

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## Medical technology guidance

### SCOPE

#### **The UroLift system for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia**

## **1 Technology**

### **1.1 *Description of the technology***

The UroLift System is used to perform a prostatic urethral lift, a procedure which is undertaken to relieve lower urinary tract symptoms by retracting the enlarged prostate and so widening the prostatic urethra. This provides an alternative to current standard surgical interventions such as transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP). The UroLift system uses adjustable implants to retract excess prostatic tissue away from the urethral lumen. This is intended to give symptomatic relief of urinary outflow obstruction without cutting or ablation of tissue.

The UroLift system is comprised of two main single use components: the UroLift delivery device and UroLift implant. The delivery device consists of a needle shaped probe that is designed to access the prostatic urethra. This is attached to a handheld pistol grip mechanism that is operated by the clinician and used to deploy and secure one UroLift implant. The UroLift implant consists of a superelastic nitinol capsular tab, PET monofilament, and a stainless steel urethral end-piece. One end of the implant is anchored in the urethra and the other on the outer surface of the prostatic capsule, retracting the prostatic lobe away from the urethra. Multiple UroLift systems (typically about 4) are used during the same procedure. The procedure can be performed with the patient under local or general anaesthetic.

## **1.2 Regulatory status**

The UroLift system received a CE mark in November 2009 as a prostatic retraction implant for use in the treatment of urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH). The instructions for use specify that the UroLift System is for use in men over the age of 50.

## **1.3 Claimed benefits**

The benefits to patients claimed by the sponsor, compared with standard care are:

- Reduction in diminished ejaculatory or sexual function
- Reduced need for post-operative catheterisation and reduced catheterisation time
- A quicker return to pre-treatment activities following treatment
- Reduced risk of hospital-acquired infection as the UroLift system is a day procedure, which does not require inpatient hospitalisation.

The benefits to the healthcare system claimed by the sponsor, compared with standard care are:

- Reduction in hospital length of stay, since UroLift is conducted as a day procedure
- Reduction in inpatient resource use, such as theatre operating time and associated staffing costs and resources.
- Significantly lower number of post discharge follow-on visits, both in primary care settings and in an outpatient setting, saving physician resources
- Reduced adverse event profile, leading to savings associated with the cost of complications associated with other surgical procedures
- Reduced costs from the avoidance of conditions brought on by treatment neglect such as atonic bladder, chronic kidney infection or failure, or detrusor sphincter dyssynergia, from the use of UroLift system in men who would not otherwise consider surgical treatment

## **1.4      *Relevant diseases and conditions***

The UroLift system is intended for use in the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) where conservative management options have not been successful, or are not appropriate, and surgery, usually transurethral resection of the prostate (TURP) or holmium laser enucleation of the prostate (HoLEP), is indicated. It is indicated for use in men from this group who are over the age of 50 with prostate sizes no greater than 100 cc (100 g).

The prevalence of BPH increases with age; around 60% of men aged 60 or older and over 80% of men aged 70 or older experience some symptoms due to BPH. BPH is the most common cause of lower urinary tract symptoms (LUTS), including urinary outflow obstruction.

LUTS secondary to BPH cause symptoms such as poor urinary stream, frequent micturition, and nocturia. Untreated, this can result in urinary tract infection (UTI), acute or chronic urinary retention, and renal failure. Although LUTS secondary to BPH do not usually cause severe illness, they can have adverse effects on normal daily activities and sexual function, considerably reducing a man's quality of life, and may point to serious pathology of the urogenital tract.

The severity of LUTS can be assessed using the International Prostate Symptoms Score (IPSS). A score of 8-19 is classified as moderate severity, while 20-35 is classified as severe. Moderate-to-severe LUTS are present in about 40% of men older than 50 years of age, rising to 90% of men in their eighties. Moderate to severe LUTS are estimated to affect up to 3.4 million men in the UK, and up to 15,000 men undergo TURP annually in England and Wales to relieve symptoms.

