NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Professional Expert questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: **Self-expanding implant insertion into the intersphincteric space for faecal incontinence IP1764**

Name of Professional Expert: Jennie Grainger

Job title: Consultant Colorectal Surgeon

Professional Regulatory Body: GMC ☐

Registration number: 6135550

Specialist Society: ACPGBI, TPFS

Nominated by (if applicable): Shahab Siddiqi

1 About you and your speciality's involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

☐ Yes.

Comments:

1.2 Is this procedure relevant to your specialty?

☐ Yes.

Comments:

I am a colorectal surgeon with a special interest in pelvic floor surgery and the treatment of faecal incontinence.

1.3 Is this procedure performed by clinicians in specialities other than your own?

☐

☐ No – To my knowledge this would only be performed by a colorectal surgeon

Comments:

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☐ I have done this procedure at least once.

☐ **I do this procedure regularly.**

Comments:

I was the pelvic floor fellow with Carolynne Vaizey at St Marks Hospital, London and performed a number of these procedures with her. I have also done some with Andy Clarke in Poole, plus have started to introduce this service in my unit. Due to the selection criteria for this procedure I wouldn't describe its use as 'regular'. I suspect high volume centres will be performing this once a month.

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

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ **I take part in patient selection or refer patients for this procedure regularly.**

Comments:

I am happy with the indications for this procedure and patient selection.

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

☐ I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ **I have had no involvement in research on this procedure.**

☐ Other (please comment)

Comments:

There is little evidence for this in the literature currently, hence the introduction of a national database to try and generate more numbers to assess efficacy

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

☐ **Fewer than 10% of specialists engaged in this area of work.**

☐ Cannot give an estimate.

Comments:

I suspect this is a niche area with very few surgeons even within pelvic floor offering this treatment

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

☐ Yes

Comments:

2.2 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☐ **A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.**

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

A couple of variants are available. It is not 'novel' but there is a lack of efficacy

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

There isn't a comparable procedure. Patients who are suitable would instead be offered non-surgical approaches such as an anal insert or irrigation. This adds to the repertoire of treatments available and complements but doesn't compare

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

There will be a national register set up via Andy Clarke in Poole in association with THD. Andy Clarke also registered a multicentre prospective evaluation of surgical outcomes and faecal incontinence scores study to assess Sphinkeeper to determine how effective the treatment is.

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or 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.

At the recent Pelvic Floor Society conference, Andy Clarke presented his results of his cohort of patients. This is unpublished data.

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

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

Adverse events reported in the literature (if possible please cite literature)

Anal discomfort

Extrusion of implant

Other complications such as sepsis, bleeding, abscess or fistula were not reported in Ratto et al, Techniques in Coloproctology. 2016:20(1): 59-66 or in the more recent study La Torre et al, Sphinkeeper for faecal incontinence: a preliminary report. Colorectal disease, August 2019

Anecdotal adverse events (known from experience)

Sepsis

Migration of implant

Pain

Theoretical adverse events

3.2 Please list the key efficacy outcomes for this procedure?

Improvement in quality of life scores
Improvements in faecal incontinence scores e.g. St Mark's incontinence score

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

Limited long-term data from efficacy and safety viewpoint

3.4 What clinician training is required to do this procedure safely?

Training regarding appropriate indication and patient selection
Training in the technical aspect of using the device

3.5 What clinical facilities are needed to do this procedure safely?

MDT setting for patient selection
Theatre under GA wit recovery facilities
Often recommended that this is performed under ultrasound guidance so training in endoanal ultrasound and a compatible endoanal ultrasound would be needed

3.6 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

The use of ultrasound is recommended and would be classed as best practice

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

Patients discussed within MDT prior to selection
Failed non-surgical treatment
Complications
Use of concomitant antibiotics
Number of extrusions

4.1 Beneficial outcome measures. This 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:

St Marks Incontinence Score
Number FI episodes per week
Faecal incontinence quality of life score (FIQL)
Other quality of life measures may be appropriate.

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

Immediate
Bleeding
Sphincter damage
Acute urinary retention
Pain

Up to 2 weeks post op
Infection
Pain
Device extrusion
Abscess
Reaction to implant

Late
Device extrusion/ migration
Sepsis
Fistulation

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

☐ **Rapidly (within a year or two).**

☐ Slowly (over decades)

☐ I do not think the NHS will adopt this procedure

Comments:

There is little else to offer suitable patients so would add to the repertoire of what we can offer patients

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

☐ Most or all district general hospitals.

☐ **A minority of hospitals, but at least 10 in the UK.**

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

This should be performed in pelvic floor units and due to the numbers, I suspect not 'all' DGHs.

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

☐ Major.

☐ **Moderate.**

☐ Minor.

