

Medical technologies guidance

Collated expert questionnaires

Technology name & indication: Rezum for treating benign prostatic hyperplasia

Experts & declarations of interest (DOI)

Expert #1	John McGrath, Consultant Urologist, Royal Devon and Exeter NHS Foundation Trust, [REDACTED]		
	DOI: None		
Expert #2	Mark J Speakman, Consultant Urological Surgeon, Taunton and Somerset NHS Foundation Trust, [REDACTED]		
	DOI: Yes Member of the European Association of Urology male LUTS Guideline Development Group		
Expert #3	Neil Barber, Consultant Urological Surgeon, Frimley Health NHS Foundation Trust, Frimley Park Hospital, [REDACTED]		
	DOI: Yes		
	Type of interest *	Description of interest	Relevant dates
			Interest arose Interest ceased
<i>Indirect</i>	Occasional advisory consultant for Boston Scientific (Greenlight laser)	2016	On going
<i>Direct - financial</i>	Proctor for Teleflex/ Neotract for Urolift	2015	On going

	<i>Direct - financial</i>	Advisory consultant for Olympus/ Keymed for iTIND	2019	On going
	<i>Indirect</i>	Proctor/ advisory consultant for Procept Biorobotics for Aquablation of the Prostate	2016	On going
Expert #4	Nitin Shrotri, Consultant Urologist, East Kent Hospitals University NHS Foundation Trust, [REDACTED]			
	DOI: None			
Expert #5	Rahul Gujadhur, Consultant urological surgeon, Newcastle Upon Tyne NHS Foundation Trust, [REDACTED]			
	DOI: Yes			
	Type of interest *	Description of interest	Relevant dates	
			Interest arose	Interest ceased
	<i>Non-financial professional</i>	Travel expenses paid for by Keybodmed to attend Rezum training day at Basingstoke hospital	17 Sep 2018	17Sep 2018
Expert# 6	Professor Rajendra Persad, Consultant Urological Surgeon, North Bristol NHS Trust, [REDACTED]			
	DOI: Yes			
	Type of interest *	Description of interest	Relevant dates	
			Interest arose	Interest ceased
	<i>Indirect</i>	I use this technology currently	May 2017	continuing
	Professor Persad updated and confirmed that the only indirect conflict remains the same as above: occasionally use the technology where appropriate. (an email response on 9 th October 2019)			
Expert~ 7	Ian Pearce, Consultant Urological Surgeon and Andrologist, Manchester University NHS Foundation Trust, [REDACTED]			

	DOI: Yes			
	Type of interest *	Description of interest	Relevant dates	
			Interest arose	Interest ceased
	<i>Non-financial professional</i>	Funded trip to learn complex Urolift (1 night stay)	22/11/2018	23/11/2018
Expert# 8	Richard Hindley, Consultant Urologist, Hampshire Hospitals NHS Foundation Trust, [REDACTED]			
	DOI: Yes			
	Type of interest *	Description of interest	Relevant dates	
			Interest arose	Interest ceased
	<i>Direct - financial</i>	Payment for teaching/lecturing/proctoring of Rezum by Kebomed	March 2017	March 2019
	<i>Direct - financial</i>	Payments for teaching/lecturing/proctoring of Rezum by Boston scientific	January 2018	
	<i>Indirect</i>	Our Urology Partners LLP (Urology chambers) owns a number of websites including rezum.co.uk	January 2017	
	Richard Hindley confirmed the conflicts are unchanged (an email response on 9 th October 2019).			
Expert# 9	Mr Tamer El-Husseiny, Consultant Urological Surgeon, Imperial College Healthcare NHS Trust, [REDACTED]			
	DOI: None			
Expert# 10	Mr Jordan Durrant, Consultant Urological Surgeon, Surrey and Sussex Healthcare NHS Trust (East Surrey Hospital. Redhill), [REDACTED]			
	DOI: NON			

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1. Please describe your level of experience with the technology, for example: Are you familiar with the technology? Have you used it? Are you currently using it? Have you been involved in any research or development on this technology? Do you know how widely used this technology is in the NHS?

