



NICE medical technology adoption support for UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia – insights from the NHS

Health technology adoption programme

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1 Introduction

This resource has been developed to provide practical information and advice on NICE medical technologies guidance on [UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia](#).

It is intended to be used by both clinical and non-clinical staff planning to implement this NICE guidance and start using this technology.

NICE's Adoption and Impact programme worked with NHS organisations to share their learning and experiences of using the UroLift system. The information presented in this resource is intended for the sole purpose of supporting the NHS in adopting, evaluating the impact of adopting or further researching this technology.

The information presented is complementary to the guidance and was not considered by the Medical Technologies Advisory Committee when developing its recommendations.

The UroLift system is designed to relieve symptoms of urinary outflow obstruction without cutting or removing tissue. The adjustable, permanent implants pull excess prostatic tissue away so that it does not narrow or block the urethra. The procedure is minimally invasive and an alternative to

current standard surgical interventions for symptoms of benign prostatic hyperplasia (BPH), such as transurethral resection of the prostate. It is indicated for use in men aged 50 years and older and is contraindicated in men who have prostates larger than 100 ml and in men whose prostate has an obstructing middle lobe.

The benefits of using the UroLift system as reported by the NHS staff involved in producing this resource include:

- Potential cost savings because of fewer inpatient bed days; pre-operative process costs and follow-up appointments.
- Faster procedure time (particularly if done under local anaesthetic and without catheter), leading to increased capacity.
- Improved quality of life because of reduced post-operative pain, reduced recovery period and preserved sexual function.
- Greater choice for men at the surgical stage of their pathway which does not increase risk for further surgical interventions.
- Improved symptom control in men with multiple comorbidities for whom surgery is unsuitable.

The learning gained from existing users is presented as a series of examples of current practice. They are not presented as best practice but as real-life examples of how NHS sites have adopted this technology.

2 Current practice

NICE guidance on [lower urinary tract symptoms in men: management](#) recommends a number of surgical procedures for men with voiding symptoms presumed secondary to BPH with prostates smaller than 100 g, where symptoms are severe or if drug treatment and conservative management options have been unsuccessful or are not appropriate:

- monopolar or bipolar transurethral resection of the prostate (TURP)
- monopolar transurethral vaporisation of the prostate (TUVP)
- holmium laser enucleation of the prostate (HoLEP; at a centre specialising in the technique, or with mentorship arrangements in place)

- transurethral incision of the prostate (TUIP) as an alternative for men with prostates estimated to be smaller than 30 g.

Increasingly there are new surgical technologies and techniques to ease symptoms associated with BPH (for example, in February 2015 NICE published medical technologies guidance on [the TURis system for transurethral resection of the prostate](#), which is an alternative to monopolar TURP). However, inpatient TURP remains the current standard surgical intervention. TURP is associated with potential permanent side effects including erectile dysfunction, retrograde ejaculation and urinary incontinence. It also necessitates the use of a catheter for several days after the procedure, which may be uncomfortable.

3 Summary of NICE recommendations

NICE assessed the UroLift system for treating lower urinary tract symptoms of BPH as an alternative to current standard surgical interventions such as TURP and HoLEP.

The case for adoption is supported by the evidence. The UroLift system relieves lower urinary tract symptoms while avoiding the risk to sexual function associated with TURP and HoLEP.

The UroLift system should be considered for use in a day-case setting, where savings can best be realised in men with lower urinary tract symptoms of BPH who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe. The primary drivers in the costing model were the cost of each implant and the number of implants used per treatment.

4 Tips for adopting the UroLift system

- Before implementation, collect baseline data on current surgical interventions and develop data collection mechanisms to monitor how the technology affects quality and safety, patient experience, productivity and improved clinical outcomes (see [measuring success](#)).
- Ensure that [care pathway mapping](#) has been done to identify where the technology would fit into the proposed patient pathway. Clearly define the selection criteria and how many men will be expected to benefit from the introduction of the procedure.
- Providers and commissioners will need to agree a local tariff for the procedure that supports adoption (see [resource impact](#)).
- Oversee a trial period for training before doing the procedure independently to increase clinical confidence and efficiency (see [education](#)).

