active user of this technology. I have participated in several training steps supported by the manufacturer. The procedure has several similarities to existing laparoscopic anti-reflux surgery with some specific unique steps for the implant and therefore my previous experience as an anti-reflux surgeon is of value. The training steps included: 1. Attending an online seminar offered by an expert surgeon (webinar). 2. Joining an expert surgeon and observed cases in person at specialist centre's operating room, 3. I have operated patients under supervision of an experienced surgeon (Proctor) before performing independently. The technology is currently in use at more than 25 hospitals across Europe with more than 800 patients treated so far since CE mark approval in Europe. In the UK, the device has been already approved and used at two NHS Trusts (i.e., Imperial St Mary's London and University Hospital Southampton) and additional two NHS Trusts just approved it for use (i.e., University Hospital Birmingham and Chelsea & Westminster, London) that are due to start operating with this procedure within the next 3 months or so. There are several more Trusts that are actively considering it so may start before the end of the year.

	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	No, this procedure is expected to be only used by specialist upper gastrointestinal surgeons Both gastroenterologists and upper gastrointestinal surgeons are involved in patient selection. If a patient is selected by an experienced surgeon or gastroenterologist, they are expected to receive the intended benefit from this anti-reflux procedure.
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. I have had no involvement in research of this procedure. Other (please comment): I have undergone training for the procedure/surgery and have personal experience operating on patients with indication for this treatment.
3	Does the title adequately reflect the procedure?	Yes

	Is the proposed indication appropriate? If not, please explain.	Yes
	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?	The procedure has several similarities to the existing standard of care laparoscopic anti-reflux procedure in terms of safety and ease of operation. Mostly, it is a straightforward typical laparoscopic abdominal procedure with an addition of specific unique modifications and steps related to the implant placement and positioning. While there are many similarities in terms of certain steps of the procedure, overall, it is an innovative approach in anti-reflux surgery that utilises an intentional approach to restore the normal function of the anti-reflux barrier via repair of hiatal hernia, re-creation of the gastroesophageal flap valve, and stabilisation of the newly constructed anatomy. As shown in the four-year long-term efficacy data from the CE study presented in scientific meetings, this procedure's novel mode of action leads to fewer side effects compared to the current traditional approaches. This technology completely circumvents the troublesome mode of action (i.e., encirclement of the distal oesophagus) of existing procedures, which is associated with unwanted post-operative outcomes. The procedure's safety and efficacy data look excellent so far. Based on patient outcomes from the CE study and real-world experiences reported by leading experts in the UK and Europe, this technology offers a unique opportunity to achieve superior and sustainable patient outcomes in the long run. The procedure entails total/comprehensive restoration of normal anatomic and physiologic function of the anti-reflux barrier to treat GERD. By contrast, existing anti-reflux methodologies simply focus on one of these important attributes, improving closure at the distal oesophagus.
	Which of the following best describes the procedure (please choose one):	Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. Definitely novel and of uncertain safety and efficacy.

		The first in a new class of procedure. The procedure has several similarities to the existing standard of care laparoscopic anti-reflux procedure in terms of safety and ease of operation; however, it is an innovative approach in anti-reflux surgery that utilises an intentional approach to restore the normal function of the anti-reflux barrier via repair of hiatal hernia re-creation of the gastroesophageal flap valve, and stabilisation of newly constructed anatomy.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	According to the ongoing collection of evidence from clinical studies published and presented in leading scientific meetings, this procedure can be used as a surgical treatment alternative to the standard of care for general GERD patients and the results reported are very encouraging. Furthermore, this new technology can immediately fulfil an urgent unmet need for “difficult-to-treat” or “no adequate options at all” patient subgroups, such as those with concomitant ineffective oesophageal motility and large hiatal hernia where there is a dire need for an effective treatment. For this patient subgroup, this new product may be the only hope in the near term.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No, there are no substantial modifications related to the device. The surgical technique for this procedure has been standardised by consensus of an international group of senior upper gastrointestinal surgeons. Not relevant – there is no existing guidance

Current management

6	Please describe the current standard of care that is used in the NHS.	The current standard-of-care treatment options in the UK NHS include fundoplication.