Expert #1	<p>I am familiar with the technology.</p> <p>I have not previously used it.</p> <p>I have no prior involvement in research or development of this technology.</p> <p>I understand it is used in approximately 5 centres in the UK currently though that number is probably increasing.</p>
Expert #2	<p>I am familiar with the technique and have followed the publications on the subject as a member of the EAU male LUTS guideline group. I have recently chaired sessions at the European Urology Annual meeting on this topic.</p> <p>I have not used this technique myself</p> <p>We are not currently using it in my hospital</p> <p>I have not been involved in any research on the device – other than writing the EAU 2019 guideline</p> <p>It is not yet widely used in the UK, but I have spoken with Richard Hindley who has the widest experience of it and am aware that a number of UK centres are now starting.</p>
Expert #3	<p>I am familiar with the technology and have performed a small number of cases</p> <p>I have not been involved in any formal registered research as there have been no such trials in Europe – to my knowledge there has only been one quality trial performed – that being Rezum vs sham in the US with the aim of gaining FDA approval.</p> <p>Following recent publicity in the UK, leading to patient demand, increasing number of departments and urologists are looking to offer this technology</p>
Expert #4	<p>Yes, I am familiar with it</p>

	<p>I have attended a Training course and am trained to perform the procedure.</p> <p>Not yet. The business case in our department has gone through and we are in the process of setting up a date for our mentor to attend for a supervised session.</p> <p>No</p> <p>This technology is used widely in 3 units in the UK but more units are being set up.</p>
Expert #5	Have attended the training day on its use, appraised the literature and in process of putting a business case for its use in my unit.
Expert#6	I have used this technology clinically on many occasions since 2018 and am currently using it because of very favourable results and patient experience. I am familiar with the technology and safety aspects. I am not actively researching but am auditing results.
Expert#7	<p>I am familiar with this technology – purely from an academic stand point.</p> <p>I have not used this technology but I am aware of its use both within the NHS and in the private sector.</p> <p>I have not been involved in any research in relation to this or other competing technologies and have no conflict of interest</p>
Expert#8	<p>I am very familiar with the technology. I performed the first case in the UK in March 2017 and since then almost 400 men have had this procedure performed by myself or colleagues. There is nobody currently in the UK with more experience.</p> <p>Yes I am continuing to use it.</p> <p>We are prospectively collecting data and have presented this at meetings including the AUA and BAUS meetings. We are soon to submit our results for publication.</p> <p>It is fairly quickly being offered at more centres around the UK. I have been involved with training other Surgeons.</p>
Expert#9	<p>Part of the team that 1st introduced the Rezum to the UK. Been regularly performing it since January 2018. Majority of the cases performed under local anaesthesia & sedation as day cases.</p> <p>Outcome data presented internationally at the EAU meeting in Barcelona.</p> <p>Not widely used yet on the NHS</p>
Expert#10	<p>I have started using Rezum two months ago and have now finished the initial supervision period with the company representative and will be carrying out one or two procedures weekly from here on.</p> <p>I have had no prior involvement with the technology apart from launching the business case to start using it at my hospital. As part of the introduction of this, my cases are being audited, but does this does not constitute research.</p> <p>As far as I am aware, 10 sites in the UK are now using this technology.</p>

2. Has the technology been superseded or replaced?

Expert #1	No.
Expert #2	No
Expert #3	No
Expert #4	No, it hasn't. But it closely competes with Urolift, which appears to have a higher re-operation rate
Expert #5	No
Expert#6	No
Expert#7	No
Expert#8	No
Expert#9	No
Expert#10	No

Current management

3. How innovative is this technology, compared to the current standard of care? Is it a minor variation or a novel concept/design?

Expert #1	It is a minor variation. The majority of surgery for bladder outlet obstruction in men involves tissue removal or destruction using a form of energy. This is another energy form but the principles are the same.
Expert #2	It is an innovation that uses a newer energy to achieve internal ablation of the prostate. In that sense it is similar to transurethral needle ablation (TUNA) of the prostate that was investigated and used in the 1980s – 1990s

Expert #3	In concept Rezum is a modern reincarnation of previous interstitial ablative treatments – the innovation being the use of steam to ablate tissue rather than other forms of heat or chemical
Expert #4	It is a novel concept
Expert #5	Innovative in the sense that it uses water vapour to decrease prostate size by necrosis over time.
Expert#6	It is a major innovation for producing similar results with much less trauma and metabolic upset
Expert#7	I believe this to be a minor variation of current novel technologies in that the greatest advance is the concept of day case outflow surgery which has been established with TURiS and more latterly with Urolift
Expert#8	It is a novel concept. Heating by convection rather than conduction. The steam injected trans-urethrally into the prostate condenses and the tissue is ablated. The steam is confined to the compartment or zone into which it is injected. It is not under high power.
Expert#9	Novel in its technology and design
Expert#10	The technology is essentially TUNA – an old technology that has been repurposed and updated. In its current form – utilising steam/water vapour it is a new concept and technology.

4. Are you aware of any other competing or alternative technologies available to the NHS which have a similar function/mode of action to the notified technology? If so, how do these products differ from the technology described in the briefing?