- Develop robust protocols for procedure competence and ensure local governance arrangements are in place (see [insights from the NHS](#)).

5 Insights from the NHS

Frimley Health NHS Foundation Trust

Frimley Park Hospital, part of [Frimley Health NHS Foundation Trust](#), is a district general hospital located in Surrey which serves a population of more than 400,000 across north-east Hampshire, west Surrey and east Berkshire. It has 750 beds and 4200 staff.

The urology department at Frimley Park Hospital comprises 4 consultant urological surgeons. The team offers TURIs, the GreenLight laser and the UroLift procedure as options for men with BPH. The hospital does 250–300 surgical interventions per year for BPH.

Having taken part in the BPH6 trial^[1], which compared the UroLift system with TURP, the team championed UroLift as an intervention that should be routinely offered to NHS patients. A lead project team was established, which consisted of a consultant urological surgeon, a nurse specialising in lower urinary tract symptoms and a deputy directorate manager.

At the end of the trial the team developed a business case to approve the use of the UroLift system on a routine basis. Although the national tariff is likely to change in the future, the 2015/16 national tariff system (2015/16) does not cover the full cost of the UroLift system so the business case needed to emphasise the clinical and financial benefits for the trust and men before final approval was given. The business case focused on the following:

- that the procedure can be done as a day case
- UroLift is associated with low readmission rates
- careful patient selection (suitable for day case, prostate size).

The surgeon who was trained for participation in the trial started to offer the UroLift procedure to NHS patients in October 2014.

The UroLift procedure is done in the operating theatre by the consultant urological surgeon with the support of the theatre staff, meaning that training is needed for everyone involved. The manufacturer organised and funded the surgeon's training at the start of the trial, which involved:

- watching at least 2 cases

- practising on a simulator and model
- undertaking cases in theatre at Frimley Park under the mentorship of a manufacturer representative.

The manufacturer also trained theatre staff in ordering and handling the single-use delivery device and implants.

As the surgeon became more confident the team moved from using general anaesthesia and urinary catheterisation to doing the procedure under sedation and without urinary catheters. All UroLift procedures at Frimley Park are done by 1 trained surgeon, so there are enough cases to allow the development of expertise in this procedure. On average, the surgeon uses 3 implants per procedure. At Frimley Park Hospital the procedure is generally only done on prostate sizes 60 ml or less. The surgeon noted that as their experience has increased, they have needed to use slightly fewer implants per procedure.

Men are selected (that is, they are suitable for a day-case procedure) and identified for the procedure using the existing care pathway for BPH, although the team have made some changes to the pathway to better incorporate the UroLift system (see below). This involves a nurse specialist and a GP with special interest or a consultant urological surgeon assessing all men referred to secondary care. Men at the surgical stage of the pathway (that is, where symptoms are severe and conservative management has failed or is inappropriate) for whom surgery is an option are given information about all appropriate surgical options, including the UroLift procedure. They are then seen by a consultant urological surgeon to discuss these options in more detail. Men who choose the UroLift procedure are generally those who wish to preserve their sexual function or do not want TURP. There is currently demand for the procedure from men outside the hospital's usual catchment area. This is provided for those who have funding agreed from their local clinical commissioning group.

The team has made a number of changes to the care pathway for BPH to incorporate the UroLift system, including:

- Assessing the size of the prostate and the presence of a middle lobe by cystoscopy (or in some cases ultrasound). This often means an additional outpatient appointment and is not part of the routine pathway for BPH.
- After confirmation that the UroLift procedure is appropriate, the patient follows the same day-case pathway as all other urological day-case procedures, including the GreenLight laser.
- Following patient discharge, the nurse follows up by phone at 3 weeks and again at 3 months.

The surgeon aims to carry out a number of UroLift procedures in the same theatre session in order to maximise capacity. The number of UroLift procedures that can be done in a single session is limited by the number of tailored scopes available in the hospital (each of which needs to be sterilised between use).

