NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP269/3 Endoluminal gastroplication for gastro-oesophageal reflux disease**

Your information

Name:	Benjamin Charles Knight
Job title:	Consultant Surgeon
Organisation:	Portsmouth Hospital University Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Surgeons, AUGIS, BOMSS
Nominated/ratified by (if applicable):	AUGIS
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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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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 family with the technology and have seen it being performed. I have no personal experience in performing the procedure.
	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	I don't think this is being offered on any NHS hospitals to my knowledge

	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.
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 endoscopic approach to reflux. Several endoscopic therapies have been tried for reflux (such as stretta and esophyx) but non so far have proven any long term benefit. 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 likely be alongside standard care as not all patients would be suitable

Current management

5	Please describe the current standard of care that is used in the NHS.	Laparoscopic Fundoplication – some centres are offering LINX

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?	Fundoplication LINX (some centres) Reflux stop (not routinely available on NHS) Stretta (not routinely available on NHS)

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?	Incisionless Less gas bloat and GI side effects
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those that have had major abdominal surgery or gastric surgery in the past Potentially patients with pre existing gastric symptoms of bloating, IBS symptoms or dysphagia
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?	I think unlikely. Early results are broadly similar to standard care. There is no good long term data.
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 - Large capital outlay. Longer procedure time
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)?	Likely more
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	General anaesthetic ability in the endoscopy suite

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. Considerable surgeon and team training

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	Adverse events reported in a study included perforation (19.8%), followed by laceration 17.6%, bleeding (9.2%), and pleural effusion (9.2%). The most common patient complications were treated using endoscopic clips (12.3%), chest tube or drain insertion (12.3%), use of endoscopic retriever device (11.1%), esophageal stent (8.6%), and emergent or open surgery (11.1%).
15	Please list the key efficacy outcomes for this procedure/technology?	Operative time. Resolution of reflux. Cessation of PPI use. Reported dysphagia and gas bloat.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Long learning curve. Long operative time. Unclear long term efficacy. No long term data. Serious adverse events reported.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes – as above.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK.

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.	Not aware of recent conference papers
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not known

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 2000 antireflux surgeries are performed each year. However, we only currently operate on a tiny percentage of eligible patients as most are not referred from primary care. I would estimate 5-10% of current patients might be eligible.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Long learning curve. Capital outlay
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?	Resource demand. Theatre time. Cost

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	It desperately needs a randomised control trial – comparing LINX, Anti-reflux surgery and TIF
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: Less gas bloat Less dysphagia Less short term pain Adverse outcome measures: Perforation, visceral damage, bleed, mediastinal abcess, long operative time, effectiveness of the procedure.
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I commonly perform almost all types of laparoscopic antireflux surgery using various modalities but do not currently perform endoscopic antireflux surgery

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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:	**Benjamin Knight**
Dated:	**13/05/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP269/3 Endoluminal gastroplication for gastro-oesophageal reflux disease

Your information

Name:	Christopher Sutton
Job title:	Consultant Upper GI Surgeon and Head of Service Leicester Royal Infirmary
Organisation:	University Hospital of Leicester NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	AUGIS, BOMSS, IFSO, Association of Surgeons, BMA
Nominated/ratified by (if applicable):	AUGIS
Registration number (e.g. GMC, NMC, HCPC)	4014397

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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: Are you familiar with the procedure/technology?	I have been a consultant surgeon for 13 years. I am head of service for surgery for my trust. I additionally chair the medical equipment executive and am procurement lead for surgery. In terms of anti-reflux procedures I routinely preform Nissen, Watson, Toupet, Paraoesphogeal hernia repair, LINX, endostim and stretta. I have been trained in Reflux Stop and as a registrar in endocinch. I preformed the UK's first endoscopic suturing with Overstitch. I am familiar with the procedure being evaluated but have not performed it myself.
	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?	It is not used widely within the NHS
	– Is this procedure/technology performed/used by clinicians in specialities other than your own?	Gastroenterologists may perform this
	– If your specialty is involved in patient selection or referral to another specialty for this	I have no experience with the technique although I am familiar with it

	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.
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, concept and design Definitely novel and of uncertain safety and efficacy.
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?	Addition to current practice

Current management

5	Please describe the current standard of care that is used in the NHS.	Hiatal repair and fundoplication performed laparoscopically

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?	There are other endoscopic procedures but nothing exactly like this