Expert #1	Rezum would be competing with technologies already embedded in NHS care such as TURP, TUVF, HoLEP etc
Expert #2	It is a relatively minimally invasive treatment (MIT) for lower urinary tract symptoms (LUTS), usually performed as a daycase and is therefore a 'competitor' to Urolift, prostate artery embolisation or the iTIND stent device although these all use different interventions to achieve their effect.
Expert #3	Interstitial ablation has been performed using TUNA (Transurethral needle ablation), TUMT (Transurethral Microwave therapy), Interstitial laser ablation and intra-prostatic ethanol ablation

	Rezum, uniquely, employs steam to ablate tissue – the method of energy delivery is described as being more efficient and achieving better, larger areas of ablation compared to the technology above
Expert #4	There is no technology available which is completely similar. The Urolift is slightly less/similarly invasive The principle of the Urolift involves holding the walls of the prostate apart, while the Rezum involves submucosal steam vapourisation of prostate tissue.
Expert #5	No
Expert#6	There are some which are suitable for only a limited number of patients with smaller prostates and without median lobes, In other words this technology is more widely applicable and more health economically viable in my opinion
Expert#7	No
Expert#8	A competing option would be Urolift and other minimally invasive procedures such as PAE. It is also in some ways competing with the laser therapies, TURP and medication too. It sits in the middle between medication and the bigger procedures such as TURP. The advantages of Rezum over Urolit is that Rezum removes prostate tissue and the re-treatment rates are lower if one examines the US data.
Expert#9	No
Expert#10	The target patient population for Rezum is also suitable for treatment with Urolift. Urolift is essentially a competing technology procedure – a short, day-case surgical procedure for the management of enlarged prostates with lower side effects than TURP. The clear difference between the two is that Rezum actually ‘clears’ and reduces the volume of prostate tissue. Urolift merely uses anchored sutures to move the tissue away from the urethra.

Potential patient benefits

5. What do you consider to be the potential benefits to patients from using this technology?

Expert #1	Based on research and company information, it is claimed to have shorter operative time, a reduced length of stay in hospital and less blood loss than earlier treatments.
Expert #2	It is less invasive (although less effective) than a TURP and patients can be discharged the same day (although with a catheter in situ for 4-5 days).
Expert #3	Rapid procedure, performed under heavy sedation, as a true daycase – discharge within hours with a catheter. Removal of which requires at least one further attendance.
Expert #4	Low risk minimally invasive Day case surgery under GA/LA with a low re-operation rate.
Expert #5	Day case procedure Could be under w sedation- thus catering for higher risk patients for GA No/limited sexual side effects Could be used for patients with a median lobe
Expert#6	More durable effects in terms of outcome and much less trauma and side-effects than the current TURP practiced widely in the NHS
Expert#7	The potential benefit of this lies with its potential cost effective saving and reduced patient contact time which is beneficial to the patient and to the health care delivering organisation. The potential reduction in side effect profile compared with standard TURP has already been achieved with Urolift
Expert#8	A risk free procedure (no ED or incontinence) which is reliably day case and in the NHS would be a huge benefit as it is quick to perform. It is possible to perform 5 cases in a morning compared with TURP which is 3 cases and PAE 1 or 2.
Expert#9	Day case procedure Local anaesthesia + sedation Faster return to work Minimal impact on sexual function and continence
Expert#10	Short procedure, Day-Case. More cost effective than TURP. -Potential to perform under sedation or local anaesthesia.

	<p>-Actually removes excess prostate tissue</p> <p>-Low risk of erectile dysfunction & retrograde ejaculation as compared TURP</p>
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6. Are there any groups of people who would particularly benefit from this technology?

Expert #1	It looks to be broadly applicable to all groups where the prostate volume exceeds 30ml as a median lobe is not a contra-indication.
Expert #2	It is likely that patient choice and NHS waiting times for alternative therapies that may drive its implementation
Expert #3	Any man with moderate to severe lower urinary tract symptoms , not in urinary retention and with a prostate volume of less than 80mls, who would balance out a lower (but not nil) risk of negative impact of sexual function against a lesser improvement in symptoms compared to the reference standard procedure of TURP
Expert #4	<p>Patients at high risk of a long GA and bleeding.</p> <p>Another group worth looking at in a new study would be patients with Long term catheters who have UTIs (CAUTIs), who could be catheter free after low risk surgery. The long term effects would be fewer patients with catheters in the community, fewer CAUTIs, less use of antibiotics and therefore less antibiotic resistance in years to come. But this is an idea, and needs a proper study</p>
Expert #5	Younger patients on 1)medical therapy and affected by side effects for medication 2) those unwilling to consider conventional outflow surgery due to potential sexual side effects
Expert#6	Many patients requiring prostate surgery are frail, with multiple comorbidities. This is particularly suitable for them
Expert#7	<ol style="list-style-type: none"> 1. Patients deemed to be too unfit for GA/spinal surgery. 2. Patients with outflow obstruction and an enlarged median lobe which would be a contraindication to Urolift
Expert#8	Sexually active men with gland volumes 25-90 mls.
Expert#9	<p>Suitable for patients unfit for general anaesthesia</p> <p>Also younger patients wishing to preserve their sexual function</p> <p>Patient with enlarged median lobe (not suitable for Urolift)</p>
Expert#10	-Men with prostate volumes <80cc (potentially 80cc-100cc is feasible in selected cases)