The nurse specialist collects post-procedure data including symptom scores and patient satisfaction, in line with the BPH 6 trial.

Table 1 BPH procedures done in Frimley Park Hospital

Procedure	Number of procedures: September 2014 to September 2015	Admission status	Estimated theatre time (minutes)
UroLift	75	Day case	25
TURis	190	Inpatient	60
GreenLight	80–90	Day case	60

The team concluded that compared with TURP, using the UroLift system:

- reduces the number of formal follow-up appointments (of the 75 procedures done, only one needed a subsequent clinic appointment)
- may increase the number of interventions done in 1 theatre session because of a faster procedure time
- improves post-procedure symptoms and patient satisfaction with respect to quality of recovery and preservation of sexual function
- reduces readmission rates particularly for urosepsis and bleeding.

The adoption of the UroLift system at Frimley Park Hospital has been driven by the urology surgeons' view that patient satisfaction and quality of life for men at the surgical stage of the pathway will be enhanced if they are offered more choice about management of their symptoms. The team plan to explore how a specific UroLift procedure pathway can be developed, including how it could be offered in an ambulatory setting alongside other simple urological procedures.

St Helens and Knowsley Teaching Hospitals NHS Trust

St Helens and Knowsley Teaching Hospitals NHS Trust provides a range of acute healthcare services including inpatient, outpatient, maternity and emergency services across Whiston and St Helens hospitals. The urology department at the trust comprises 5 consultant urological surgeons. The team offers the following surgical interventions for men with BPH: bipolar and monopolar TURP, HoLEP, TUIP and the UroLift procedure. Four surgeons are trained in using the UroLift system. The team does over 200 surgical interventions for BPH per year.

The consultant urological surgeons actively seek new technologies and developments to improve their clinical practice. Aware of the problems around sexual function that can happen as a result of treatment for BPH, they were interested in the UroLift system when it became available on the UK market. They considered that the device's FDA approval, supportive NICE guidance and available data all supported the case for adoption.

The trust formed a project team that comprises the clinical director of urology (clinical champion), the directorate manager, the directorate accountant and the directorate business manager. A pilot project was planned and sanctioned through the trust's 'new technology' process, with final approval from the chief executive. Information provided included:

- benefits to the trust (reduced admissions, reduced theatre time)
- potential future cost savings (despite there being a current shortfall between the cost of the procedure and payment)
- benefits for men (preserved sexual function, less post-operative pain, quicker return to work)
- NICE interventional procedure guidance on insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia.

The UroLift system pilot started in autumn 2014. A pilot approach has allowed the department to control numbers, monitor results and ensure they are properly equipped to offer the procedure to all eligible men once an appropriate national tariff is agreed.

Before implementing the device, 4 of the consultant urological surgeons undertook the manufacturer's training programme. The manufacturer also trained theatre staff in equipment handling and the ordering process for consumables.

Men are referred to the consultant urological surgeons using the existing care pathway for BPH, through a number of routes:

- referral from the prostate assessment clinic (which receives referrals from GPs)
- direct referrals from GPs and other urologists
- identification of hospital in-patients (men with retention).

Most men who choose the UroLift procedure do so in order to preserve their sexual function or to specifically avoid TURP. Before the procedure, men have a flexible cystoscopy (or in some cases ultrasound) to assess their suitability for the UroLift procedure.

In the pilot, the UroLift procedure is offered to men with BPH who have a small to moderate prostate with no middle lobe and low anaesthetic risk. Any men having the procedure are added to the day-case list. The care pathway for a urological day case is well established in the trust because of the many other urological procedures it offers. The pre-operative process for a UroLift procedure is relatively simple (unlike, for example, TURP, which requires blood group and cross matching). The procedure itself is done under general anaesthetic. Four implants are needed per procedure, although a smaller prostate may only require 3. If a urine catheter is used, it is removed 4 hours after the procedure. If there are no complications the patient is discharged in line with the existing urology criteria-led discharge policy.

