Medical Technologies Evaluation Programme

MT 241 - UroLift System for the treatment of symptoms of urinary outflow obstruction secondary to benign prostatic hyperplasia

Expert Adviser Questionnaire Responses

Name of Expert Advisers	Job Title	Professional Organisation/ Specialist Society	Nominated by	Ratified
Professor Raj Persad	Consultant Urological Surgeon and Uro-oncologist	British Association of Urological Surgeons	Sponsor	Yes
Professor Thomas McNicholas	Consultant Urological Surgeon	British Association of Urological Surgeons	Sponsor	Yes
Mr Mark Speakman	Consultant in Urology	British Association of Urological Surgeons	NICE	Yes
Mr Neil Barber	Consultant Urologist	British Association of Urological Surgeons	Sponsor	Yes
Mr Andrew Thorpe	Consultant in Urology	British Association of Urological Surgeons	NICE	Yes
Mr Gordon Muir	Consultant Urologist	British Association of Urological Surgeons	NICE	Yes
Professor Mark Emberton	Consultant Urologist	British Association of Urological Surgeons	NICE	Yes
Mr Francis Keeley	Consultant Urologist	British Association of Urological Surgeons	NICE	Yes
Mr Mark Feneley	Consultant Urologist	British Association of Urological Surgeons	NICE	Yes
Mr Hashim Hashim	Consultant Urological Surgeon	British Association of Urological Surgeons	NICE	Yes

YOUR PERSONAL EXPERIENCE (IF ANY) WITH THIS TECHNOLOGY

Question 2: Please indicate your experience with this technology?

Expert Advisers	I have had direct involvement with this	I have referred patients for its use	I manage patients on whom it is used in another part of their care pathway	I would like to use this technology but it is not currently available to me
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Yes**	**Yes**	**No**	**No**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Yes**	**Blank**	**Blank**	**Blank**
Mr Mark Speakman **Consultant in Urology**	**Yes**	**Yes**	**Yes**	**No**
Mr Neil Barber **Consultant Urologist**	**Yes**	**No**	**No**	**No**
Mr Andrew Thorpe **Consultant in Urology**	**No**	**No**	**No**	**Yes**
Mr Gordon Muir **Consultant Urologist**	**Yes**	**Blank**	**Blank**	**Blank**
Professor Mark Emberton **Consultant Urologist**	**No**	**No**	**No**	**Yes**
Mr Francis Keeley **Consultant Urologist**	**No**	**No**	**Yes**	**Yes**
Mr Mark Feneley **Consultant Urologist**	**Yes**	**Yes**	**Yes**	**Yes**

Expert Advisers	I have had direct involvement with this	I have referred patients for its use	I manage patients on whom it is used in another part of their care pathway	I would like to use this technology but it is not currently available to me
Mr Hashim Hashim **Consultant Urological Surgeon**	No	No	**Yes**	**Yes**

Any Comments?	
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**As it has not been approved for funding in the NHS locally I have used it only in private practice, albeit reasonably frequently.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Blank**
Mr Mark Speakman **Consultant in Urology**	**Blank**
Mr Neil Barber **Consultant Urologist**	**Blank**
Mr Andrew Thorpe **Consultant in Urology**	**It is unavailable at my trust but I am impressed with the results from a recent randomised trial of Urolift vs TURP.**
Mr Gordon Muir **Consultant Urologist**	**Early user of technology**
Professor Mark Emberton **Consultant Urologist**	**Blank**
Mr Francis Keeley **Consultant Urologist**	**This is only available in the private sector locally.**
Mr Mark Feneley **Consultant Urologist**	**Blank**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Used it on models at conferences**

Question 3: Have you been involved in any kind of research on this technology? If Yes, please describe?

Expert Advisers	Yes/No	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Yes**	**I have performed research in the form of an observational study in my own cohort of patients (and one other colleague's).**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Yes**	**I have advised since inception and more recently contributed to a user Registry (known as "GUSTO"). Recently I published the results of an open series incorporating a range of experienced international users to define the technique, in order to produce an instructional video for education.** **1. McNicholas TA, Woo HH, Chin PT, Bolton D, Fernandez Arjona M, Sievert KD, et al. Minimally invasive prostatic urethral lift: surgical technique and multinational experience. Eur Urol. 2013; 64(2):292-9.**
Mr Mark Speakman **Consultant in Urology**	**Yes**	**I was involved in an RCT comparing this with TURP during 2012-2013. The study was called BPH-6.**
Mr Neil Barber **Consultant Urologist**	**Yes**	**National P.I BPA-6**
Mr Andrew Thorpe **Consultant in Urology**	**No**	**Blank**
Mr Gordon Muir **Consultant Urologist**	**Yes**	**Early adoption, prospective registry**
Professor Mark Emberton **Consultant Urologist**	**No**	**Blank**
Mr Francis Keeley **Consultant Urologist**	**No**	**Blank**
Mr Mark Feneley **Consultant Urologist**	**No**	**Blank**
Mr Hashim Hashim **Consultant Urological Surgeon**	**No**	**Blank**

THIS PRODUCT (TECHNOLOGY) AND ITS USE

Question 4: How would you best describe this technology?