7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No, specifically regarding the mode of action. This technology has a unique mechanism of action that comprehensively restores the anti-reflux barrier without focusing on only one of its failed attributes (per the other methods). Existing anti-reflux surgical procedures (i.e., Fundoplication and magnetic sphincter augmentation) predominantly encircle the distal oesophagus, whether totally or partially, to prevent retrograde flow of gastric contents. This new device avoids such encirclement, and therefore, posited to *a priori* reduce the manifestation of post-operative side effects associated with oesophageal encirclement, which include dysphagia, odynophagia, gas bloating and inability to belch and vomit. Such symptoms in general negatively affect patients' quality of life. Furthermore, this device treats acid reflux better, since it both restores the normal physiological situation by restoring the three factors of the anti-reflux barrier (as described in the white paper from AFS), LES positioning, flap valve and hiatal repair. Most importantly, the implantation of this device functions as a stabilizing factor to maintain this optimal anatomy and thereby physiological situation. The device as acts as a mechanical stop to prevent re-herniation of the lower oesophageal sphincter into the chest cavity. This has shown to be an advantage in all patients thus also in cases with large hiatal hernias (>3 cm) pre-operatively, which currently have very poor treatment outcome with about 50% recurrence rate. Based on research from Switzerland on severe patients with both motility disorder and large and small hernia, the European Notified body has recently accepted an increase in indication of use to include also large hernia patients.

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	According to presentations at congresses from various surgeons, published clinical results and data on file accumulated on an ongoing basis, this new technology provides excellent safety and efficacy outcomes also in patients with refractory GERD. More specifically, patients are likely to experience significant improvement in quality of life and reduction of reliance on PPI therapy while experiencing a very low rate of safety issues. This treatment seems to be a superior alternative for all patients. In addition, it expands the indication to patient groups that lack any good treatment today, represented in a real-world setting, such as severe cases involving: Barrett's esophagus, advanced esophagitis and difficult-to-treat comorbidities such as esophageal dysmotility and large hiatal hernia. Despite such obstacles in surgical treatment of GERD, this technology is likely to provide good results also in such patient groups.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	As previously iterated, difficult-to-treat cases with concomitant oesophageal dysmotility or large hiatal hernia present patient subgroups that would benefit from treatment with this procedure. Additionally, patients with previously failed anti-reflux surgery would also benefit from this new technology.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Patients with poor oesophageal motility currently do not have satisfactory therapeutic options and are often sent back and forth between their GP and the local secondary care gastroenterology department. The use of this procedure would likely resolve such issues in these patients while also improving symptoms and quality of life. As a result, patients would be expected to be discharged following symptom resolution, presumably not utilising further GP and gastroenterology resources that can be allocated elsewhere. Furthermore, based on excellent long-term outcomes reported so far, the post-operative interventions or complications (i.e., short-term oesophageal dilatation, re-herniation, post-operative dysphagia, and re-operation) commonly observed in existing treatment options are expected to be largely eliminated or minimised after symptom resolution. Ultimately, the burden on the healthcare system would be substantially reduced due to significant reduction in post-op complications, symptoms, hospital and GP visits, productivity gains, etc., which have been evaluated by York's HEC showing the cost-benefit superiority of RefluxStop compared to standard of care published in JME. This is reflected in two recently published analyses assessing the cost-effectiveness and budget impact of RefluxStop in the UK NHS, finding it to be highly likely to be cost-effective (against PPI-based medical management, Fundoplication, and magnetic sphincter augmentation) [1] and associated with substantial

		reductions in post-operative complications (i.e., surgical failures, re-operations, and endoscopic oesophageal dilatations) at a marginal budget impact [2]. 1. Harper S, Grodzicki L, Mealing S, et al. Cost-effectiveness of a novel, non-active implantable device as a treatment for refractory gastro-oesophageal reflux disease. J Med Econ. 2023;26(1):603-613. 2. Harper S, Grodzickki L, Mealing S, et al. Budget Impact of RefluxStop™ as a Treatment for Patients with Refractory Gastro-Oesophageal Reflux Disease in the United Kingdom. J Health Econ Outcomes Res. 2024;11(1):1-7.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The clinical facilities necessary for this procedure are expected to be the already established specialized NHS centres of excellence providing standard abdominal laparoscopic operations.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	As a novel procedure, the manufacturer provides a comprehensive training programme; however, any surgeon having experience with standard laparoscopic fundoplication techniques likely has a short learning curve with implementation of this procedure.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Given that the RefluxStop procedure does not involve encircling and putting pressure on the oesophagus, the device is designed to avoid most of the side effects that occur in other anti-reflux procedures and are burdensome for the patients, especially dysphagia, gas bloating and inability to belch and vomit. One foreseeable complication of importance is the possible migration or penetration of RefluxStop. No such complication has occurred in the CE study's both 4 and 5-year follow-up. However, both the device and procedure have been designed to mitigate potential harm caused by such complications. First of all, the device is encapsulated in the stomach wall forming a tear-drop shape formed by the encapsulated device protruding into the stomach cavity. Thereby in the unlikely event of such complications, the device will enter the stomach cavity. The RefluxStop™ device is designed in five separate pieces. The individual pieces of the device are as small as 15 mm and will easily pass through the pylorus (the opening into the intestine), the intestinal tract and out through the anus thereby avoiding re-operation measures, if such an event occurs, which is likely to occur unnoticed. Recurrence of reflux symptoms will