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?	Avoiding laparoscopic surgery
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those at higher risk of conventional laparoscopic surgery eg previous laparotomy
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 Invasive
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)	Potential for this to be daycase surgery therefore reducing length of stay – it maybe cost neutral
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)?	It may be cost neutral – if daycase rates increased
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

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	Oesophageal or pharyngeal perforation.
15	Please list the key efficacy outcomes for this procedure/technology?	Treatment of reflux
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Long term results and perforation risk
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes as above
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.	I have not revisited the literature for several years on this exact topic
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	EsophyX has a 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)?	A large proportion of the population has reflux, only a minority seek surgical treatment for this. This technique is unlikely to drive more procedures – it will move some people to a different approach. I suspect the number each year would be in the low hundreds.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Training
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?	Cost, Novelty, Training and NICE approval plus absence of IPAC code

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	A properly powered randomised trial
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: Reflux resolution/improvement Improvement in quality of life Reduction in dysphagia or bloating rates compared to fundoplication Longevity of symptom relief Increase daycase rates Adverse outcome measures: oesophageal perforation, poor symptom control, short resolution of symptoms, difficulty in revising to another procedure, cost of technology
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments

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

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Choose an item.			
Choose an item.			

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Print name:	**Chris Sutton**
Dated:	**25th May 2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP269/3 Endoluminal gastroplication for gastro-oesophageal reflux disease

Your information

Name:	Ian Beales
Job title:	Clinical Associate Professor & Consultant Gastroenterologist
Organisation:	Norfolk and Norwich University Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Society of Gastroenterology
Nominated/ratified by (if applicable):	British Society of Gastroenterology
Registration number (e.g. GMC, NMC, HCPC)	3407466

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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 familiar with the workings, mechanism and performance data of all the currently used or advocated antireflux techniques. I do not perform any of the interventional procedures myself, either endoscopic or surgical. However, I do supervise a clinical service that oversees the investigation and management of gastro-oeosphagedal reflux disease in the secondary, tertiary and even more specialist sectors. This includes physiological assessment and management before and after the anti-reflux procedures.
	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	I do not use this technology. At present it is probably not used much in the NHS, although there are likely a few early adopters and “experimenters.” It is much more likely that this technology is already being provided in the private sector. Although the technology is available, speed of update will depend on (1) whether it has proven and relaibel intermediate and long term benefits (doubtful) (2) the overall cost effectiveness and whether purchansing this now would save costs in the long term (3) NHS tariff being available. We can look at the example of radiofrequency ablation (Stretta procedure) which has been available for some years (albeit of doubtful efficacy) and is used very sparingly in the NHS as of 2022. The procedure would be performed by endoscopists, these could be from a gastroenterology or a surgical background. Most of those interested in performing this in the NHS will be from my on specilaity (gastroenterology), in the private sector, I would expect more surgeons to be interested.

	procedure/technology, please indicate your experience with it.	The vast majority of the assessment and section of patients for this procedure, will be done by myu own speciality, medical gastroenterology even if the procedure would be done by a different specialist within gastroenterology.
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 extensive bibliographic research on this. 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 peer reviewed review papers and original papers on this and also written short-review papers, 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 innovative in that it is a non-surgical approach to this situation. However it is not unique in that a variety of endoscopic antireflxu procedures are being developed and in various stages of evolution. There are several techniques of antireflex plication, the hardware for these continues to evolve but it is important to stress that the results from the different specific technologies are probably not interchangeable. Although the procedures and techniques are not particularly novel, if one is lookin at for how long they have been available, they all should be regarded as novel in terms of limited published data and particularly the lack of intermediate and long term data and cost-effectiveness data. Definitely novel and of uncertain safety and efficacy.
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?	This could potentially happen, although more likely to from part of a portfolio of possible treatment options. However this is only true, if the procedures were to be found to be robustly effective and cost effective in the intermediate and long term.