Expert Advisers	It is a minor variation on existing technologies with little potential for different outcomes and impact	It is a significant modification of an existing technology with real potential for different outcomes and impact	It is thoroughly novel - different in concept and/ or design to any existing
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	No	**Yes**	No
Professor Thomas McNicholas **Consultant Urological Surgeon**	Blank	Blank	**Yes**
Mr Mark Speakman **Consultant in Urology**	No	No	**Yes**
Mr Neil Barber **Consultant Urologist**	No	No	**Yes**
Mr Andrew Thorpe **Consultant in Urology**	No	No	**Yes**
Mr Gordon Muir **Consultant Urologist**	Blank	Blank	**Yes**
Professor Mark Emberton **Consultant Urologist**	No	**Yes**	**Yes**
Mr Francis Keeley **Consultant Urologist**	No	No	**Yes**
Mr Mark Feneley **Consultant Urologist**	No	No	**Yes**
Mr Hashim Hashim **Consultant Urological Surgeon**	No	No	**Yes**

Any Comments?	
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**There is overlap here. the concept is old (e.g. urethral stents tried to achieve the same thing in holding open the prostatic urethra, but failed because of encrustation infection and dislodging) but the technology is new - this is a 'distraction' technique or 'urethral lifting' of the prostatic urethra, NOT a stenting.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Novel concept - remodelling the prostatic tissue. Novel device and implants to achieve remodelling and symptom benefits without upsetting sexual function.**
Mr Mark Speakman **Consultant in Urology**	**Although we have had prostatic stents in the past in the same part of the urethra this is rather different.**
Mr Neil Barber **Consultant Urologist**	**Blank**
Mr Andrew Thorpe **Consultant in Urology**	**It is a relatively easy to use technology and safe with good outcomes.**
Mr Gordon Muir **Consultant Urologist**	**Blank**
Professor Mark Emberton **Consultant Urologist**	**Blank**
Mr Francis Keeley **Consultant Urologist**	**Most new technologies used to treat benign prostatic obstruction have tried to replicate the traditional treatment (TURP) by removing prostatic tissue or heating it so that it dies off. Their advantages are chiefly to do with safety, but TURP has over the past 30 years become a much safer operation due to resection in saline, for example. The only similar concept to this technology was the prostatic stent, but that created a large surface in contact with urine and had problems due to migration. This avoids both of those problems.**
Mr Mark Feneley **Consultant Urologist**	**Blank**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Blank**

Question 5: What is the most appropriate use (e.g. clinical indication) for the technology?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Can be used in both young and old without a prostatic median lobe. The young, as it avoids the side-effects and sexual dysfunction that both conventional surgery and tablets can cause and the old because there is no haemodynamic upset or bleeding causing a threat to their circulating volume and therefore cardiovascular system.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**1. Men with lower urinary tract symptoms unresponsive or inadequately responsive to standard drug therapy or who are intolerant of drug therapy due to side effects or interference with sexual function and fertility.** **2. Men with lower urinary tract symptoms who are not prepared to undergo lifelong drug therapy.** **3. Men with lower urinary tract symptoms who are not prepared to undergo irreversible standard surgical options (TURP or laser) due to side effects or interference with sexual function and fertility.** **4. Men with lower urinary tract symptoms who have measurable benign enlargement of the prostate (so that the implants can gain purchase i.e. not men with bladder neck muscular obstruction and minimal prostatic enlargement.**
Mr Mark Speakman **Consultant in Urology**	**Men with bothersome LUTS/BPH who have either not responded well to combination medical therapy or men who would rather have a minimally invasive surgical treatment rather than long term medication.**
Mr Neil Barber **Consultant Urologist**	**Symptomatic benign prostate disease in (sexually) active men**
Mr Andrew Thorpe **Consultant in Urology**	**The slightly younger male with an enlarged prostate and bladder outflow obstruction who is refractory to medical management, needs an operative intervention, but wishes to maintain sexual function**
Mr Gordon Muir **Consultant Urologist**	**Outpatient alternative to TURP, use in high risk patients, men who wish to preserve sexual function**
Professor Mark Emberton **Consultant Urologist**	**Typically a man with LUTS who has not responded to or cannot tolerate drug therapy and wants a minimally invasive procedure that does not compromise sexual function.**

Mr Francis Keeley **Consultant Urologist**	**The most common scenario would be a man requiring treatment for lower urinary tract symptoms related to benign prostatic obstruction who wishes to avoid sexual dysfunction. The symptoms would be moderate to severe but not so severe as to cause urinary retention. Most will have failed some form of medical therapy due to intolerance or lack of efficacy. A second smaller group would be a man with similar symptoms who is at high risk for surgery (TURP) due to medical comorbidities, uncorrectable bleeding risk or anticoagulants that cannot safely be stopped.**
Mr Mark Feneley **Consultant Urologist**	**Treatment of prostatic obstruction and relief of lower urinary tract symptoms, with preservation of sexual function, particularly suitable for men who cannot tolerate or take medical therapies and/or who cannot have or decline other types of prostatic surgery.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Young men who have bladder outlet obstruction secondary to benign prostatic enlargement, to reduce the risk of retrograde ejaculation or those owho are at high risk of prolonged surgery.**

COMPARATORS (including both products in current routine use and also "competing products")