	<p>-Younger men (50-60yrs) with mild-moderate symptoms who do not wish to take medication</p> <p>-Older, frail men (85yrs+) for whom a procedure under general anaesthetic is not sensible.</p>
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7. Does this technology have the potential to change the current pathway or clinical outcomes? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Expert #1	If the claimed benefits are robust, it could reduce the demands on theatre time and in-patient hospital stay.
Expert #2	It is unlikely to result in improved objective outcome although may do well in the short term with the important subjective patient reported outcomes.
Expert #3	Compared to TURP/ laser prostatectomies – the speed of this procedure allows more men to be treated per unit of OR time and frees up in-patient bed occupancy. This is balanced against at least one visit for subsequent removal of catheter. It is less effective in terms of degree of symptom improvement than standard surgical approaches but at least as effective as other minimally invasive options
Expert #4	Yes, certainly. A shorter Day case pathway after initial follow up, and as I have said above, decreasing the number of catheters in the community.
Expert #5	Yes- the operation takes less time compared to TURP/ HoLEP and therefore a greater number of patients could be treated on an operating list- benefit of decreasing waiting times for outflow surgery which is high nationally
Expert#6	Yes, Yes and Yes
Expert#7	<p>It potentially could change treatment pathways for bladder outflow surgery due to benign prostatic enlargement leading to reduced negative side effect profile.</p> <p>Without true, robust adequately powered studies, it is difficult to determine whether outcomes would be improved or indeed whether patients would experience fewer returns to hospital and fewer interventions over a prolonged time period.</p> <p>It could lead to less invasive therapy if its efficacy proves to be durable and cost effective over time</p>
Expert#8	Yes, yes and yes. It could completely change the BPH treatment pathway. In the future fewer and fewer men will have or need a TURP or enucleation technique if we offer minimally invasive procedures earlier on before the symptoms are too severe and the gland volume too large.

Expert#9	<p>Yes.</p> <p>Shorter hospital stay.</p> <p>Less invasive.</p> <p>Less impact on the sexual function and continence.</p> <p>Reduce the waiting list</p>
Expert#10	<p>Yes. The main concern at the moment, in my opinion, is the lack of data on the longevity of the procedure (due to it being new). If it is proven that the outcome of the procedure is sustained for as long as a TURP (as well as improving symptoms an equal amount and removing comparable amounts of tissue) – then it has the potential to replace a great many TURP procedures. This could have a massive positive impact across the NHS on the number of beds occupied overnight.</p> <p>Additionally, there is, in theory, the potential to carry the procedure out in an outpatient clinic and potentially in a ‘one-stop’ clinic for assessment of LUTS, diagnosis and treatment. Personally, I would not be prepared to carry the procedure out in a clinic, with an anaesthetist, at this time. Perhaps in 1-2 years, with the backing of more data, this is a possibility.</p>

Potential system impact

8. What do you consider to be the potential benefits to the health or care system from using this technology?

Expert #1	In terms of the health or care system, this technology may improve productivity in theatres and reduce the reliance on in-patient beds.
Expert #2	It can be performed quickly and as a day case procedure
Expert #3	Primarily, Rezum represents another minimally invasive surgical option for patients and with it the benefits of a quick procedure with rapid discharge – still requiring an anaesthetic and a further attendance for catheter removal
Expert #4	Whilst it will increase the number of patients having surgery due to it being a low risk procedure, it will decrease the number of patients with Long term catheters who are not offered high risk surgery.
Expert #5	1) Caters for category of patients who do not want to be on medical treatment but also do not want conventional surgery due to sexual side effects