Current management

5	Please describe the current standard of care that is used in the NHS.	Standard NHS care for this particularly, very focussed group of patients (PPI-dependent gastrooesopahgeal reflux disease (GORD) without a significant hiatal hernia or comorbidity and without obesity) comprises various options depending on the patients' wishes. The options are (1) is to continue with symptomatic control with a PPI. This is safe and effective and although a variety of risks have been associated with PPIs, these risks are small and this strategy is perfectly acceptable to most patients (2) attempt PPI-withdrawal using pH monitoring as a guide. Many patients with apparent PPI-dependent reflux, do not actually have reflux possibly very mild reflux. Ambulatory pH testing can identify those without significant reflux and this can be used to define the group where acid suppression can be successfully withdrawn (3) antireflux surgery.Laparoscopic fundoplication is a safe, effective, well-proven, robust and cost-effective in the long term treatment for PPI-dependant GORD. There are well documented complications but this is an option for patients that would rather avoid PPIs. The classical surgical option is laparoscopic fundoplication, laparscopic magnetic sphincter augmentation is a newer surgical technique. This avoids some of the complications of fundoplication and appears safe and effective, although there are no long term data on this technique. It is not widely available in the NHS at present.

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?	There are several competing techniques. Radiofrequency ablation (Stretta procedure). Is an endoscopic procedure, usually performed under GA. Although advocated for PPI-dependant GORD, the randomized trials showed no useful effect on clinical outcomes or physiological changes in this particular patient group. There are two distinct endoscopic plication devises GERD-X and EsophX. These work on the same principle but use different technologies. The EsophyX has a greater body of literature on efficacy but usually required GA. The GERD-X is newer and can be perfomed without GA but has less supporting data. Neither have been compared with the gold standard of laparoscopic fundoplication and effects on physiology after 12 months have not been shown to be robust. There is also a further technology for endoscopic plication the MUSE system. The complications associated with this specific technique do seem to be considerably greater and more frequent that the GERD-X and EsophX devices. All of the above need special proprietary technology. There are at least 3 different other anti-reflux endoscopic procedures. Anti-reflux mucosal ablation, anti-reflux mucosal resection and anti-reflux band ligation. These can be performed using standard endoscopy equipment that is already available and used for other purposes, such a the treatment of bleeding lesions or oesopahegal varices. There are various hybrid procedures that combine various constituents of these 3 techniques. Although the technology and procedures required for these latter 3 technology are relatively simple and easily available and less costly than the GERD-X and EsophX devices, there are even less data on the results with these techniques.

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?	The potential is the treatment of a portion of patients with GORD with a single endoscopic procedure and avoidance for the long-term use of PPIs. This effect may be relatively small as the longer-term data on endoscopic plication techniques, suggest that with increasing time there is a signfincant failure rate of the plication as the fasteners are pulled through and the plication breaks down and reflux recurs. Control of acid reflux declines after 12 months and with longer term studies (5 years), the majority (60% or more) of patients have resumed PPI. So these do not seem to produce long term freedom from PPIs. Some observatuional studies suggest only 45% of patients with true GORD have stopped PPIs 12 months after an endoscopic plication However these do seem to avoid some of the rare, but well known complications of fundoplication.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	This is a very clearly defined group. Confirmed gastro-oesophageal reflux disease, without severe erosive oeosphagitis, without a hiatal hernia or at most a small (2-3 cm) hiatal hernia. Without obesity and with PPI controlled symptoms. Those with obesity or a large hiatal hernia are better treated by bariatric surgery or restoration of the normal anatomy with a fundoplciaton respectively. The plication device studies generally excluded those with severe oeosphagitis, so we do not know what the results in the group are. Patients need to have confirmed GORD to benefit from any sort of antireflux procedure. In many of the observational studies of the plication devices, many of the enrolled subjects did not seem to have GORD as defined by modern physiological means (usually defined as an acid exposure time of > 65).
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?	The only potential is the avoidance of PPI use in a small proportion of patients with PPI-dependant reflux disease and the associated on going costs of PPIs (inexpensive drugs) and the related health care costs of prescribing and reviewing the PPIs. As these PPI-dependant patients are not usually followed up in hospital or primary care, it is difficult to see how visits will be reduced. It will not free all patients from requiring PPIs. It may provide an alternative to laparoscopic surgical approaches, although there are considerable and robust data on the long-term outcomes and cost effectiveness of laparoscopic 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)	This is difficult to answer because (1) no clear good quality randmised trials with adequate design and economic analysis (2) this technology has not been compared to the gold-standard alternative in this situation (lap fundoplcaication). Overall lap fundoplication is cost-saving in the long-term but this is dependant on the long-term robustness of surgery, which has not been shown for the endoscopic plication devices. Additionally, the rate of recurrent PPI use is higher with the plication devices than with surgery. So, it seems likely that these new technologies and procedures will not be cost saving in the immediate future. If these procedures were new drugs, I do not think NICE would be preapraed to look at them, given the poor quality of the outcome studies plus the lack of economic data.
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)?	In the short term, the costs would seem to be higher. There will be costs of the specific plication devices, plus the procedural and staff costs for the procedure, including the lost opportunity costs, given that access to endoscopy services are finite and these extra endoscopy procedures would require endoscopy time. The alternative of merely continuing on a PPI, requires minimal staff and no resources but does include long-term drug costs.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Training of staff and oversight of performance. Acquisition of the endoscopy devices needed to perform the procedure. Otherwise any suitable endoscopy unit could perform these.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	The endoscopists performing the procedure will require specific training.

