NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP973/2Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease**

Your information

Name:	Benjamin Knight
Job title:	Consultant
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Professional organisation or society membership/affiliation:	AUGIS, BOMSS
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6057598

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. 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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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x☐ 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.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	Observed and followed American data for the last 8 years. Attended several courses and expert training days on the topic Developed a business case to introduce into my NHS practice Personally performing the procedure for the last 18 months
	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	Currently not routinely used. I am part of a very small number of NHS consultants performing the procedure (circa 5). I think the procedure will become more common place and has benefits over traditional anti-reflux surgery. I envisage MSA to fulfil 30-50% of my personal anti-reflux practice over the next 12-24 months. We are currently the highest volume anti-reflux department in the UK – this would equate to 30-40 procedures a year. No No

	procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	It is a novel approach which conveys benefit in a certain cohort of patients. Over 15000 devices have been implanted world wide though with comparable/potentially better results than the current standard of care Definitely novel and of uncertain safety and efficacy. However, I think the safety and efficacy has been proven in the United States.
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?	Likely in addition. It will never completely replace standard of care as some patients are not suitable

Current management

5	Please describe the current standard of care that is used in the NHS.	Laparoscopic fundoplication

6	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?	Not exactly, but RefluxStop has just come to market. It works in a different way to MSA but it is similar in the fact it is trying to augment the lower oesophageal sphincter.However, the technology is vastly different

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Less pain Earlier resumption of normal diet Less GI side effects Quicker operating times Potentially less revision rates
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Probably more suited in those overweight compared to standard Patients with pre-existing functional gut disorders (E.g IBS) probably do better
9	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 Yes
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	This really depends on the surgeons current pathway! However, I think overall it should cost about the same
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Slightly increased initial capital cost, but likely savings in future healthcare burden

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Nil
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. I would recommend a short proctoring session from an experienced surgeon and a targeted course

Safety and efficacy of the procedure/technology

14	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	No more than current standard of care Dysphagia (5-10% but often transient), Erosion - <0.5% (becoming even less common). Explantaion (2-5%), endoscopic dilation (5%)
15	Please list the key efficacy outcomes for this procedure/technology?	Less bloating Less flatulence Normal post operative diet Equivocal rates of reflux control compared to standard Shorter operating time Less post operative pain Lower rates of revision surgery

16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Initial concerns regarding erosions of the device into the oesophagus. However, this was due to the wrong size device being fitted in the early stages of implantation. Since this has been addressed, erosion rates are extremely rare.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Historic concerns regarding the placement of a prosthesis around the oesophagus stemming from the angechik device. However, this device is completely differenent in its mechanism of action of placement.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present.

Abstracts and ongoing studies

19	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.	ALSGBI ASM 2021. ROBOTIC ANTIREFLUX SURGERY USING WITH THE LINX DEVICE Presenter: Mr B Knight Author(s): Mr B Knight, Mr G Van Boxel, Mr S Mercer, Mr N Carter Institution: Portsmouth Hospitals University NHS Trust, United Kingdom Aims: Video presentation assessing the technique and indications of robotic anti-reflux surgery with an augmented magnetic sphincter (LINX). Methods: The case is a 46 year old gentleman with chronic reflux and a small hiatus hernia. He had normal manometry with positive pH testing and reflux on a barium swallow. The patient elected for the LINX device. Anti-reflux surgery was performed with a 3 port Robotic technique on a DiVinciX. Results: Hiatal cruroplasty and implantation of the LINX device was successfully performed robotically. Operative time was 35 minutes and performed as day surgery. Conclusion: The video highlights the benefits of articulating instruments and enhanced magnification when placing the device. The robotic platform offers advantages in identification and dissection of the posterior vagus nerve and a potentially shorter operative time. Key statement: Video presentation highlighting the technique and advantages of using the robotic platform to implant a magnetic sphincter augmentation device
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	I believe that Johnson and Johnson hold a registry of implanted devices. Also, Sheraz Marker in oxford is proposing an RCT comparing MSA vs Fundoplication (GOLF study). It is still in trial development phase.