	2) Day case procedure, shorter operating time – cost savings and decreasing waiting times for outflow surgery
Expert#6	Lowered side-effects and complications which come at a cost to the patient and to the NHS. less time in hospital and less time in the operating theatre giving advantages to the NHS in health economic terms
Expert#7	<ol style="list-style-type: none"> 1. Reduced patient contact time 2. Cost saving 3. Greater patient flow through the healthcare system 4. Greater utilisation of day case 5. Greater adoption of out-patient therapy for bladder outflow surgery <p>Fewer interventions and treatments for negative side effects</p>
Expert#8	We need to move away from in-patient procedures. TURP is no longer justified for the majority. Rezum will allow patients to have timely treatment without bed cancellation when there are no in-patient beds. It is a very quick to perform procedure with early same day discharge.
Expert#9	<p>Less theatre time</p> <p>Shorted hospital stay (day case as compared to average 2 days LOS with the TURP)</p> <p>Could help reducing the waiting list</p> <p>Free hospital bed</p> <p>Better outcomes – from a sexual function and continence aspects</p>
Expert#10	The main benefits at this time are cost-saving. In bypassing the need for an overnight bed and taking patients off of medication for symptoms – money is saved. TURP, due to the need for an overnight bed in most cases, costs the health service more than Rezum which allows same-day discharge.

9. Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the technology likely to cost more or less than current standard care, or about the same?

Expert #1	It has the potential to offer reduced costs if the release of in-patient beds is realised.
Expert #2	It is likely to cost less than the 'gold-standard' TURP but is more likely to need repeating in the future

Expert #3	Capital and disposable costs are higher than the standard TURP, however, this is balanced against a much shorter procedure time and the lack of requirement for in-patient stay. There are also the inevitable costs of a subsequent hospital attendance for removal of catheter and an almost 15% chance that a further attendance for similar will be required. Furthermore, from the submitted data, Rezum is associated with a relatively high rate of post operative urinary tract infections which also will have cost implications
Expert #4	The way it has been priced, it will cost the same or a little less. The NHS should bulk buy to decrease costs.
Expert #5	Less or same.
Expert#6	After paying for the generator the costs are more favourable than the current options of TURP or laser. Even the generator itself costs less than the current standard energy source for TURP I believe
Expert#7	I don't think there is enough information to make an informed comment on this. The device cost is clearly stated but the life span of the device is quoted in years, not number of cases, therefore the only way of determining cost effectiveness would be on a unit by unit basis with the knowledge of the number of likely cases to be performed over the lifespan of the machine. For true cost effectiveness assessment greater follow up would be required to assess the number of post operative healthcare encounters over time and this needs to be costed and compared to other therapies. Time to return to work for the patient should also be assessed
Expert#8	We are investigating this at the present time. I think it will be equivalent or less expensive. The longer term durability is not known but I suspect will be favourable. The early retreatment rates from the US data are favourable – 4.4% at 4 years.
Expert#9	Longer term data is needed especially to assess the need for future retreatment, but likely to be cost effective or at least neutral on the long term.
Expert#10	In the longer term, less. This was the entire basis for the successful business case at my Trust to introduce Rezum.

10. What do you consider to be the resource impact from adopting this technology? Could it, for example, change the number or type of staff needed, the need for other equipment, or effect a shift in the care setting such as from inpatient to outpatient, or secondary to primary care?

Expert #1	There are no substantial impacts to resourcing as far as I can tell from the literature.
Expert #2	It will move surgical interventions from in-patient theatres and inpatient beds to day case theatres and day case treatment, but will need additional nursing involvement for the delayed trial without catheter
Expert #3	Rezum requires either heavy sedation or a general anaesthetic, so there is little scope for relocation out of an operating theatre. However, being quick and all men having a post-operative catheter, means that all patients can be discharged after treatment very quickly ie a true daycase procedure performed in a daycase environment
Expert #4	It will see treatment offered more in the DayCare setting and smaller hospitals. Some may be private hospitals with the "Choose and Book" NHS facility.
Expert #5	More slots for patients having planned trials without catheter- patients go home same day but will have to return to have their catheter removed at 2 -4 weeks which requires resources in terms of staffing and premises
Expert#6	Briefer theatre stay, lighter anaesthetic, less staff as it is a simple and less complex procedure than the standard. Eg no fluid monitoring and very little irrigation used. Much easier monitoring for the anaesthetist and less anaesthetic requirement.
Expert#7	I do not believe this technology has any significant staffing implications. The main resource impact is the up front cost of the technology machine and the unknown factor of how many treatments the machine would perform during its lifespan. The number needed to treat to "break even" would need to be calculated and this would need to be taken in conjunction with the number of cases per year so that inflationary influences could be adjusted for
Expert#8	Yes it could ultimately lead to a shift towards outpatient procedures for BPH. The first battle will be to get all these procedures into the daycare setting but then yes outpatient is possible as the procedure can be performed under LA with sedation although some patients do require a GA.
Expert#9	Patients have the Rezum procedure as a day case surgery under Local anaesthesia & sedation. They go home on the same day with a catheter for at least one week, and then they return to a TWOC (trial without a catheter) clinic to have the catheter removed.