Question 6: ***Given what you stated is the appropriate indication (clinical scenario) for its use, what are the most appropriate "comparators" for this technology which are in routine current use in the NHS?***

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**TURP and Greenlight laser or Holep (holmium light laser)**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Drug therapy with alpha blockers, phosphodiesterase inhibitors and/or 5alpha reductase inhibitors. Surgical therapy by TURP is the most appropriate comparator or laser methods of "prostatectomy".**
Mr Mark Speakman **Consultant in Urology**	**At the top end TURP or BNI are direct comparators although it is a much less invasive procedure. Prostatic stents would have been the direct comparator but these are rarely used these days**
Mr Neil Barber **Consultant Urologist**	**TURP, Greenlight PUP, HOLEP**
Mr Andrew Thorpe **Consultant in Urology**	**TURP, bladder neck incision, holmium laser prostatectomy and Greenlight laser prostatectomy**
Mr Gordon Muir **Consultant Urologist**	**TURP, laser prostatectomy**
Professor Mark Emberton **Consultant Urologist**	**An RCT against surgery would struggle to recruit. Possibly medication as a head to head.**
Mr Francis Keeley **Consultant Urologist**	**TURP, laser TURP (green light, thulium or holmium), medical therapy.**
Mr Mark Feneley **Consultant Urologist**	**Transurethral resection of prostate**
Mr Hashim Hashim **Consultant Urological Surgeon**	**TURP**

Question 7: "Competing products": Are you aware of any other products which have been introduced with the same purpose as this one?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**None that I am aware, of although the TIND in the states seems to have a similar principle of action though it is only designed to stay in for 5 days**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**None with the same mechanism. Several with the same intention i.e. relief of urinary symptoms.**
Mr Mark Speakman **Consultant in Urology**	**No**
Mr Neil Barber **Consultant Urologist**	**No**
Mr Andrew Thorpe **Consultant in Urology**	**No**
Mr Gordon Muir **Consultant Urologist**	**No**
Professor Mark Emberton **Consultant Urologist**	**Yes there are a few devices around. My colleague at UCLH is trying to get a trial up and running with a similar device that is not implanted.**
Mr Francis Keeley **Consultant Urologist**	**Roughly 25 different lasers, prostatic stents, TUNA (transurethral needle ablation), TUMT (transurethral microwave therapy), prostatic embolisation.**
Mr Mark Feneley **Consultant Urologist**	**No**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Prostatic stents, but many have been withdrawn**

POSSIBLE BENEFITS FOR PATIENTS

Question 8: What are the likely additional benefits for patients of using this technology, compared with current practice/ comparators?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Speedy recovery, day case so shortened hospital stay and no need for expensive in-patient theatre use, no bleeding or need for transfusion with very little chance of infection. Early postop return to normal activity. Easily removed if any problems occur.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Versus medical therapy: avoids need to take very long-term drug therapy; avoids drug side effects; preserves normal sexual function and fertility. Versus surgery: day case or ambulatory surgery under sedation or local anaesthetic instead of more involved anaesthesia and several nights stay in hospital; avoids major surgery especially if unfit; preserves fertility; preserves sexual and especially ejaculatory function which is otherwise often destroyed (usually permanently) by surgery and damaged significantly by drug Rx.**
Mr Mark Speakman **Consultant in Urology**	**Less invasive. Much shorter hospital stay. No negative impacts on ejaculatory or sexual function.**
Mr Neil Barber **Consultant Urologist**	**Very rapid return to normal activity, rapid improvement in symptoms, maintenance of normal sexual function/sensation**
Mr Andrew Thorpe **Consultant in Urology**	**Better post-op sexual function, less bleeding, shorter length of stay**
Mr Gordon Muir **Consultant Urologist**	**Minimally invasive, very safe, outpatient treatment, no sexual dysfunction**
Professor Mark Emberton **Consultant Urologist**	**Less invasive than surgery - does not affect ejaculatory function**
Mr Francis Keeley **Consultant Urologist**	**Rapid recovery, preservation of sexual function.**
Mr Mark Feneley **Consultant Urologist**	**Relief of prostatic obstruction and lower urinary tract symptoms.** **Additional benefits include preservation of sexual function, and that the procedure is minimally invasive, performed as a day case.**

Expert Advisers	Comment
Mr Hashim Hashim **Consultant Urological Surgeon**	**Reduced risk of retrograde ejaculation**

Question 8.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Yes. There are no obstacles with the exception of needing a flexible cystoscopy first to rule out a median lobe.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**These benefits are highly likely to be realised. Symptomatic benefits reported from trials exceed those usually seen with drug therapy. So far there is no evidence of ejaculatory damage and even some evidence of improvement in erectile function (seems to accompany improvement of lower urinary tract symptoms). Obstacles: With data only out to 5 years there is still no certainty about longer term outcomes. We know ALL treatments, including "gold standard" therapies, have a failure rate and/or a "redo" rate with time and so will this.**
Mr Mark Speakman **Consultant in Urology**	**Yes. BPH 6 study should clarify this**
Mr Neil Barber **Consultant Urologist**	**Cost of implants**
Mr Andrew Thorpe **Consultant in Urology**	**Yes. The only obstacle I foresee at present is pricing and the NHS tariff - it has currently been placed in the wrong HRG grouping.**
Mr Gordon Muir **Consultant Urologist**	**Cost of implants**
Professor Mark Emberton **Consultant Urologist**	**Yes**
Mr Francis Keeley **Consultant Urologist**	**Yes, but the degree of urinary symptom improvement is possibly less than other technologies. The major obstacles are funding (the device is relatively costly) and inertia/scepticism on the part of urologists. There is a perception that this procedure will fail the test of time and will only serve to enrich urologists in the private sector (like many of its predecessors).**