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)?	Approximately 2500 anti reflux procedures are performed each year in the UK. I would estimate 30-50% of these would be eligible for MSA However, it is estimated that around 15% of the UK adult population take PPI medication. Therefore 5-6 million people could be eligible!!
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Non known
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Initial capital outlay
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	A well constructed UK RCT comparing partial fundoplication vs MSA
25	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.	Beneficial outcome measures: Operative time Less Post operative pain Hospital stay Lower Gastro intestinal side effects PPI use post operatively GERD QOL Adverse outcome measures:

	− Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Dysphagia Re-operation rate Explantation rate Erosion rate Readmission rate (12 months)

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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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.			

x ☐ 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:	**Ben Knight**
Dated:	**31/03/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP973/2Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease**

Your information

Name:	Mr Dhiren Nehra
Job title:	Consultant Upper GI Surgeon
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Professional organisation or society membership/affiliation:	Association of Surgeons of GB&I, Association of Laparoscopic Surgeons, Surgical Society of Alimentary Tract USA, Fellow of the American College of Surgeons
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 3637566

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

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example:	10 yr experience of Laparoscopic insertion of magnetic titanium ring (Magnetic Augmentation of Sphincter - MAS) for gastroeosophageal reflux disease in NHS and Independent Sector
	Are you familiar with the procedure/technology?	Yes
	Have you used it or are you currently using it?	Yes
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	Used all over UK although few centres (approx 5 with over 100 cases) Our centre has performed 150 cases in 10 yr period. It is likely to gain popularity and may replace the traditional laparoscopic antireflux fundoplication procedure.
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	Upper GI and Bariatric Surgeons
	− If your specialty is involved in patient selection or referral to another specialty for this	Yes we are involved with patient selection but patients may be referred by gastroenterologist for consideration of surgery due to failure of medical treatment

	procedure/technology, please indicate your experience with it.	
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. YES I have done research on this procedure in laboratory settings (e.g. device-related research). NO I have done clinical research on this procedure involving patients or healthy volunteers. YES in patients only as part of a registry I have published this research. YES at national meetings. In process of publishing as a scientific paper I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	It's a novel approach with an implanted device but available worldwide mainly in Europe and USA with over 40,000 procedures carried out and several publications endorsing its efficacy Established practice and no longer new. **Established** 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.

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?	It would be used as an addition to current method however with currently encouraging results due to fewer side effects, safety profile and long term effectiveness that it has the potential to become the first line of treatment

Current management

5	Please describe the current standard of care that is used in the NHS.	Laparoscopic Nissen or Toupet Fundoplication using patients stomach fundus to create a wrap around the gastroesophageal junction
6	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?	Endoscopic plication methods and Stretta These are minimally invasive endoscopic procedures. Not widely available in the NHS and there is question mark regarding the long-term efficacy and durability of these procedures

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Fewer side effects of gas bloat and dysphagia. Allows patients to belch or vomit if required (difficult with the fundoplication) More effective in controlling symptoms, long lasting with fewer recurrences. More importantly the device can be removed or reversed
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with severe and/or long standing reflux disease who are intolerant or resistant to medical treatment or concerned about the long term side effects of Proton Pump Inhibitors (PPI) medication
9	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 , decreased reliance on medication and diminish side effects of long term intake of PPI – overall cost saving in comparison to lifelong medication. Fewer re-operative rate and failure of surgical treatment compared to conventional technique of fundoplication
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	At present slightly more expensive as the device is approx. £3000 however there is additional advantage as the MAS procedure involves less dissection and less time compared to fundoplication; and can be done as a day case. The rest of the cost of staff, equipment and care is same. With increased use the device is likely to become cheaper.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Same with potential to become less
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes a program of clinical proctorship and validation

Safety and efficacy of the procedure/technology

14	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	Erosion rate – 0.15% Migration rate – 0% potentially 0.5% Removal or explant rate – 2.7%. It was higher in the early period when the device fitting size was deemed too snug or small. Dysphagia to certain food such as bread is a known side effect of magnetic ring implant. The rates can be as high as 66% in the early post operative but most resolve by 6 months however the rate of persistent dysphagia at 1 yr is 7% but this is diminishing due to better understanding of sizing of the device Dysphagia and chest pain
15	Please list the key efficacy outcomes for this procedure/technology?	Significant resolution of reflux symptoms. Decreased in acid exposure as measured by a 24 hr pH study, Eliminate the use of or significant reduction in use of PPI antireflux medication. Long term benefit as there is lower recurrence rate.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Device loosens with time, late erosions ,
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Long term effects of a foreign implant in the GI tract
18	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 having expertise in Upper GI laparoscopic hiatal surgery 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