	<p>This will need an increase in capacity of TWOC clinics to cope with the increased demand.</p> <p>As compared to the standard TURP procedure/HoLEP – most patients have their TWOC before they are discharged.</p>
Expert#10	<p>As detailed above – at this time, there is no large impact on resources in either direction (apart from the patients not requiring overnight stay and the nursing that involves).</p> <p>There is indeed potential to establish this service in an outpatient setting which could have a huge positive impact on resources, however, this is not likely to happen immediately for anyone adopting the technology. Currently, both myself and my staff are still familiarising ourselves with the technology and it easiest to ensure a smooth service in a full operating theatre environment, with an anaesthetist looking after the patient.</p>

11. Are any changes to facilities or infrastructure, or any specific training needed in order to use the technology?

Expert #1	<p>Minor needs. Clearly, robust training in the novel technology but it looks like many of the skills required would be transferable from existing operative experience.</p>
Expert #2	<p>Most urology units have good access to day case operating facilities</p> <p>It does require specific training in the technique at another centre with proper expertise in the technique</p>
Expert #3	<p>None</p>
Expert #4	<p>Yes, a simple course for Endo urologists, Mentoring and a reasonable volume of audited cases would ensure good outcomes, so not many changes are needed.</p>
Expert #5	<p>Staff and surgeons will require training and mentoring – 10-20 cases</p>
Expert#6	<p>Simple training to set up the device – can be learned in one session of 40 minutes</p>
Expert#7	<p>No changes to infrastructure but in common with all new technologies, the likely learning curve needs to be determined and a robust training and mentorship program will need to be developed and implemented at all sites.</p>

Expert#8	No change in facilities or infrastructure. CNS support for reassurance in the early post-op period is useful. It is an easy procedure to perform. The key to success is managing expectations as the improvement in symptoms post procedure is not immediate. There can be some light haematuria and dysuria in the first few weeks.
Expert#9	Buying/leasing the equipment and staff training.
Expert#10	No. Technology can be adopted immediately and used in an operating theatre. Supervision from a company representative is needed for the first 10 cases, to ensure correct usage and teach staff. The technology is relatively simple, but not simple enough to use straight away without some teaching.

12. Are you aware of any safety concerns or regulatory issues surrounding this technology?

Expert #1	No
Expert #2	In the absence of any high quality RCTs on either safety or efficacy it is impossible to answer this question properly.
Expert #3	None
Expert #4	No
Expert #5	No
Expert#6	The surgeon user must be trained appropriately for optimum administration of the therapy. On the other hand the side-effects of suboptimal use are not dangerous as for example misuse of the laser!
Expert#7	No
Expert#8	No safety concerns as far as I am aware.
Expert#9	None
Expert#10	No

General advice

13. Please add any further comments on your particular experiences or knowledge of the technology, or experiences within your organisation.

Expert #1	N/A
Expert #2	<p>There is a single study from America that enrolled men to either Rezum or sham treatment for 3 months, at which point sham treated patients were offered Rezum – and most accepted this. They have been followed through with major publications at annual intervals on both their outcomes and low impact on sexual dysfunction out to 4 years (presented at EAU Barcelona 2019)</p> <p>There is still a genuine need for a proper RCT comparing it with either TURP or another accepted minimally invasive device such as Urolift, looking at both its safety and efficacy.</p> <p>The ad hoc comparison of data from 2 completely separate trials of Rezum and Urolift is not a substitute for a genuine RCT.</p> <p>This is important for patient safety and reassurance before its widespread adoption in the NHS.</p>
Expert #3	<p>Unlike all other BPH surgical technologies that have come to MTEP – TURiS, Greenlight laser and Urolift – there is no published prospective randomised multi-centre data measuring Rezum against a standard of care (be it medical therapy or TURP) nor any financial cost/ benefit analysis of that high quality data. Such data was seen as a prerequisite for MTG for the above listed other treatment options and by comparison to the still recognised reference standard ,TURP, (as in all the other submissions) informed measurements of differences in process, outcomes and costs as a surgical intervention.</p>
Expert #4	<p>The Urolift, PAE, Greenlight laser and HoLEP are competing technologies. BPH centres/clinics specifically offering all treatments should be set up by the NHS around the country (Like the Shouldice specialist clinic in Canada for Inguinal Hernia operations)</p>
Expert #5	None
Expert#6	<p>Patients do not get pathology/histology as for normal TURP so there needs to be assurance pre-op that cancer has been out ruled. But this is normal practice</p>
Expert#7	NA
Expert#8	<p>There is the potential for this technology to be used not just for those men with troublesome LUTS due to BPH but perhaps also for men in urinary retention. This is under investigation – a retention Rezum multi-centre study in the UK is due to start later this year we hope.</p>
Expert#9	Good, safe and effective treatment.