		most likely occur within a year, but no other harm is expected in a normal case. Lastly, the device is radiopaque, allowing visualization on X-ray. In rare cases, an early penetration into the stomach cavity is caused by poor blood circulation in the stomach wall, which may be caused by a defect in patient's blood supply or too tight invagination or damaged stomach outer surface/serosa. Other general potential surgical harms (type and frequency) are equivalent to other types of laparoscopic anti-reflux surgery. According to published literature and data on file accumulated on an ongoing basis, procedure-related AEs are rare. Patients having known silicone allergy may experience hypersensitivity reactions and therefore should be avoided in patient selection for this new procedure. Since the procedure has several similarities to existing anti-reflux surgeries (e.g., fundoplication), the general procedure-related safety profile involving complications such as bleeding, infection, pulmonary or anaesthesia-related side effects are likely to be similar. Re-herniation is likely to be reduced by RefluxStop due to its principal action of acting like a mechanical stop hindering and reducing such side effects. The 4-year long-term safety outcomes data looks very promising and consistent with the real-world data presented by several anti-reflux experts in scientific meetings. Relevant literature sources pertaining to AEs are reported at the end of the document. Anecdotal AEs: N/A Theoretical AEs: silicone-induced hypersensitivity
14	Please list the key efficacy outcomes for this procedure/technology?	The key efficacy outcomes for this new technology include reduction in dysphagia and odynophagia, reduction in reflux symptoms (e.g., heartburn, regurgitation, gas bloating, ability to belch/vomit), reduction in PPI use, normalisation of 24-hour pH monitoring results, which are manifested in the improvement of the Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) score and patient satisfaction.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The procedure seems to be quite safe and effective. No major concerns.

16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not currently known or reported.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	**Published abstracts:** • Harsányi L, Kincses Z, Altorjay Á. Treating acid reflux without compressing the food passageway: 3-year outcomes with the RefluxStop implant. Zeitschrift für Gastroenterologie. 2023;61(08):401. DOI: 10.1055/s-0043-1771713 • Borbély Y, Haltmeier T, Prevost GA, Dipietro Martinelli C, Kröll D. RefluxStop – A Novel Device to Address Gastroesophageal Reflux Disease in the Context of Esophageal Hypomotility. British Journal of Surgery. 2023;110(Supplement_5). DOI:10.1093/bjs/znad178.022 • Borbély Y, Kröll D, DiPietro Martinelli C, Haltmeier T, Prevost G. 442. The RefluxStop procedure as a novel surgical technique for management of gastroesophageal reflux disease: Two-year follow-up data at a hospital in Switzerland. Diseases of the Esophagus [Internet]. 2023; 36(Supplement_2). DOI: 10.1093/dote/doad052.233 • Fringeli Y, Kessler U, Linas I, Zehetner J. Laparoscopic Hiatal Hernia Repair with RefluxStop: Outcomes in 30 Patients with a Minimal Follow-Up of 12 Months. British Journal of Surgery. 2023;110(Supplement_5). DOI: 10.1097/sle.0000000000001256 • Lehmann T, Simkus M, Oehler C. Topic: Endoscopic Foregut Surgery (Including Endobariatrics) Abstract ID: 82A Retrospective Chart Review of 79 Patients Undergoing