19	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.	Recent our UK presentations – SP5.1.8 Long term outcomes of laparoscopic magnetic sphincter augmentation for gastro-oesophageal reflux disease: High patient satisfaction with low dysphagia rates Yasmin Tabbakh, Caoimhe Walsh, Tai Joum Tan, Dhiren Nehra British Journal of Surgery, Volume 108, Issue Supplement_7, October 2021, znab361.117, https://doi.org/10.1093/bjs/znab361.117 Invited speaker at the Association of Upper GI surgeons AUGIS 2021 Non-Fundoplication Anti-Reflux Surgery- LINX vs Endoluminal Dhiren Nehra
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

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)?	30% of patients with life affecting reflux disease who are currently unhappy or inadequately treated with PPI medication. Prevalence of reflux disease is 18-27 % of the population therefore if this technology is proven to be safe and provides long term effectiveness then it can be rolled out to many more patients then currently treated with fundoplication which is less than 1 %

22	Are there any issues with the usability or practical aspects of the procedure/technology?	None. It is established for over 10 yrs world wide
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Potential serious complication of erosion of device in the long term however the current erosion rate at 10 years follow up is approximately 0.15%
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Long term outcome and dysphagia rates
25	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:	Beneficial outcome measures: Effectivity – 1) To measure the Gerd quality of life scores over 5-10 yr period 2) to study the use of PPI medication post-surgery . % patients able to reduce medication by more than 50% 3) Maintain physiological function of belching, vomiting and reduction in gas bloat 4) Recurrence rates – long term follow-up 10 years Adverse outcome measures: Early readmission rate Device erosion and migration at 5 and 10 yrs Adverse events related to persisting dysphagia or odynophagia and intervention such as dilatation Explant rate

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Comparison with the historic Angelchik antireflux device with fear of high device erosion are unfounded. This may be related to the dynamic magnetic yield of the MAS device and the protective nature of the fibrous capsule around the titanium. Personal experience of post-surgery endoscopy shows that the device remains in situ and maintains the integrity of the gastroesophageal junction. MAS may provide long term and even permanent treatment of gastroesophageal reflux disease

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Providing preceptorship to support surgeons who wish to undertake the MAS procedure	**Dec 2013**	**Ongoing**
Choose an item.			
Choose an item.			

X 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:	**Mr Dhiren Nehra**
Dated:	**23/04/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP973/2Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease**

Your information

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Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text.4651383

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

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1	Please describe your level of experience with the procedure/technology, for example:	3 years, approx. 35 procedures
	Are you familiar with the procedure/technology?	Yes
	Have you used it or are you currently using it?	Currently
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	Approx. 3 centres NHS. Prob 10 in private sector Still restricted by cost and lack of RCT. With time use will increase
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	No
	− If your specialty is involved in patient selection or referral to another specialty for this	Referrals from gastro/GP

	procedure/technology, please indicate your experience with it.	
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 put forward an RCT to look at LINX in Barrett's patients. I am also involved as a specialist in a review paper requested by J&J. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	I would say this is now standard of care Established practice and no longer new.
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?	Some patients are not suitable due to poor oesophageal motility or large hiatus hernias.

Current management

5	Please describe the current standard of care that is used in the NHS.	Laparoscopic Nissens or partial fundoplication

6	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

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Less anatomical disruption, reversible, easy to place and longevity
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Young with good oesophageal motility
9	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?	Less revision procedures and better long term reflux control
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	The procedure is more likely to be a day case than current standard of care. The procedure time is shorter. The device itself is more expensive. If no requirement for revision procedure, less medication and less time of work, there would be a net cost benefit from this procedure
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Initial costs are higher, but may regain costs long-term.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Limited as surgeons already experienced in this type of surgery.