Expert Advisers	Comment
Mr Mark Feneley **Consultant Urologist**	**Yes. Obstacles, in general: prostate size (very large) or prominent median lobe would exclude certain patients from being suitable for this procedure, and these factors would be routinely identified by prior clinical assessment.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Yes, but mainly relevant for those who are still wanting to have a family and sexually active**

Question 8.2: How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for patients are being realised?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Quality of life scores. Time in theatres, time in hospital,**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**By using validated symptom scores for urinary and sexual (especially ejaculatory) function. Recording of cessation of drug prescriptions. Recording of secondary treatments necessary.**
Mr Mark Speakman **Consultant in Urology**	**Already a good number of international publications**
Mr Neil Barber **Consultant Urologist**	**In patient stay, rate of readmission, cost of complications, re-operation rate**
Mr Andrew Thorpe **Consultant in Urology**	**length of stay, erectile dysfunction questionnaires, quality of life scores, return to stable health status and return to work etc.**
Mr Gordon Muir **Consultant Urologist**	**Audit of costs and outcomes in clinical practice. Data for sexual function is dramatic.**
Professor Mark Emberton **Consultant Urologist**	**PROMS**

Expert Advisers	Comment
Mr Francis Keeley **Consultant Urologist**	**In terms of economics, potential prescription drug savings must be included in the analysis. Perioperative savings seem obvious, since it is a short procedure done as a day case. Evaluation of clinical parameters is standard: lower urinary tract symptom scores, flow rates, and IIEF (sexual function scores).**
Mr Mark Feneley **Consultant Urologist**	**Measures of symptom relief, sexual function, need for post-operative catheterisation (usually not), hospital stay (usually day-stay), complications (usually minor and short duration), durability.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Very difficult to measure. Use questionnaires.**

Question 8.3: How good is this evidence for each of these additional benefits?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**This has been published in the European journal of Urology and the BJUI.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Good data from one randomised controlled study.** **Roehrborn CG, Gange SN, Shore ND, Giddens JL, Bolton DM, Cowan BE, et al. Multi-Center Randomized Controlled Blinded Study of the Prostatic Urethral Lift for the Treatment of LUTS Associated with Prostate Enlargement Due to BPH: The L.I.F.T. Study. The Journal of urology. 2013.** **Cantwell AL, Bogache WK, Richardson SF, Tutrone RF, Barkin J, Fagelson JE, et al. Multicentre prospective crossover study of the 'prostatic urethral lift' for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. BJU international. 2014; 113(4):615-22.** **McVary KT, Gange SN, Shore ND, Bolton DM, Cowan BE, Brown BT, et al. Treatment of LUTS secondary to BPH while preserving sexual function: randomized controlled study of prostatic urethral lift. The journal of sexual medicine. 2014; 11(1):279-87.**
Mr Mark Speakman **Consultant in Urology**	**By device standards excellent.**
Mr Neil Barber **Consultant Urologist**	**Very good-well designed studies, clean data published.**

Expert Advisers	Comment
Mr Andrew Thorpe **Consultant in Urology**	**Compares well in recently published RCT**
Mr Gordon Muir **Consultant Urologist**	**RCT data available**
Professor Mark Emberton **Consultant Urologist**	**RCT**
Mr Francis Keeley **Consultant Urologist**	**Limited to several small but well-conducted trials with limited follow-up.**
Mr Mark Feneley **Consultant Urologist**	**Good, from published randomised studies.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Weak**

Question 8.4: Please add any further comment on the claimed benefits of the technology to patients, as you see applicable

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Many patients do not cope with the stress of surgery given the group with BPH have a high incidence of co-morbidities - antihypertensive, anticoagulant therapy etc. also many do not like the length if inactivity recommended after TURP. This system allows almost immediate return to normal activity and function**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**There is no record that I am aware of, of UroLift making any man significantly worse or of severe adverse events so it seems safe. UroLift can be repeated and does not preclude any standard therapy being offered subsequently if necessary for progression of disease or if the clinician's judgement regarding suitability for UroLift was misplaced.**
Mr Mark Speakman **Consultant in Urology**	**Blank**
Mr Neil Barber **Consultant Urologist**	**Having performed over 30 cases, my experience is exactly as suggested in published data and therefore repeatable**

Expert Advisers	Comment
Mr Andrew Thorpe **Consultant in Urology**	**Nil**
Mr Gordon Muir **Consultant Urologist**	**Blank**
Professor Mark Emberton **Consultant Urologist**	**Reversible**
Mr Francis Keeley **Consultant Urologist**	**There is considerable doubt and scepticism that this is a long-term solution, as it does not affect the size of the prostate gland or the natural history of the disease process. The short to medium term benefits to patients, however, are obvious. I see it as a reasonable alternative to medical therapy, which is very easy to prescribe but less easy to tolerate -- alpha blockers and 5-alpha reductase inhibitors are not easy to take for many men, who then are faced with an operation or nothing.**
Mr Mark Feneley **Consultant Urologist**	**Specific surgical training in the procedure is important in achieving maximal benefit for candidate patients.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Blank**