After the procedure, follow-up involves an outpatient appointment at 4 weeks followed by another at 12 weeks. The department plans to review this follow-up schedule when more men have had the procedure.

All men who have had the UroLift procedure are entered onto a specifically designed [in-house database](#). Pre- and post-operative International Prostate Symptom Score (IPSS) and International Index of Erectile Function (IIEF) scores are recorded and entered onto the database by a clinical fellow.

Table 2 BPH procedures done in St Helens and Knowsley Teaching Hospital NHS Trust

Procedure	Number of procedures: January 2015 to June 2015	Average length of stay	Estimated theatre time (minutes)*
UroLift	7	N/A (day case)	10–30
Bipolar TURP	75	1–2 days	30–75
Monopolar TURP	17	1–2 days	30–60

HoLEP	6	1–2 days	60–120
Bladder neck incision/TUIP	5	1–2 days	10–30
*Excluding 35 minutes induction and recovery time in all cases.			

As the surgeons become more confident in their skills they anticipate that the UroLift procedure will be done without catheterisation and more quickly under sedation or local anaesthetic, with recovery in a comfortable chair and discharge the same day. The urology team is also considering whether the UroLift system could be used to address incontinence and the need for long-term catheterisation in older men with multiple comorbidities for whom TURP is not suitable. The team is currently in discussions with the trust's continence service to explore this further.

^[1] Sønksen J, Barber NJ, Speakman MJ, et al. (2015) Prospective, randomized, multinational study of prostatic urethral lift versus transurethral resection of the prostate: 12-month results from the BPH6 study. [European Urology](#).

6 How to implement NICE's guidance on the UroLift system

The experiences of these NHS trusts have been used to develop practical suggestions for how to implement NICE guidance on the UroLift system.

Project management

In order to gain maximum benefit, the technology should be adopted using a project management approach. NICE has produced the [Into Practice guide](#) which includes a section on what organisations need to have in place to support the implementation of NICE guidance.

Project team

The first step is to form a local project team who will work together to implement the technology and manage any changes in practice.

Individual NHS organisations will determine the membership of this team and how long the project will last. In order to implement this guidance in an effective and sustainable way, consider the following membership of the team:

- **Clinical champion:** could be the clinical director for urology or a consultant urological surgeon with an interest in the surgical management of BPH. They should have the relevant knowledge and understanding to be able to drive the project, answer any clinical queries and champion the project at a senior level.
- **Project manager:** could be someone in a clinical or managerial role who will be responsible for the day-to-day running of the project, co-ordinating the project team and ensuring the project is running as planned.
- **Management sponsor:** could be the directorate manager, directorate accountant or directorate business manager. They will be able to help assess the financial viability of the project, drive the formulation of a business case and help to demonstrate the cost savings achieved. It is the experience of both trusts that respect and support from the managerial teams for the clinician's aims and goals facilitated adoption of the UroLift system.
- **Key stakeholders:** consultant urological surgeons, deputy directorate manager, nurse specialists and theatre scrub nurses will be valuable members of the project team because they are directly involved in the management and provision of the service.
- **Clinical audit facilitator:** to help set up mechanisms to collect and analyse local data related to the project metrics and audit needs. A nurse specialist or medical fellow with interest or a project in this area could fulfil this role.

Early questions that the team may wish to consider are:

- How will the project be funded? Can local payment arrangements be implemented with the clinical commissioning group in order support adoption? (See [resource impact](#).)
- How will local metrics be identified and measured?
- Who will be responsible for collecting clinical data?
- How will the required education be provided?
- How to ensure all eligible men are informed of this procedure and offered the choice where appropriate?
- Are there any obvious challenges and how can these be overcome?