Safety and efficacy of the procedure/technology

14	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	Risks include; 1) Device removal 5% 2) Device erosion 0.1% Common problem is dysphagia up to 3 months post insertion. In the region of 20-30% of patients require endoscopic intervention. Dysphagia resolves. Most problems resolve by 6 months. Good long term tolerability.
15	Please list the key efficacy outcomes for this procedure/technology?	God long-term reflux control
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Data is now reaching 10 years with good results. Less complications than other commonly used devices such as gastric band
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Lack of RCT, but I cannot imagine it will be easy to recruit to this when patients have usually already decided on the type of procedure they require prior to consultation
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK. Cannot predict at present.

Abstracts and ongoing studies

19	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.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Applications are currently being made for an RCT comparing LINX and Nissens.

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)?	Several thousand anti-reflux procedures are carried out in the UK each year. I wold imagine 30-40% of these could be eligible.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	no
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	no

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	no
25	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:	Beneficial outcome measures: Endoscopic interventions/removal/QOL/reflux control/reoperation Adverse outcome measures:

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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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:	**Click here to enter text. JA Gossage**
Dated:	**Click here to enter text. 18/4/22**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP973/2Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease**

Your information

Name:	Mr S A Wajed
Job title:	Consultant Upper GI Surgeon
Organisation:	Royal Devon & Exeter Hospital
Email address:	saj.wajed@nhs.net
Professional organisation or society membership/affiliation:	Royal College of Surgeons or England, Association of Upper GI Surgeons, Association of Laparoscopic Surgeons, American & European Foregut Societies
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	GMC 3669095

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. 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 the process 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.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? 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 a Consultant Upper GI surgeon with a specialist interest in reflux disease who has been in continuous practice in this field at this level for 18 years. I have been performing laparoscopic magnetic sphincter augmentation (MSA) for chronic gastro-oesophageal reflux disease (GERD) since June 2012, and have performed over 100 procedures. During and prior to this time, I have participated and been involved in a number of scientific, academic and clinical meetings where there has been extensive discussion regarding all aspects of the technology, including the surgical technique, clinical indications and outcomes, and which helped modify indications and advance the technique. I have acted as a preceptor for surgeons who have wished to introduce this into the clinical practice in the UK and Europe Yes The technique is available in a limited number of specialists reflux centres, where individual clinicians have taken an interest in being able to offer this as part of their clinical practice. This has been challenging in the NHS setting where it has sometimes been difficult to present a successful business case. The ambiguity of NICE guidance on this matter may have prevented or limited its incorporation into some organisations who were unwilling to pay for the one-off cost of the implant which is not required for standard practice. There has been a greater proliferation in the private market, where patient-led demand through self-pay or via lobbying individual insurance companies has been more successful. The technique is currently only performed Upper GI Surgeons. Referrals to our services come from general practice, gastroenterology, ENT, respiratory medicine and directly from patient's themselves.

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. **YES** I have done research on this procedure in laboratory settings (e.g. device-related research). **NO** I have done clinical research on this procedure involving patients or healthy volunteers. **YES** I have published this research. **YES, see reference link below** I have had no involvement in research on this procedure. **NO** Other (please comment): https://pubmed.ncbi.nlm.nih.gov/29364013/
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	This is a novel technique, which offers a less invasive approach to the surgical management of chronic reflux. It involves the implantation of a mechanical device at the gastro-oesophageal junction to create a dynamic barrier as opposed to anatomical reconfiguration involving wrapping the upper stomach around this area (tissue fundoplication) which is a more extensive procedure. It makes the surgical alternative to chronic drug therapy/dependency or conservative management more attractive to a wider spectrum of patients, due to it is less invasive nature and potentially less functional gastrointestinal side effects. **Established practice and no longer new.**
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?	The procedure offers an alternative to patients who may be reluctant to undergo existing surgical options (tissue fundoplication), but also unsatisfied on their current management which may involve drug therapy/dependency and significant dietary/lifestyle modifications.