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)	The adverse events do seem to be relatively uncommon. Dysphagia after endoscopic plication is said to occur in about 10% of cases and can usually be dealt with by endoscopic diltation. Although this does require extra endoscopic procedures and follow-up. Serious adverse events occur in 2-3% of cases, these include perforation and bleeding. Most of these compilations are serious enough to require admission to hospital (about 90% require admission) but usually these can be dealt with by endoscopic means, surgery has been

	Anecdotal adverse events (known from experience) Theoretical adverse events	required for perforation. Mortality does seem to be rare, although the overall numbers treated by endoscopic plication are relatively small.
15	Please list the key efficacy outcomes for this procedure/technology?	(1) Improvement in reflux symptoms as measured by a documented symptom score. This needs to be assessed in the long term. 12 months minimum but even that is too shourt and longer periods at least 2 years and ideally 5 years need to be defined. This is long-term condition and shourt term results are irrelevant (2) Control of the physiological abnormalities that cause GORD and the persistence of this control (3) Use of PPIs during follow up. A time point at 2 years and later would be required here (4) Cost effectivess in the longer term 3 year of more (5) Overt comparison both comparing the plication techniqies with laparoscopic fundoplication and magnetic sphincter augmentation and comparing the different endoscopic plication devices and also comparing to other endoscopic anti-rflux procedures.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	(1) The robustness and persistence of the plication. Long term effects and results of fundoplication are known. The endoscopic plication does seem to degrade with time. (2) The efficacy in a well defined GORD population with disease consistent with a UK population – with clearly defined true GORD, confirmed physiologically and not just those with symptoms of heartburn (3) The efficacy in other groups outside the initially defined infications – those with incompletely PPI-responsie diseae, those with greatly elevated acid exposure or severe reflux oesophagitis
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The efficacy and relative cost effectiveness compared to the laparoscopic procedures. Whether the procedures produce a lasting benefit.
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. A minority of hospitals, but at least 10 in the UK. The answer to this is somewhere between these two. The technology will not be difficult to acquire, if someone is willing to purchase and fund the procedure. Most endoscopy units in district general hospitals would have the facilities and resources to take on the plication procedures. A more limiting factor may prove to be the availability of suitable GI physiology

		support for the diagnosis and decision making related to the management of these patients. These facilities are present in a considerable number of hospitals but not all DGHs.

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.	Nil specific. A comprehensive literature search will reveal the important data.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	None that I am aware off, although I would not be surprised if there were.

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)?	This is difficult to answer. It depends on what figure the patients are given for being free of PPI. If the worst case scenario is taken (on 45% off at 12 months and > 60% subsequently), it seems unlikely many patients will take this option. However, PPI-dependent GORD is very common and even a small percentage of this is a significant number of cases.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Nil specific. Endoscopic techniques continue to evolve. The procedures will need specific givernance and the operators will require training.

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?	(1) The uncertainly over the longer term results (2) The balance between short term costs (expensive to fund the procedure and disposable equipment) and longer term savings (possible but uncertain). The short-termism inherent in annual budgets for health care purchasers make it difficult to impossible to get such innovations funded.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Well-designed randomised controlled trials comparing PPI-treatment, laparoscopic surgery and the endoscopic plication devices, with significant duration, well-defined patients with definite GORD and cost-effectivess analysis. These data are available for lapaoscopic surgery and these well-performed trials have greatly influenced how well use the surgical approaches. These is not reason these techniques should not be analysed in exactly the same way.
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: Improvement in physiological parameters Improvement in GORD symptoms Improvement in quality of life % free of PPI Adverse outcome measures: Complications % requiring PPI treatment
26	Is there any other data (published or otherwise) that you would like to share with the committee?	None at present

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	None at present

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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.	No conflicts of interest.		
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:	**Ian Beales**
Dated:	**8/May/2022**