Care pathway mapping

NICE has produced advice on [mapping care pathways](#) to help organisations through the technology adoption process. The 2 sites involved in the production of this resource identified the key steps needed:

- Patient identification and choice: it is estimated that the UroLift procedure will be appropriate for up to 1 in 4 men needing surgery for lower urinary tract symptoms of BPH.
 - Men referred to secondary care for BPH should be given information about all the surgical options available in the trust which may be suitable for them.
 - The UroLift system offers particular benefits for those men who wish to preserve sexual function, have blood clotting disorders or for whom general anaesthetic would be unsuitable.
 - Men for whom the UroLift procedure is thought suitable should be referred to a trained consultant urological surgeon in the trust.
- Assessment: by cystoscopy (or in some cases ultrasound) to establish the size of the prostate and the presence of a middle lobe. This means an additional outpatient appointment and it is not part of the routine pathway for men with BPH.
- Follow up: at 3–4 weeks, with final follow-up and discharge at 3 months. Follow up appointments were either in outpatients or by phone.

Measuring success

In order to demonstrate the benefits of adopting the UroLift system it is important to take measurements before, during and after implementation. Some of these measures will not be routinely collected and sites must consider a data collection methodology that is appropriate to the service. NICE interventional procedure guidance on [insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia](#) recommends that reported outcomes should include the effects of the procedure on symptoms and quality of life, the duration of benefits, the need for further procedures and complications.

Because the UroLift system offers an additional option for men with BPH, the sites involved in developing this resource suggested that outcome measures should include patient satisfaction scores. These could include:

- IPSS

- Sexual function scores including:
 - IIEF
 - ejaculatory function score
 - sexual health inventory for men (SHIM)
- total number of surgical interventions for BPH

Other outcome measures could include:

- length of stay
- procedure time
- use of catheter and duration of catheterisation
- flow rate
- Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD)
- length of benefit
- readmission rates and the need for further procedures

Overcoming implementation challenges.

Table 3 shows the challenges reported by NHS sites that have implemented the UroLift system.

Table 3 Reported implementation challenges when using the UroLift system

Implementation challenge	Solution
Capital and ongoing revenue costs in the absence of an appropriate tariff.	Securing the necessary <u>funding</u> will require a collaborative approach between the provider and commissioner. Prepare a <u>business case</u> including full cost considerations for the UroLift system compared with current procedures across a complete service budget.

Clinical acceptance of a new procedure.	<p>Securing engagement from all members of the urology team can be challenging and can pose a risk to successful adoption of the technology.</p> <p>Select appropriate <u>metrics</u> to demonstrate clinical benefits, safety and demand.</p> <p>Provide adequate <u>training</u>, information and evidence base for the use of the technology.</p> <p>It is anticipated that the UroLift procedure may be suitable for up to 25% of men with BPH voiding symptoms, so it would not be essential for all surgeons to be trained. However, all will need to be able to identify suitable men and refer them as appropriate.</p>
Abbreviations: BPH, benign prostatic hyperplasia.	

Resource impact

NICE has published a costing statement that can be used by NHS commissioners and providers to better understand the local costs associated with adopting the UroLift system.

The NICE statement for a UroLift procedure identifies the unit cost of 1 UroLift procedure (including 4 implants) to be £2405.

The UroLift procedure (irrespective of the number of implants used) is currently expected to map to the Healthcare Resource Group (HRG) LB26Z (Intermediate Endoscopic Prostate or Bladder Neck Procedures). The 2015/16 elective tariff for LB26Z is £1214 (2015/16 enhanced tariff option).

There is a proposal to map the UroLift system to a different HRG code, LB70 (complex endoscopic prostate and bladder neck procedures), which will include a specific combination code for the UroLift procedure. The 2015/16 elective tariff for LB70 ranges from £2024 (without complications) to £2307 (with complications).

Business case

Developing a business case should be a priority for the implementation team. Local arrangements for developing and approving business plans will vary from trust to trust, and each organisation is likely to have its own process in place.

NICE has produced advice on [building a business case](#) to help organisations with technology adoption.

The business case will need to demonstrate how the UroLift system can lead to cost savings in terms of reduced beds days, simpler pre-operative processes and increased capacity. It should also demonstrate an improved quality of service offered to men in terms of enhanced choice.

