NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1701/2 Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia**

Your information

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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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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 familiar with the procedure. I have recruited patients into a prospective pan European trial and have performed the procedure under the auspices of a local audit after completion of recruitment into that trial. I have performed some 50 or so procedures over some 5 years now I am recognised as a key opinion leader for this treatment and prior to the pandemic, led industry run teaching to interested urologists from the UK I have presented on this procedure in terms of both technique and analysis of outcome data at a number of international conferences
	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	To my knowledge, this procedure is only offered on the NHS through Frimley Health, thanks to the background of involvement in trials. Other units and urologists are definitely interested in exploring the opportunities afforded by this technology for their patients, but have had difficulty launching a service thanks to the current NICE guidelines and the need to be doing so within some kind of recognised, registered local study. In some cases, the process of doing so has been interrupted by COVID, others are waiting for/ hoping for a change in IPG This procedure would and should only be offered and performed by urologists

	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 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):	This technology represents a completely different approach to all existing procedures in the field of symptomatic BPH and male LUTS. Saying that, the aim to remodel the bladder neck and prostatic urethra is not a new concept, it is simply the approach in doing so that is novel Definitely novel and of uncertain safety and efficacy. However, there is now a significant amount of both safety and efficacy data; including a prospective multi-centred randomised trial vs sham, 2 multicentred prospective European studies and a single centre prospective study with long term data. Over 400 men have now been included in high quality study data
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 procedure sits squarely with urolift and Rezum in the category of a minimally invasive surgical procedure for symptomatic BPH – so represents an alternative to those options. As a group, these MISTs represent an alternative to the standard resecting surgical options of plasma TURP, monopolar TURP, Greenlight laser PVP and Holmium Laser enucleation of the prostate

Current management

5	Please describe the current standard of care that is used in the NHS.	TURP remains the most commonly performed procedure in the UK
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?	This procedure employs a unique mode of action Urolift (prostatic urethral lift procedure) employs implants to distract or pull apart obstructive prostate tissue to relieve obstruction. Rezum (water vapour ablation) employs the delivery of steam into the tissue of prostate in order to ablate the tissue with heat and result in slow shrinkage of the obstructive tissue to relieve obstruction. TURP and the lasers, employ energy to cut out or vaporise tissue to create a wide cavity through the prostate to relive obstruction

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?	A MIST that avoids the need for permanent implants or the heat destruction of tissue with not dissimilar outcomes to those approaches in terms of symptom improvement and with no impact upon sexual function, be it in terms of changes in ejaculatory function (no new dry ejaculation) or upon erectile function
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Likely younger men with smaller prostate volumes, who seek a treatment alternative to both medication and standard resecting procedures such as TURP or the lasers, with the desire to avoid negative impact upon sexual function and ensure a rapid return to normal activities
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?	It represents a further MIST option that could encourage further movement of patients from the in patient to the day case setting, in a predictable and reliable way. Hence relieve pressure on in patient beds, avoid unexpected overnight bed occupancy, with a low risk of complications that might lead to primary or secondary care emergency/ urgent attendance.
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 quick and I perform the implantation under sedation in 10 mins. The device is then removed under local anaesthetic in a treatment room or clinic type setting 5 to 7 days later. The equipment used is standard and readily available in all urology units. The only cost is the that of the device itself
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)?	I would expect the cost of the procedure to neutral / or close to it compared to the other MIST procedures
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Day unit or minor ops setting for device placement – treatment room or clinic setting for removal under local anaesthesia (lignocaine gel)

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training is required to help identify the target and appropriate group of patients, understanding of the device mechanism and how to remove it. Technically this is a very straight forward procedure, with little expertise required.

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	Following implantation and period of time device is in place: failure to void, haematuria, urinary frequency, urinary urgency, pain After removal: failure to void, but if void OK, any haematuria and associated urinary symptoms tend to settle in a day or 2. Risk of UTI There have been no incidences of incontinence, ejaculatory dysfunction or erectile dysfunction to my knowledge. The main adverse events beyond the above relate to persistence of symptoms
15	Please list the key efficacy outcomes for this procedure/technology?	Improvements in IPSS, QOL, maximum flow rate, improvements in post void residual volume, impact on SHIM and reoperation rates over time
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Longest published follow up data is for 3 years and from a single centre using first generation device
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):	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.	None relevant beyond the peer reviewed published data
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	In set up phase for MT08 – randomised prospective multicentred European trial of device vs TURP Looking to launch 2022 (delayed because of COVID)

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)?	As for urolift and Rezum
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	none

	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?	No. The ambition to run a randomised trial vs the 'standard of care' TURP should be supported. Of the MISTs for symptomatic BPH, only urolift has been part of such a trial. Rezum has not been set up in such a comparative trial against a standard of care be it medical treatment or surgical and as such will not gain the level of evidence base and recommendations from urological bodies across the world that urolift has ie level 1a evidence
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: Improvements in IPSS/ QoL, max flow rate and post void residual volumes at 3 months and 1 year Time scale of return to all normal activities Adverse outcome measures: Impact of sexual function: SHIM scores Clavien -Dindo graded complications Separately Clavien -Dindo complications >=3 Reintervention rates Over first year post treatment

Further comments

23	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
Lecturer/proctor (advisory)	Olympus Keymed & iTIND	2019	on going
"	Teleflex & wolijt	2014	on going
"	Procept Biorobotics & Agrabblation of the prostate	2016	on going

☑ 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.

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Dated:	**Click here to enter text.**	24 NOV 2021