NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1816 - Laparoscopic morcellation of uterine fibroids**

Your information

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Email address:	
Professional organisation or society membership/affiliation:	British Society for Gynaecological Endoscopy, European Society for Gynaecological Endoscopy
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 4425177

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	I have been performing laparoscopic myomectomies and hysterectomies since 2001 and have used the morcellation technique since. I am familiar with the techniques and its evolution during this time. Our group probably has one of the largest experiences with these procedures and we have published our experience with laparoscopic myomectomy and morcellation in 2017 involving 514 patients. I am aware that the procedure is widely used around the UK, both in the NHS and private sector, although there has been some reduction in the use after 2014 when the FDA statement on 'power morcellation' was released. I was the President of the British Society for Gynaecological Endoscopy at the time and have been involved in dealing with the impact of this statement since then. I am not aware of other regular use of this technology outside gynaecology.

2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research.
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):	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?	Laparoscopic morcellation has been around for more than quarter of a century and has been the standard care for many years. It was an essential component of transition from open myomectomy to laparoscopic myomectomy. Modifications have been made to it since 2014 (such as adding in bag morcellation) or some clinicians switching to manual morcellation.

Current management

5	Please describe the current standard of care that is used in the NHS.	As above.

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?	Manual morcellation or performing open myomectomy/hysterectomy.

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 benefits include converting may open myomectomies to laparoscopic myomectomy which is known to be associated with shorter hospital stay, quicker recovery and reduced postoperative pain.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Premenopausal women who have relatively few fibroids who would be suitable for a laparoscopic myomectomy would benefit from this procedure.
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?	As stated above, this is already the standard care.
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)	It is likely to reduce overall costs to the healthcare service by reducing hospital stay. Quicker recovery would reduce cost to the society and the women who undergo 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)?	If compared to open myomectomy, there would be the additional cost of morcellator device.
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, these devices must be used by trained staff only!

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	Morcellation can cause internal organ injury. In the longer term remaining small pieces of fibroids can continue to grow in the abdominal cavity and can cause a condition called peritoneal leiomyomatosis, use of a bag reduces or eliminates this risk. If the fibroid turns out to be malignant, morcellation can cause spread of cancer and compromise the prognosis. However, myomectomy itself is likely to compromise the prognosis in the first place.
15	Please list the key efficacy outcomes for this procedure/technology?	
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As explained above, the FDA statements in 2014 and the subsequent ones caused controversy and this is still an ongoing issue.
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.

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.	

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)?	It is difficult to know the nationwide use of morcellator, but I expect this would be some hundreds.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	As above
23	Are you aware of any issues which would prevent (or have prevented) this	We have been using this technology already in our organisation.

	procedure/technology being adopted in your organisation or across the wider NHS?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Prospective data collection to include all patients where this technology is used would be important.
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: Reduction in number of open myomectomies (there are a number of RCTs demonstrating the benefits of laparoscopic myomectomy over open myomectomy) Adverse outcome measures: Visceral injury due to use of morcellator Peritoneal leiomyomatosis Spread of malignant/potentially malignant tissue and its impact on survival

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:	**Ertan Saridogan**
Dated:	**22 December 2020**