POSSIBLE BENEFITS FOR THE HEALTHCARE SYSTEM

Question 9: What are the likely additional benefits for the healthcare system of using this technology, compared with current practice/ comparators?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**The expense compared to TURP is very impressive. there is reduced pressure on in-patient beds and less time in theatre which contributes overall to secondary care cost efficiency improvements**

Professor Thomas McNicholas **Consultant Urological Surgeon**	**Will satisfy an as yet unmet need for men who fail with drug treatment yet cannot proceed to invasive and ablative surgery.** **Can help manage waiting list pressures by transfer of some TURP/laser cases to UroLift.** **Allows transfer of inpatient cases to day case or ambulatory facilities with savings on bed days and release of main theatre resources.** **Reduced complication rate generally.** **Highly unlikely to need transfusion.** **Less likely to need prescription of PDEi drugs on the SLS system.**
Mr Mark Speakman **Consultant in Urology**	**Short length of stay**
Mr Neil Barber **Consultant Urologist**	**True day care procedure-less risk of complication and cost thereof**
Mr Andrew Thorpe **Consultant in Urology**	**Short length of stay, lesser morbidity, easy to teach to junior staff**
Mr Gordon Muir **Consultant Urologist**	**Day case therapy, avoiding use of inpatient beds**
Professor Mark Emberton **Consultant Urologist**	**Reduced cost?**
Mr Francis Keeley **Consultant Urologist**	**Less theatre time and hospital stay. Less medical therapy. Potentially fewer doctor visits.**
Mr Mark Feneley **Consultant Urologist**	**Minimal need for secondary interventions associated with transurethral resection (the alternative). E.G. usually no need for post-operative catheterisation with its complications, no need for trial without catheter, avoids hospital stay, complications are usually minor and short in duration**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Daycase and shorter hospital stay**

Question 9.1: Is each additional benefit likely to be realised in practice? What are the likely obstacles?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Yes. only obstacle is that no Trust wants to take on new technology right now - even where there are significant savings and improved healthcare changes possible - as in this case.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Benefits likely to be realised eventually. Obstacles will be: Coding issues which will deter purchasers; current reluctance of purchasers to invest in new treatment options; limitations on budgets; lack of awareness of a new option such as this.**
Mr Mark Speakman **Consultant in Urology**	**Yes**
Mr Neil Barber **Consultant Urologist**	**Cost of implant, training, patient selection**
Mr Andrew Thorpe **Consultant in Urology**	**I feel the benefits should be realised but it will require very careful audit and follow up of patients undergoing this procedure - results from RCT's are often far more superior to real life scenario's hence the importance of careful audit.**
Mr Gordon Muir **Consultant Urologist**	**Blank**
Professor Mark Emberton **Consultant Urologist**	**Yes**
Mr Francis Keeley **Consultant Urologist**	**The cost is likely not to be less to the payer than TURP, but the hospital costs are likely to be less. The number of doctor visits is uncertain but plausible, since repeat prescriptions are likely to be unnecessary.**
Mr Mark Feneley **Consultant Urologist**	**Yes, that would be the expectation for most cases, with appropriate case selection.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Yes**

Question 9.2: How might these benefits be measured? What specific outcome measures would enable assessment of whether additional benefits for the healthcare system are being realised?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**as above. unit cost comparisons but also speed of rehabilitation, readmission rates and TURP rates afetr the procedure**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Recording of TURP/laser rates in the population and how they change. Recording of waiting lists and duration of wait. Recording of day case surgery rates for UroLift (dependant on coding to identify these cases. Recording of cessation of drug prescriptions. Recording of secondary treatments necessary.**
Mr Mark Speakman **Consultant in Urology**	**LOS**
Mr Neil Barber **Consultant Urologist**	**As above**
Mr Andrew Thorpe **Consultant in Urology**	**Main one will be length of stay, re-admission rates and outcomes after 5 years in terms of re-operation rates.**
Mr Gordon Muir **Consultant Urologist**	**Blank**
Professor Mark Emberton **Consultant Urologist**	**Health Economic evaluation.**
Mr Francis Keeley **Consultant Urologist**	**The need for either medical or surgical treatment after the procedure needs to be measured.**
Mr Mark Feneley **Consultant Urologist**	**I would expect measurements of the benefits outlined to be self-explanatory. Comparative costings are more complex, and require a comprehensive evaluation of factors including procedure, pre-operative and post-operative care costs, therapeutic benefits, intervention risks, complications and their management, over time to include medium term follow-up.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Shorter hospital stay**