Comments:

6 Other information

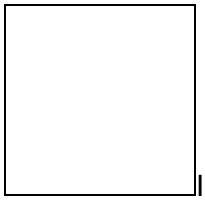
6.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Comments:

7 Data protection and conflicts of interest

7.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The professional expert questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

 I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our privacy notice

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7.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures. Conflicts of Interest for Specialist Advisers

Declarations of interest form			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**
Consultant Colorectal	I am currently working as a consultant colorectal	April 2018	Ongoing

Surgeon with interest in pelvic floor, Countess of Chester Hospital	surgeon who runs a pelvic floor practice within my hospital with an interest in dealing with patents with OASI and faecal incontinence. Due to this I have an interest in formal guidance for the use of injectable implants for FI		
External Affairs Officer the Pelvic Floor Society	I am the current external affairs officer for TPFS where I am responsible for how the TPFS is perceived publicly, maintaining their social media and am current webmaster	April 2018	April 2021
External Affairs Committee member for ACPGBI	I currently sit on the external affairs committee for the Association of Coloproctologists for Great Britain and Ireland where I advise about external issues, disseminate information regarding courses, aid in newsletters and website matters	July 2019	July 2021
Faecal incontinence course faculty, Cardiff	I am faculty for a course looking at the management of faecal incontinence which includes wet lab. During this, I teach delegates on the course how to perform sphinkeeper. This course is supported by THD.	February 2019	
MASIC Council	I am a council member for MASIC	March 2020	

	(Mothers with anal sphincter injuries after childbirth). This is a charity and I am currently organising the NW Educational day on behalf of MASIC. This day is sponsored in part by THD		

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest. Types of interest: **Direct interests** **Financial interests** - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. *For examples of financial interests please refer to the policy on declaring and managing interests.* **Non-financial professional and personal interests -** Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. *For examples of non-financial interests please refer to the policy on declaring and managing interests.* **Indirect interests -** Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit. A benefit may arise from both a gain or avoidance of a loss.
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mirella Marlow Programme Director

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Professional Expert questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	**Self-expanding implant insertion into the intersphincteric space for faecal incontinence IP1764**	
Name of Professional Expert:	Susan Green	
Job title:	Consultant Colorectal Surgeon	
Professional Regulatory Body:	GMC	x☐
	Other (specify)	☐
Registration number:	3248256	
Specialist Society:	Pelvic Floor Society/ Association of Coloproctology	
Nominated by (if applicable):	Shahab Siddiqi	

1 About you and your speciality's involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

x☐ Yes.

☐ No – please answer no more questions and return the form

Comments:

1.2 Is this procedure relevant to your specialty?

x☐ Yes.

☐ No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

1.3 Is this procedure performed by clinicians in specialities other than your own?

☐ Yes – please comment

☐**x** No

Comments:

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

☐**x** I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

I have a lot of experience in this field (25 years) and have put in other artificial anal sphincters including Fenix magnetic sphincter . Pending completing a course and getting mentorship I will be ready to enrol my first case into the ISRCTN Sphinkeeper registry (already identified)

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

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐**x** I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

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

☐**x** I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

☐**x** Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

☐**x** Yes

☐ No - If no, please suggest alternative titles.

Comments:

2.2 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☐ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☐**x** Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

It is a new artificial anal sphincter. Several different artificial anal sphincters have been designed and implanted over the last 30 years (first report in 1987 using a modified urinary sphincter -AMS). The material, mode and place of insertion of Sphinkeeper are novel and the limited data in the literature, albeit small numbers with limited follow up, support its safety and efficacy but it has to be noted that all previous artificial anal sphincters inserted through the perineum have been discontinued due to problems with infection/ erosion or extrusion.

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

This is the only artificial anal sphincter currently on the market. The AMS and PAS artificial anal sphincters were both removed from the market and the most recent implantable device for faecal incontinence (Fenix magnetic sphincter) was withdrawn by the company before the randomised controlled trial was completed.
The only other historic procedure to mention is the dynamic graciloplasty. The fatiguable gracilis muscle was converted into a fatigue resistant muscle using chronic electrostimulation and used to form a neo-sphincter by wrapping it around the anal canal. The advantage over the artificial anal sphincters was that it wasn't a foreign material that was being implanted but it had it's own complications and I am not aware of anyone who still does this procedure in the UK.

All patients with faecal incontinence should have a trial of maximum conservative treatment before surgical intervention is considered. This includes dietary modification, drugs, anal plugs, biofeedback and rectal irrigation.
If conservative methods fail surgical management depends on the underlying cause (assessed physiologically and anatomically) and severity of the faecal incontinence. External anal sphincter injuries (usually obstetric) are traditionally treated by sphincteroplasty.
Patients with moderate/ severe faecal incontinence with or without a sphincter defect are often successfully treated by neuromodulation (sacral nerve stimulation). SNS has revolutionised the treatment of faecal incontinence and randomised controlled trials have demonstrated good long term outcome in appropriately selected patients.
Minor passive leakage may improve with injectable materials/ bulking agents that are injected either into the submucosa or intersphincteric space (aiming to provide a passive increase in resting tone) but there is little evidence in the literature to support a significant effectiveness for injectable bulking agents (only 2 studies report a > 50% improvement).
The Secca procedure delivers radiofrequency energy to the internal anal sphincter which induces scarring leading to tightening of the internal sphincter. A limited number of small studies in the literature show some short term improvement in symptoms but very few report a sustained effect.