Sites reported that having a senior managerial 'champion' to present the business case to the board was beneficial.

Trusts may also explore offering the UroLift procedure as a pilot and seeking approval for adoption from their research and development committee or through a 'new technology' process.

Education

The manufacturer provides all training needed for the UroLift system. For surgeons, this involves:

- observing a number of cases (3–5 on average)
- practising on a simulator and model
- doing the procedure under the mentorship of a manufacturer representative or mentor surgeon (1 site said that, on average, a surgeon should be competent to work independently after doing 6 procedures).

The surgeons obtained study leave and professional development leave (2 days) in order to visit off-site lecturers and procedures.

As the surgeons become more confident they can move from doing the procedure under general anaesthetic with urinary catheter to sedation or local anaesthetic and no urinary catheter. This will shorten procedure times and may lead to lower procedure costs.

If a nurse specialist is responsible for post-procedure follow-up and discharge if no complications are reported, plans will need to be in place to meet their training needs.

It is important that all healthcare professionals assessing men at the surgical stage of the BPH pathway are able to identify those in whom the UroLift procedure would be of benefit and provide information on all the options available.

7 The technology

The UroLift system is a permanent prostatic implant that is designed to reduce lower urinary tract symptoms associated with BPH by widening the lumen of the urethra. The prostatic lobes are retracted using the UroLift device and secured in this compressed position. The procedure is minimally invasive compared with a traditional transurethral resection of prostate. Typically about 4 implants are used. The UroLift system comprises 2 single-use components: a delivery device and an implant. A tailored cystoscope sheath and telescope for prostatic urethral lift procedures is required for deployment of the UroLift implant. The delivery device and implant is ordered directly from the manufacturer.

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Cost and procurement

At the time of publication, the current UK pricing is £2405 plus VAT for the UroLift procedure. This includes the components shown in table 5.

Table 5: Components associated with the UroLift procedure

Item	UroLift
Medical (consultant staff costs)	£392
Nursing	£64
Drugs (anaesthetic doses, saline and antibiotics)	£35
Clinical supplies and services (includes pre and post-operative tests and hospital bed-day costs).	£549
Equipment cost per procedure (assuming 4 UroLift systems comprising 1 delivery device with pre-loaded implant per procedure)	£1325
Other (including complications and capital)	£40
Total	£2405
Note: costs are based on the economic model submitted by the company for the UroLift medical technology appraisal and revised by the external assessment group.	

Costs may vary in different settings because of negotiated procurement discounts. Most commonly, 4 UroLift systems are used per procedure (on average, each procedure needs 4 implants). However, patients with larger or smaller prostates may need more or less.

A reusable cystoscope sheath and telescope set, suitable for use in prostatic urethral lift procedures, is needed to use the UroLift system. During the training and trial period (up to 1 year), the company provides this equipment on loan for free. Once training is completed, the equipment will need to be purchased or a loan agreed if not already available within the trust. One sterilised cystoscope is needed per patient although some surgeons may consider having a second available. The number of available cystoscopes may limit the number of patients that can have the procedure in 1 theatre session.

See the [NICE costing statement](#) to help calculate the local cost impact of adoption of the UroLift system.

For further details and more up-to-date costs, please contact the company.

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The lead at Frimley Park Hospital has declared an interest in relation to this technology. No other declarations of interest have been received. The content of this resource has been checked for factual accuracy, to ensure it is fair and balanced, and to ensure it is compliant with appropriate regulations.

9 About this resource

This resource accompanies NICE medical technologies guidance on UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia. It was developed using the [NICE Adoption and Impact Programme: Process guide for adoption support resources for health technologies](#). It is an implementation tool and discusses and summarises the experiences reported by NHS sites which have adopted this technology and shares the learning that took place.

It is the responsibility of local commissioners and providers to implement the guidance at a local level, being mindful of their duty to advance equality of opportunity and foster good relations. Nothing in this document should be interpreted in a way that would be inconsistent with this.

[Click here for more information about the Adoption and Impact Programme.](#)

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