Question 9.3: How good is this evidence for each of these additional benefits?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**These have all been published in the European journal.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**No evidence as yet. Several NHS Trusts are planning pilot studies to see e.g. Warwick, possibly East & North Herts Trust.**
Mr Mark Speakman **Consultant in Urology**	**Good**
Mr Neil Barber **Consultant Urologist**	**Blank**
Mr Andrew Thorpe **Consultant in Urology**	**At present too early- only data is from 2 year outcomes.**
Mr Gordon Muir **Consultant Urologist**	**Blank**
Professor Mark Emberton **Consultant Urologist**	**RCT**
Mr Francis Keeley **Consultant Urologist**	**Only hospital stay has been reported so far.**
Mr Mark Feneley **Consultant Urologist**	**Good, from published randomised studies.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Depends on accuracy of data collection**

Question 9.4: Please add any further comment on the claimed benefits of the technology to the healthcare system, as you see applicable

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**This technology is a clear example of where implementation in the NHS can improve care and reduce costs for a very common ailment.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	Blank
Mr Mark Speakman **Consultant in Urology**	Blank
Mr Neil Barber **Consultant Urologist**	Blank
Mr Andrew Thorpe **Consultant in Urology**	**Nil**
Mr Gordon Muir **Consultant Urologist**	Blank
Professor Mark Emberton **Consultant Urologist**	**N/A**
Mr Francis Keeley **Consultant Urologist**	Blank
Mr Mark Feneley **Consultant Urologist**	
Mr Hashim Hashim **Consultant Urological Surgeon**	Blank

FACILITIES, TRAINING AND FUNCTIONING

Question 10: Are there any particular facilities or infrastructure which needs to be in place for the safe and effective use of this technology?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Adequate individual surgical training will be necessary as well as scrub nurse familiarity with the instrumentation. this can easily be all learned with the course of one operating list**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Yes, needs a system for training and mentoring is vital as identification of appropriate patients and precise and adapted performance of the endoscopic UroLift technique to the anatomy encountered is vital to achieve good results and to avoid bleeding and discomfort. The Neotract company provide excellent education and clinical support and have developed a sophisticated Simulator for new users to train on prior to embarking on clinical cases. The video teaching is excellent.**
Mr Mark Speakman **Consultant in Urology**	**Needs some training and mentorship, but company have designed a very good simulator. Much easier to learn than a TURP.**
Mr Neil Barber **Consultant Urologist**	**Yes,- computer simulation model, surgical model, proctors and training sites**
Mr Andrew Thorpe **Consultant in Urology**	**yes - the use of simulators for surgeons in training would make the uptake of this new technology much safer for patients**
Mr Gordon Muir **Consultant Urologist**	**No- the company has an exemplary training structure**
Professor Mark Emberton **Consultant Urologist**	**Training appears straightforward**
Mr Francis Keeley **Consultant Urologist**	**No**
Mr Mark Feneley **Consultant Urologist**	**Standard operative facilities are needed: day surgery units are appropriate and sufficient.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Mentoring and simulation training**

Question 11: Is special training required to use this technology safely and effectively?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Yes**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**As above. This method needs high level endoscopic skill (any bleeding or misplaced initial implants predispose to procedure failure) and well developed urological judgement (to select the correct candidates). It has been designed to be intrinsically safe but to get the best results urological expertise is necessary, of a level expected of a specialist already performing TURP on to which expertise needs adding specific experience with the device.**
Mr Mark Speakman **Consultant in Urology**	**Yes. See above**
Mr Neil Barber **Consultant Urologist**	**Yes**
Mr Andrew Thorpe **Consultant in Urology**	**Yes, see comment above, I think the learning curve would be much shorter for both consultants and trainees as compared to TURP, however it should be understood that TURP is an excellent anatomical operation which is applicable to all prostate sizes and shapes. The UroLift, procedure is far more subjective in the placement of the staple devices being used - hence I think there may be a greater room for error in terms of the product placement.**
Mr Gordon Muir **Consultant Urologist**	**Yes-simulator and mentoring**
Professor Mark Emberton **Consultant Urologist**	**The skills can be acquired in a one day workshop**
Mr Francis Keeley **Consultant Urologist**	**Very easy to learn. The company has a great training model.**
Mr Mark Feneley **Consultant Urologist**	**Yes, for medical and theatre staff**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Yes**

Question 12: Please comment on any issues relating to the functioning, reliability and maintenance of this technology which may be important to consider if it is introduced

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Once placed in situ, no maintenance is necessary.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Has been entirely reliable in my experience of approx. 20 cases.**
Mr Mark Speakman **Consultant in Urology**	**Good to date. Will be better when a multiple clip applicator is available. Currently need one device per clip.**
Mr Neil Barber **Consultant Urologist**	**After training, & easy to use, reliable. Minimal investment.**
Mr Andrew Thorpe **Consultant in Urology**	**This is a technology where the only available equipment in non - reusable hence it will be expensive.**
Mr Gordon Muir **Consultant Urologist**	**No issue.**
Professor Mark Emberton **Consultant Urologist**	**N/A**
Mr Francis Keeley **Consultant Urologist**	**None**
Mr Mark Feneley **Consultant Urologist**	**The technology uses single-use disposable instrument for device deployment. The procedure follows standard endoscopic principles, and utilises specific autoclavable endoscopic equipment.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Uses special kit and not interchangeable with current cystoscope kits**

COSTS

Question 13: Please provide any comments on the likely cost consequences of introducing this technology. In particular, please comment on the implications of this technology replacing the comparator/s you have described above