	<p>No safety issues</p> <p>An additional option to consider when counselling patients about BPH treatment options. Won't replace other modalities such as the HoLEP for example, especially in very large prostates (more than 80cc).</p>
Expert#10	Nothing additional to add.

Other considerations

14. Approximately how many people each year would be eligible for intervention with this technology, either as an estimated number, or a proportion of the target population?

Expert #1	I would anticipate that REZUM would sit alongside existing technologies. I have not used the system previously so I do not feel able to predict what percentage of 'conventional' surgeries it may displace.
Expert #2	Potentially 50% of men currently on medical drug therapy and approx. 50% patients undergoing TURP could be considered and hence the critical need for proper research studies
Expert #3	15 - 20% of men presenting with bothersome lower urinary tract symptoms
Expert #4	All patients having TURP can have this treatments plus the high risk patients who are treated with Long term catheter
Expert #5	15 000 annually in England
Expert#6	As a proportion of the target population 100% of those currently receiving TURP –it will also allow treatment of patients who have long term catheters with (expensive UTIs etc)complications in the community as they are too frail for TURP
Expert#7	<p>I would estimate that based on HES data suggesting approx. 25,000 outflow surgical cases per annum and estimating that at least 80% would be suitable, 20,000 patients would be eligible.</p> <p>In addition, with the availability of such a minimally invasive procedure with minimal negative side effects, a significant number of patients currently coping with their symptoms with less than fully effective medical therapy will potentially opt for intervention.</p>

	Without knowing the prescribing data for alpha blockers and 5 alpha reductase inhibitors in the UK, a realistic estimate of actual numbers would be impossible, but I would suggest could be in the region of 8-10,000 once fully established.
Expert#8	There is dispute re numbers – If we say 20,000 men per year then I suspect it would be suitable for 60-70% (14,000). We must also consider that this minimally invasive treatment may be a better option for younger men on 1 or 2 tablets (which can have worse side-effects than the surgical interventions) in many cases. This potential extended indication needs to be evaluated in larger studies.
Expert#9	I would expect that one third of the target population (men with symptomatic BPH requiring surgery) could be eligible for the Rezum
Expert#10	Our local population in Surrey is 1.8million. I anticipate carrying out 100-150 cases in the next 12months.

15. Would this technology replace or be an addition to the current standard of care?

Expert #1	Addition
Expert #2	It could be a substitute for drug therapy in patients unwilling or unable to take drugs and could be an alternative to TURP in patients who accepted less symptom improvement, less improvement in flow rate and reducing residual volume for less impact on ejaculatory function
Expert #3	Addition
Expert #4	Addition with some replacement
Expert #5	It will be an addition and is unlikely to replace current standard
Expert#6	I think it will replace 80-90% of TURP

Expert#7	I think potentially be an addition to Urolift but depending upon cost effectiveness comparison, may replace
Expert#8	Addition in the short-medium term. Longer term it or one of the other newer technologies could replace the current standard. NB The current gold standard is often stated as being TURP. I (and many other experts) now feel that the new gold standard is to have a portfolio of options tailored to the individual needs of the patient.
Expert#9	In addition. Won't replace other modalities such as the HoLEP for example, especially in very large prostates (more than 80cc).
Expert#10	Interesting question. I think, based on my experience thus far, that it could replace up to half of all TURPs. It also seems evident though that a great many patients who would not have previously had a TURP and would have been satisfied by long-term medication for their symptoms would now have this procedure instead of taking medication.

16. Are there any issues with the usability or practical aspects of the technology?

Expert #1	No
Expert #2	Appears to be a straightforward procedure in the hands of appropriately trained specialists
Expert #3	No
Expert #4	None
Expert #5	No
Expert #6	No real issues
Expert#7	No
Expert#8	No – easy to learn. Established training courses for surgeons. One hand piece per case. Never a need to use additional hand pieces (compared with urolift where the cost depends on the number of implants used).
Expert#9	In my experience, not ideal for very large prostate glands (HoLEP is the gold standard) or for patients with recurrent prostatitis.

Expert#10	No, it is actually very simple to use, once you have been taught how.
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17. Are you aware of any issues which would prevent (or have prevented) this technology being adopted in your organisation or across the wider NHS?