The difficult group of patients whom Sphinkeeper is targeted at is patients with severe faecal incontinence to formed stool which has a significant effect on quality of life and who have failed or are deemed unsuitable for the above surgical techniques. The only other surgical option at this stage would be a stoma.

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

There are no large studies or randomised controlled trials in the literature. There are several small case series. There is one registry in the UK (ISRCTN61603070)

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or 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.

Pelvic Floor Society Annual Meeting November 2019 Plymouth
Andrew Clarke presented his personal series to date

Largest case series in literature (published Aug 2019) M.La Torre et al
13 consecutive patients , 6 month FU period. Showed improvement in Cleveland Clinic Faecal Incontinence score and a reduction in Faecal incontinence episodes per week. No infective complications reported but 2 prosthesis extrusions and one prosthesis dislocation

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

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

Adverse events reported in the literature (if possible please cite literature)

Prosthesis extrusion

La Torre M et al Colrectal Disease Aug 2019

2 out of 13 patients at 1 month FU after surgery

Prosthesis dislocation/ migration (defined as a prosthesis not at same level as other implants)

La Torre M et al Colorectal Disease Aug 2019

1 out of 13 patients at 6 months after surgery

Ratto C et al Tech Coloproctol 2016 Jan; 20(1):59-66

In series of 10 patients - partial dislocation of 1 prosthesis detected on endoanal U/S post op. Caused anal discomfort which resolved after 1 week

de la Portilla F et al International Journal of Colorectal Disease March 2017, Vol32, Issue 3 pp 437-440

Gatekeeper not Sphinkeeper (only 6 rather than10 implants) but in series of 7 patients reported at 3 months FU 24 out of 42 prostheses in 5 of 7 patients had displaced but treatment considered successful in 3 out of 7 patients

No reports in literature of any infective complications

Verbal report from Andrew Clarke – in his series no infective complications, one patient had minor erosion into anal canal but didn't require intervention and didn't extrude

Somewhat to my surprise no assessment of symptoms of obstructive defaecation (ODS) in any of series pre op and no reported problems with ODS post op (one series reported no obstruction to passage of stool at 3 months but high fibre diet/ stool softeners were prescribed)

Andrew Clarke verbally reported no problems with ODS post op in his series

Anecdotal adverse events (known from experience)

Theoretical adverse events

See above comments re ODS

From experience with previous artificial sphincters infection has to be a risk

3.2 Please list the key efficacy outcomes for this procedure?

All results in literature are preliminary/ short term results
At 6 months max resting anal pressure, total number of episodes of FI/ week and Cleveland Clinic FI score all improved significantly but FIQL score improvement not significant

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

Only limited data / small numbers/ short term FU available in literature

3.4 What clinician training is required to do this procedure safely?

Minimum requirements should be:
-Member of established pelvic floor team with regular pelvic floor MDT participation

-Industry run course to familiarise surgeon and scub team with the technique and equipment
-Mentor for first couple of cases with then ongoing support from company representative
-All cases discussed at MDT pre op and data collected in National Sphinkeeper Registry
-Audit of outcomes

3.5 What clinical facilities are needed to do this procedure safely?

Must be done in operating theatre under strict aseptic technique. Although described as possible to do under local anaesthetic, particularly when learning technique would advise should be under general or spinal anaesthesia

3.6 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

No – appears to be being introduced cautiously in pelvic floor units with the necessary expertise with support from industry, who are running courses.
As mentioned above Registry set up and centres doing the procedure appear to have engaged with the registry

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This 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:

As per ISRCTN registry for Sphinkeeper

Questionaires completed by patients

1. **Immediately after surgery**
2. **6 months**
3. **12 months**

Surgical outcomes and complications will be recorded

Primary outcome measures (at baseline, 3 and 6 months):

1. **Vaizey/ St Mark's FI score**
2. **FI QOL score**

Secondary outcome measures (at baseline, 3 and 6 months):

1. **Post operative complications (periprosthetic abscess or anal fistula)**
2. **Correct distribution of implants measured by EAUS**

3. **Anorectal physiology with resting and squeeze pressures recorded**

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

As above but suggest should also record ODS symptoms both pre and post op

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

x☐ Rapidly (within a year or two).

☐ Slowly (over decades)

☐ I do not think the NHS will adopt this procedure

Comments:

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

☐ Most or all district general hospitals.

x☐ A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

☐ Major.

☐ Moderate.

☐**x** Minor.

Comments:

If safe and efficacious I don't anticipate the number of procedures done will be very high as it will be reserved for only a well defined group of patients with moderate/ severe FI, significantly affecting QoL who have exhausted other treatment options

6 Other information

6.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Comments:

7 Data protection and conflicts of interest

7.1 Data Protection

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☐ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our privacy notice

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Declarations of interest form			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**

* Guidance notes for completion of the Declarations of interest form

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Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mirella Marlow Programme Director