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**I understand there is a saving of £1000 per case when compared to TURP**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**I suspect cost will initially be somewhat less than TURP but much depends on the success of moving patients from the inpatient to the day case or ambulatory environment. Device costs are likely to fall if mass production ensues.**
Mr Mark Speakman **Consultant in Urology**	**Currently unit costs of 4 clips (the average needed is approx. £1400) - may well reduce with greater numbers.**
Mr Neil Barber **Consultant Urologist**	**Little investment needed. Implant is main cost and lack of very long term data inevitable and the other main issue.**
Mr Andrew Thorpe **Consultant in Urology**	**The technology at present would be more expensive than holmium and Greenlight laser for the device, but there may bed savings in length of stay and bed occupancy. Worldwide there are about 1.2 million interventions operatively a year for BPO, so if this technology does take off there could be major implications financially.**
Mr Gordon Muir **Consultant Urologist**	**Will be cost neutral if carried out as outpatient treatment, but long term durability data needs to be assessed.**
Professor Mark Emberton **Consultant Urologist**	**Depends on the indication and durability - it could compete with lifelong generic medication or an effective once in a lifetime operation (TURP).**
Mr Francis Keeley **Consultant Urologist**	**See comments above.**

Mr Mark Feneley **Consultant Urologist**	**For some patients, the technology may replace the need for TURP, doing so as a minimally invasive alternative using far less hospital resources, but incurring costs of disposable devices.** **For other patients, transurethral resection may not be an option, and for those patients the technology offers effective treatment in men who do not have other surgical options and exclusion criteria do not apply. This may be beneficial in relation to the alternative of long-term non-surgical management (e.g. intermittent or permanent catheteristion) and disease-related consequences (e.g. urinary infections).**
Mr Hashim Hashim **Consultant Urological Surgeon**	**As far as I am aware, the cost is more than a TURP. There are no long term data and whether these patients will need a TURP in the future is not known, therefore increasing the costs.**

GENERAL ADVICE BASED ON YOUR SPECIALIST KNOWLEDGE

Question 14: Is there controversy about any aspect of this technology or about the care pathway?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**I do not believe there is.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**No**
Mr Mark Speakman **Consultant in Urology**	**Not yet, very well received recently at the American Urology Association meeting, not been widely promoted in this country yet.**
Mr Neil Barber **Consultant Urologist**	**No, beyond long term efficacy and retreatment rate.**
Mr Andrew Thorpe **Consultant in Urology**	**No**
Mr Gordon Muir **Consultant Urologist**	**No**
Professor Mark Emberton **Consultant Urologist**	**No - we are all amazed it works so well.**

Expert Advisers	Comment
Mr Francis Keeley **Consultant Urologist**	**Yes**
Mr Mark Feneley **Consultant Urologist**	**No**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Yes, there is no concensus as to where in the pathway of treating BPH this should be placed.**

Question 15: If NICE were to develop guidance on this technology, how useful would this be to you and your colleagues?

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Tremendously useful in this case**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Would be very helpful**
Mr Mark Speakman **Consultant in Urology**	**Very**
Mr Neil Barber **Consultant Urologist**	**Yes**
Mr Andrew Thorpe **Consultant in Urology**	**Very useful - but it would need very careful audit, please see comments above.**
Mr Gordon Muir **Consultant Urologist**	**Blank**
Professor Mark Emberton **Consultant Urologist**	**Very**
Mr Francis Keeley **Consultant Urologist**	**Very useful as funding has been an obstacle**
Mr Mark Feneley **Consultant Urologist**	**Helpful for colleagues, primary care doctors and patients**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Very useful to be able to place it appropriately in the care pathway.**

Question 16: ***Do any subgroups of patients need special consideration in relation to the technology (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)? Please explain why***

Expert Advisers	Comment
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Not in general, but those with a large median lobe probably ought not be included.**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**Men with very big prostate size, especially with prominent "middle lobes" are less suitable (the implants cannot be inserted into "middle lobes" to achieve an effect) and such men can largely be identified by preliminary US in clinic. Some will require day case or office (usually local anaesthetic) endoscopy before a decision about suitability. This method can be performed under minimal sedation which will suit the less fit man. In the US trial most men were implanted under local anaesthetic which makes treatment of even very unfit men a possibility. We are exploring whether the British male will be so accommodating!**
Mr Mark Speakman **Consultant in Urology**	**Only really suitable for men with small and moderate prostates (<75cc approx.).**
Mr Neil Barber **Consultant Urologist**	**No**
Mr Andrew Thorpe **Consultant in Urology**	**because it is a minimally invasive procedure it may be very useful in patients who are medically unfit due to the perceived reduction in blood loss, operative time etc.**
Mr Gordon Muir **Consultant Urologist**	**High risk patients and those who do not wish the 80% chance of sexual dysfunction with traditional TURP.**
Professor Mark Emberton **Consultant Urologist**	**There are contraindications such as very large prostates and median lobes.**
Mr Francis Keeley **Consultant Urologist**	**Men in general with urinary symptoms are reluctant to visit a doctor and are understandably wary of surgical interventions.**