		the RefluxStop Procedure to Manage Gastroesophageal Reflux Disease: Safety and Efficacy. Foregut. 2023;3(3):401. DOI: 10.1177/26345161231196002 **Conference presentations** • *Elshafei M, Lehmann T, editors. RefluxStop implant for gastroesophageal reflux disease: clinical outcomes at almost 2 years in a pooled cohort of 158 patients from two German hospitals. SAGES; 2024 17-20 April 2024; Cleveland Ohio.* Key findings were that, after surgery, total GERD-HRQL score was reduced to median of 2 (0-4) reduced from baseline of 22 (19-31.5), representing a decrease of 90.9% ($p<0.001$). At baseline, 96.5% patients were actively using PPI medication reduced to 3.6% at follow-up. All patients with dysphagia at baseline (11.4%) had resolution at follow-up, however 5 patients (3.2%) reported de-novo mild dysphagia that resolved spontaneously without intervention. No patients needed post-operative esophageal dilatation. Two patients (1.3%) had the device penetrate early into the stomach cavity without complications (believed due to pouch being sutured too tightly), one of whom later had re-operation with Toupet fundoplication. Hiatal hernia recurred in two patients (1.3%); in both cases the hernia was repaired keeping the device intact in its invaginated fundus pouch that was repositioned. • *Elshafei M. One-year follow-up of 15 patients with gastroesophageal reflux disease managed with the novel RefluxStop device. Høstmøtet (Norwegian Surgical Society) Conference; 2023 October 26-28, 2023; Oslo, Norway.* Key findings were that, at one year, GERD-HRQL score improved 82%. Heartburn and regurgitation symptoms improved or completely resolved in all patients except one. No patient had post-operative dysphagia. No reoperation or oesophageal dilatation was required, and no readmissions within the year.
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	• NCT02759094 Evaluation of Safety and Effectiveness of the RefluxStop Device in the Management of GERD (active, not recruiting). • NCT05870163 Post-Market Registry for the Evaluation of RefluxStop in GERD Treatment. Number of enrolled patients (91) – Germany (43), Switzerland(24), Italy(19) and Norway(5) • RXI005 / RENEW RCT (RCT RefluxStop vs. Nissen): to be conducted in o Austria (submitted to Ethical Committee and waiting for approval)

		○ Switzerland (submitted to Ethical Committee and waiting for approval) ○ Germany (submitted to Ethical Committee and waiting for approval) ○ Italy (under preparation) ○ Spain (under preparation) ○ UK (under preparation) • RXI008 / IM REVOLUTION RCT (RCT RefluxStop vs.PPI): under preparation and to be conducted in Austria, Switzerland, Germany, Italy, Spain, and UK
20	Please list any other data (published and/or unpublished) that you would like to share.	• Bjelović M, Harsányi L, Altorjay Á, Kincses Z, Forsell P. Non-active implantable device treating acid reflux with a new dynamic treatment approach: 1-year results: RefluxStop™ device; a new method in acid reflux surgery obtaining CE mark. BMC Surg. 2020;20(1):159. DOI: 10.1186/s12893-020-00794-9. • Harsnányi, L, et al. Treating acid reflux without compressing the food passageway: 4-year safety and clinical outcomes with the RefluxStop device in a prospective multicenter study. Surg Endo, 2024, Accepted for publication June 2024. • Fringeli Y, Linas I, Kessler U, Zehetner J. Laparoscopic Large Hiatal Hernia Repair With RefluxStop: Outcomes of Six Months Follow-up in Thirty Patients. Surg Laparosc Endosc Percutan Tech. 2024;34(2):143-9. DOI: 10.1097/sle.0000000000001256 • Fringeli Y, Linas I, Kessler U, Zehetner J. Short-term results of laparoscopic anti-reflux surgery with the RefluxStop device in patients with gastro-esophageal reflux disease and ineffective esophageal motility. Langenbecks Arch Surg. 2024;409(1):78. DOI: 10.1007/s00423-024-03264-5 • Schoppmann SF. Multicentric short term and safety study of ineffective esophageal motility patients treated with RefluxStop device. Scientific Reports. 2024. doi:Accepted for publication June 2024.

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Hard to estimate as the most suitable cohort is a subset of refractory GORD patients, however we anticipate a few hundred patients nationally could be treated with this new procedure in the initial years. Over 9 million people in the UK suffer from GORD today, of which at least 10% do not benefit from medical treatment. Anti-reflux surgery is considered in patients with chronic GERD who experience inadequate response, are intolerant to, or do not wish to continue lifelong medical therapy (such as PPIs). Today, approximately 2000-2500 anti-reflux procedures are performed annually in the UK.
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Efficacy outcomes: • Symptoms relief • 24-hour pH monitoring • Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) score • PPI usage • Patient satisfaction • Heartburn • Regurgitation Safety outcomes: • Dysphagia (reported as an AE or with GERD-HRQL dysphagia subscore >2) • Esophagus dilatation • Device-related SAEs • Intra- and post-operative AEs

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Ahmed Ahmed**
Dated:	**02/07/2024**