Current management

5	Please describe the current standard of care that is used in the NHS.	**Surgery:** laparoscopic fundoplication **Medical therapy:** Long-term use of PPIs, H2 antagonists other antacids, prokinetics, analgesics and mood enhancing drugs. **Conservative:** Dietary, lifestyle modifications, living with symptoms and consequences of advancing disease
6	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

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Long-term relief of chronic reflux symptoms with improvement in quality of life and wellbeing. Elimination or significant reduction in drug therapy/dependency and the potential side effects/long-term complications of these medications Prevention of long-term damage to the oesophagus (scarring, metaplasia) Limitation of possible functional GI disease from drug therapy and dietary modifications.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	YES: Those with earlier stage reflux disease, who may be unwilling to undergo the more radical operation of fundoplication. They are often reluctant to undergo a procedure which involves significant and irreversible re-configuration of their upper gastrointestinal anatomy and that is also associated with potentially troublesome side effects including bloating and flatulence. [These patients tend presents some years later when reflux symptoms become much worse and drug therapy less effective by which time irreversible structural and functional changes to their oesophagus and gastrointestinal tract may have occurred] There is also a possible role in patients who develop reflux symptoms after weight loss surgery (e.g. sleeve gastrectomy) or may have had previous antr-reflux surgery. This area is under evaluation. Patients with a significant level of functional symptoms may be better suited to MSA, as gastro-intestinal side-effects after fundoplication can be very troublesome and make the situation worse
9	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: Patients with proven symptomatic but early stage gastro-oesophageal reflux disease should be offered MSA as an alternative to long-term/permanent drug therapy. YES: May avoid patients having to have increasing drug therapy over many years. May help prevent the development of chronic oesophageal disease such as scarring and metaplasia that may then later required intervention (dilatation, ablation or resection). Improvement in quality of life at an early stage of the disease may prevent associated problems of chronic reflux such as functional gut, respiratory and laryngeal-pharyngeal symptoms and mental health issues, which in turn may require further investigations and treatment by several different specialities. These are often very unsatisfactory and can result in patients being prescribed with a wide variety of drugs with limited benefit.

10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	MSA is associated with a finite fixed cost of the implant. However, from the surgical point of view this is can be offset due to the minimally invasive nature of the procedure, which requires less additional surgery equipment, disposables and theatre operating time. The majority of patients can have the procedure done as a day case and therefore require less inpatient stay or bed usage time. The readmission, re-consultation and re-intervention rate with side effects some problems is less following MSA compared to fundoplication. The elimination of chronic reflux in the majority of patients will lead to less cost related management of these individuals due to further consultations, investigations and treatments and ultimately they may still require to anti reflux surgery after further sometimes long periods of suffering. The detrimental impact on productivity due to absence from work, or less effectiveness whilst at work, social and mental health issues can be lessened. Overall, therefore, health care services will stand to benefit from definitive early management of chronic reflux disease, which will therefore be cost effective to the service as a whole.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Overall the cost should be equivalent to, or less than the current standard
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Specialist Reflux Consultant Upper GI surgeons should just observe the procedure being done, and then be preceptored for 1 or 2 cases before embarking on independent practice.

Safety and efficacy of the procedure/technology

14	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	Risk of device erosion, device displacement (hiatal herniation). Possible limitation on the use of MRI on individual patients in the future for investigations for other possible future illnesses. Device erosion rate is 0.3% and has been falling (technique has modified with time). Swallowing dysfunction (dysphagia/ spasm) and hiatal herniation similar to fundoplication.
15	Please list the key efficacy outcomes for this procedure/technology?	Satisfactory control of reflux symptoms Improvement in quality of life/wellbeing Elimination or significant reduction in drug therapy/dependency Re-intervention for procedure related problems
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Results beyond 10-15 years not known. Role in post-bariatric patients and revisional patients yet to be fully evaluated
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No
18	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. - where there is a Specialist Reflux Upper GI Surgeon and supported by high quality theatre facilities with access to endoscopy, interventional radiology and oesophageal physiology.**

Abstracts and ongoing studies

19	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.	No recent updates on existing published literature that would alter current management or decision making. Recent publications confirm safety and long erm efficacy. Role in previously considered borderline cases with advanced disease including Barrett's, hiatus hernia and motility disorders now being regarded with less caution/ contra-indication.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	LINX Registry