Mr Mark Feneley **Consultant Urologist**	**Patients who cannot have transurethral resection of prostate, for justifiable individual or medical reasons, may represent a specific group for whom this procedure may an option for specific consideration.** **Patients requiring surgery who are considering fathering children would be another specific patient group, and subgroup of the above.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Different age groups of men especially those who are sexually active, and those on anticoagulants and have high morbidity or not fit for prolonged procedures.**

CONFLICTS OF INTEREST

Question 18.1: Do you or a member of your family have a personal pecuniary interest? The main examples are as follows:

Expert Advisers	Consultancies or directorships	Fee-paid work	Shareholdings	Expenses and hospitality	Investments	Personal non-pecuniary interest
Professor Raj Persad Consultant Urological Surgeon and Uro-oncologist	No	No	No	No	No	No
Professor Thomas McNicholas Consultant Urological Surgeon	Blank	Yes	Yes	No	No	Yes
Mr Mark Speakman Consultant in Urology	No	No	No	No	No	Yes
Mr Neil Barber Consultant Urologist	Yes	Yes	No	No	Yes	No
Mr Andrew Thorpe Consultant in Urology	Yes	Yes	No	No	No	No
Mr Gordon Muir Consultant Urologist	No	Yes	No	No	No	No
Professor Mark Emberton Consultant Urologist	Yes	No	No	No	No	No
Mr Francis Keeley Consultant Urologist	No	No	No	No	No	No
Mr Mark Feneley Consultant Urologist	No	Yes	Yes	No	No	No

Expert Advisers	Consultancies or directorships	Fee-paid work	Shareholdings	Expenses and hospitality	Investments	Personal non-pecuniary interest
Mr Hashim Hashim **Consultant Urological Surgeon**	No	No	No	No	No	No

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.	
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	**Blank**
Professor Thomas McNicholas **Consultant Urological Surgeon**	**I have performed paid advisory work for Neotract who manufacture these devices.** **I have been asked by the media to comment (unpaid) on the topic.**
Mr Mark Speakman **Consultant in Urology**	**I am the President of the British Association of Urological Surgeons (from 24th June 2014).**
Mr Neil Barber **Consultant Urologist**	**I am a paid adviser & proctor for A.M.S, Intuitive Medical and Neotract. I have a small investment in Nuada Medical.**
Mr Andrew Thorpe **Consultant in Urology**	**Blank**
Mr Gordon Muir **Consultant Urologist**	**I am a paid mentor and have carried out paid consultancy for Neotract.**
Professor Mark Emberton **Consultant Urologist**	**I am advising a US based Biotech which is in Phase III with a competing product for BPH - an injectable. I am trying to use the product for prostate cancer therapy in a phase I study, though.**
Mr Francis Keeley **Consultant Urologist**	**Blank**
Mr Mark Feneley **Consultant Urologist**	**I carry out private practice and have shares in a small company, Alternative Urological Catheter Systems Ltd.**
Mr Hashim Hashim **Consultant Urological Surgeon**	**Blank**

Question 18.2: Do you have a non-personal interest? The main examples are as follows:

Expert Advisers	Fellowships endowed by the healthcare industry	Support by the healthcare industry or NICE that benefits his/her position or department, e.g. grants, sponsorship of posts
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	No	No
Professor Thomas McNicholas **Consultant Urological Surgeon**	No	No
Mr Mark Speakman **Consultant in Urology**	No	**Yes**
Mr Neil Barber **Consultant Urologist**	No	No
Mr Andrew Thorpe **Consultant in Urology**	No	No
Mr Gordon Muir **Consultant Urologist**	No	No
Professor Mark Emberton **Consultant Urologist**	No	No
Mr Francis Keeley **Consultant Urologist**	**Yes**	**Yes**
Mr Mark Feneley **Consultant Urologist**	No	No
Mr Hashim Hashim **Consultant Urological Surgeon**	No	No

If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.	
Professor Raj Persad **Consultant Urological Surgeon and Uro-oncologist**	Blank
Professor Thomas McNicholas **Consultant Urological Surgeon**	Blank
Mr Mark Speakman **Consultant in Urology**	**I have been involved in a research study evaluating the device. No honoraria were received - no personal gain.**
Mr Neil Barber **Consultant Urologist**	Blank
Mr Andrew Thorpe **Consultant in Urology**	**I have had payments for advisory boards to a number of pharmaceutical companies and I have run courses for equipment/devices companies in the past. I have also been involved as a P.I. in an RCT for AMS for TURP vs GLL but did not receive personal financial reimbursement. I have not been involved in the assessment or company involved with UroLift.**
Mr Gordon Muir **Consultant Urologist**	Blank
Professor Mark Emberton **Consultant Urologist**	Blank
Mr Francis Keeley **Consultant Urologist**	**I am Honorary Secretary and Trustee of BAUS, which receives funding from many companies, including NeoTract Inc., with technologies used for this indication.** **I receive honoraria from consulting, lectures and teaching courses for Boston Scientific and Olympus Medical amounting to no more than £5000 per annum. These companies have technologies used for treatment of the same condition (benign prostatic obstruction), but I have not been paid to speak specifically on this subject. I do not consider myself to have any conflict of interest. I do not perform this procedure in my private practice.**
Mr Mark Feneley **Consultant Urologist**	Blank

Mr Hashim Hashim **Consultant Urological Surgeon**	Blank