Expert #1	Capital costs are always a consideration as well as the additional disposable costs. If a business model demonstrated overall cost-benefits or positive impact on bed-days / theatre productivity these costs could be overcome.
Expert #2	Only the need for higher quality data on its outcomes
Expert #3	No
Expert #4	Slow uptake of new ideas and bureaucracy in many NHS hospitals
Expert #5	No
Expert #6	Yes, there is a reluctance to take on any new technology at present because of a perception that anything new must be more costly
Expert#7	Cost – in particular the initial outlay, especially in the presence of existing equipment already purchased. The cost of the maintenance contract must also be considered when assessing the cost effectiveness
Expert#8	No other than being unwilling to learn or embrace a new procedure – not a problem in my trust.
Expert#9	No
Expert#10	Nothing significant – just the usual hurdles of getting approval from managers who do not fully understand the medical conditions and treatments in use,

18. Are you aware of any further evidence for the technology that is not included in this briefing?

Expert #1	No
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Expert #2	Blank
Expert #3	Urology. 2019 Apr;126:171-179. doi: 10.1016/j.urology.2018.12.041. Epub 2019 Jan 21. Rezūm Water Vapor Thermal Therapy for Lower Urinary Tract Symptoms Associated With Benign Prostatic Hyperplasia: 4-Year Results From Randomized Controlled Study. McVary KT, Rogers T, Roehrborn CG.
Expert #4	No
Expert #5	No
Expert#6	Yes there are a number of very good publications now emerging on the use of this technology and the data is maturing and being presented globally
Expert#7	No
Expert#8	No other than our own Basingstoke data which is due to be published soon we hope. As mentioned a multi-centre study should be underway soon for men with retention.
Expert#9	No
Expert#10	As far as I am aware – Richard Hindley has the largest data set on this and has not yet published all of his data.

19. Are you aware of any further ongoing research or locally collected data (e.g. audit) on this technology? Please indicate if you would be able/willing to share this data with NICE. Any information you provide will be considered in confidence within the NICE process and will not be shared or published.

Expert #1	No – not aware of any.
Expert #2	Non-randomised cohort studies are underway looking at different patient populations including patients in acute retention.
Expert #3	Locally collected audit at Hampshire Hospitals NHS Foundation Trust and Imperial College

Expert #4	I am not aware, but all patients being offered this treatment around the UK should be part of a compulsory National audit.
Expert #5	N/A
Expert #6	There are individuals with very good data – eg Richrd Hindley. There is a user group who we are trying to develop a database and audit recording for the procedure
Expert#7	NA
Expert#8	Yes as above. We did update NICE at the previous stage of the NICE process. Our prospective data collection continues. We are pushing for a national Registry. I am also in communication with BAUS re an audit. Yes willing to share.
Expert#9	No
Expert#10	As above, Yes, I'd be willing to share my data.

20. Is there any research that you feel would be needed to address uncertainties in the evidence base?

Expert #1	Comparative studies against current standard of care would be extremely helpful along with evidence that day-case rates are high and maintained by the majority of users
Expert #2	Absolutely. There is a desperate need for one or more high-quality RCT looking at the safety and efficacy of the treatment comparing it with one or more other modalities such as TURP, another MIT or even medical therapy before widespread implementation. TUNA promised most of the same in the 1990s.
Expert #3	A monitored, prospective randomised multi-centred study versus a standard of care – 2 year follow up data minimum. A formal study vesus TURP in particular would not only illustrate the difference in degree of symptomatic relief (allowing patients to make a fully informed decision regarding choice of surgical option) but allow an accurate assessment of impact upon sexual function vs the standard surgical option, the 4 year data from McVary demonstrating a statistically significant drop in erectile function and MSHQ in sexually active men within the trial cohort following Rezum in year 4 of the Pivotal US study. Such data would also clarify whether

	Rezum truly offers any financial advantage to a healthcare system over standard of care and would allow correct comparison on this front to other minimally invasive technologies – those currently available and those in the future
Expert #4	As in 8 above.
Expert #5	health economic model actually comparing the cost and benefits of the procedure compared to other alternatives such as Urolift or TURP would be helpful.
Expert#6	The most useful research for me would be the recording of longterm data as with any technology but really there is so much that could be done. I think this is best left for the NIHR to develop studies in the future.
Expert#7	<ol style="list-style-type: none"> 1. Direct comparison over a longer period with TURP, HoLEP, Urolift 2. Robust cost effectiveness <p>Assessment and determination of learning curve</p>
Expert#8	<p>I think there is enough evidence to support the widespread adoption of this technology into the UK.</p> <p>Yes I would support a RCT but I think a trial comparing with TURP is not of value and is not comparing apples with apples. A RCT comparing minimally invasive treatments would be worth considering – perhaps also with some arms of the study randomised between medication and Rezum/other options. A large RCT of this nature would add to our knowledge.</p>
Expert#9	<p>Longer term outcome data</p> <p>Data for retention patients (who were not included in the initial studies)</p>
Expert#10	Not so much. I would value hard figures on 10 year re-operation rates, but this is still 5 years away.