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)?	Similar number to those currently undergoing fundoplication surgery
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Procedures should be carried out by specialist surgeons with access to good quality operating theatre facilities. Centres carrying out procedures should have access to endoscopy, interventional radiology and oesophageal physiology diagnostics.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Limited evidence and current NICE guidance https://pubmed.ncbi.nlm.nih.gov/29364013/ Concerns by most NHS Trusts about cost of implant which has previously not been necessary for anti-reflux surgery. Trusts themselves will not observe the long-term benefits of good reflux management but this will be realised by the Healthcare Service as a whole

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Long term studies of efficacy will be beneficial to understanding
25	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:	Beneficial outcome measures: • Operative: Operating time, complications/adverse event, length of stay. • Post-op: Early re-attendance / communication. Need for investigations/intervention • Short term (2 years): Satisfactory control of reflux symptoms, cessation/ reduction of drug therapy, improvements in health-related quality of life / wellbeing • Long term (5, 10, 15 & 20 years): On going control of reflux symptoms and drug usage. Need for further investigations and intervention. Causes of possible procedure failure or reduction in efficacy Adverse outcome measures: Acute problems relating to device necessitating intervention including removal. (e.g dysphagia, erosion, pain). Any other health issues attributable to device (2, 5, 10, 15 and 20 years)

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Experience over last ten years has been favourable. As with standard anti-reflux surgery, patient selection rather that operative technique is the most likely indicator of successful satisfactory outcomes. Surgeons offering MSA should have a special interest in reflux disease and be already dealing with high volumes of patients in clinic and operatively. They should have access to modern diagnostic facilities including oesophageal physiology.

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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:	**Mr S A Wajed**
Dated:	**13/04/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP973/2Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease**

Your information

Name:	Stuart Andrews
Job title:	Consultant Upper GI Surgeon
Organisation:	Torbay Hospital NHS
Email address:	Stuart.n.andrews@nhs.net
Professional organisation or society membership/affiliation:	GMC/RCS
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4702942

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. 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 the process 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.

☐ **X** 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.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am currently providing magnetic sphincter augmentation anti-reflux surgery on NHS
	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?	This type of surgery is currently offered by Torbay Hospital/Royal Devon and Exeter Hospital/Southampton General Hospital/Queen Alexandra Hospital Portsmouth/Epsom and St Helier Hospital/ St Georges/Kings College Hospital/Salford Royal/Leeds General Infirmary/Queen Elizabeth Hospital Glasgow, other centres likely to start
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	No
	− If your specialty is involved in patient selection or referral to another specialty for this	No

	procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	It is variation of a current form of surgery using an implant device Established practice and no longer new.
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?	As an alternative form of existing procedure (fundoplication)

Current management

5	Please describe the current standard of care that is used in the NHS.	The procedure and fundoplication

6	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?	None

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Equally as effective as fundoplication, day-case, greater patient satisfaction with outcome
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	All those currently having conventional fundoplication anti-reflux surgery
9	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, day-case and better patient satisfaction
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Likely more cost effective
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Cost of device, otherwise same
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Same as currently exist for fundoplication

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	A limited training protocol for experienced fundoplication surgeons

Safety and efficacy of the procedure/technology

14	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	Device erosion (very low <1%) Dysphagia requiring endoscopy and stretch None other than above
15	Please list the key efficacy outcomes for this procedure/technology?	Equal reflux control and better patient outcome reported measures
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Long term studies suggest safe
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Previous bad experience with angelchik device
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present.- likely 1 or 2 per region

Abstracts and ongoing studies

19	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.	Extensive publication in literature
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Registry being launched in October 2021

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)?	Approx. 1000 patients per year
22	Are there any issues with the usability or practical aspects of the procedure/technology?	None
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	None

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Awaiting a direct RCT to compare against fundoplication but probably enough retrospective/cohort studies to over a long period of time to demonstrate safety and effectiveness
25	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:	Beneficial outcome measures: Equal or better reflux control compared to fundoplication/ better patient reported outcome measures in terms of vomiting and belching. Delivered almost exclusively as day-case procedure. Adverse outcome measures: Device erosion (very low <1%), some patients develop dysphagia that requires an endoscopy and stretch.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Probably should be considered as an equal alternative to fundoplication surgery for reflux conditions

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Declarations of interests

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Choose an item.			
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Choose an item.			

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

Print name:	**Stuart Andrews**
Dated:	**24/7/2021**