## **1.5      *Current management***

The NICE clinical guideline on [lower urinary tract symptoms](#), (May 2010), recommends that surgery is offered only if voiding symptoms are severe; or if drug treatment and conservative management options have been

unsuccessful or are not appropriate. For management purposes, the guideline defines benign prostatic enlargement (BPE) as an increase in the size of the prostate gland due to BPH, and states that around 50% of patients with BPH will develop BPE.

For surgical management of voiding LUTS presumed secondary to BPE, the guideline recommends the use of monopolar or bipolar TURP, monopolar transurethral vaporisation of the prostate (TUVP) or holmium laser enucleation of the prostate (HoLEP). HoLEP should only be performed at a centre specialising in the technique, or with mentorship arrangements in place. Advice from clinical experts at the scoping stage indicated that HoLEP is an appropriate comparator for the Urolift system and is most likely to be performed instead of TURP in men with a prostate of 50 cc (50 g) or over.

The NICE clinical guideline on [lower urinary tract symptoms](#) also recommends some alternative options:

- Transurethral incision of the prostate (TUIP) can be offered as an alternative to other types of surgery to men with a prostate estimated to be smaller than 30 g.
- Open prostatectomy should only be offered as an alternative to other types of surgery to men with prostates estimated to be larger than 80 g.
- Other alternatives such as laser vaporisation techniques, bipolar TUVP or monopolar or bipolar transurethral vaporisation resection of the prostate (TUVRP) can be offered only as part of a randomised controlled trial that compares these techniques with TURP.

NICE interventional procedure guidance on the [insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia](#), (January 2014) concluded that there was adequate evidence on the safety and efficacy of the procedure to support its use, provided that clinicians have specific training in the insertion of the implants.

## **2 Reasons for developing guidance on the UroLift system for lower urinary tract symptoms secondary to benign prostatic hyperplasia**

The Medical Technologies Advisory Committee recognised that the UroLift system may offer benefits to men with LUTS secondary to BPH, in particular in those who wish to preserve sexual function, which may be compromised by TURP. It noted the potential advantages of shorter catheterisation time or of avoiding catheterisation after the procedure. The Committee considered that the claimed health system benefits such as the avoidance of an inpatient stay were plausible.

The Committee noted uncertainties about the duration of treatment effect and the possible requirement for subsequent procedures for recurrent symptoms. It also noted a lack of direct comparative evidence against TURP.

### 3 Statement of the decision problem

|   | <b>Scope issued by NICE</b>  |
|---|--|
| Population  | Men with lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) aged 50 or over, and with prostate volumes no greater than 100 cc (100 g).  |
| Intervention  | The UroLift system   |
| Comparator(s)   | Current practice varies and is changing as a result of which there are 2 comparators: <ul style="list-style-type: none"> <li>• Monopolar or bipolar transurethral resection of the prostate (TURP)</li> <li>• Holmium laser enucleation of the prostate (HoLEP)</li> </ul>   |
| Outcomes  | The outcome measures to consider include: <ul style="list-style-type: none"> <li>• Length of hospital stay</li> <li>• The need for, or duration of, catheterisation</li> <li>• Number of post discharge follow-on consultations, both in primary and secondary care settings</li> <li>• Time to re-operation and re-operation rates</li> <li>• Symptoms of BPH (using the International Prostate Symptom Score [IPSS])</li> <li>• Reduction in ejaculatory or sexual function</li> <li>• Time to return to normal activities</li> <li>• Quality of life</li> <li>• Healthcare associated infection</li> <li>• Device-related adverse events</li> </ul> |
| Cost analysis   | Comparator(s): Monopolar or bipolar TURP and HoLEP<br><br>Costs will be considered from an NHS and personal social services perspective.<br>The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared.<br>Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.  |
| Subgroups to be considered                                  | Men for whom TURP or HoLEP is unsuitable because of difficulties with blood loss or sedation.  |
| Special considerations, including those related to equality | Men who wish to preserve sexual function and fertility.  |
| Special considerations, specifically                        | This section should record any specific equality issues that may be related to the use of the device. For example is it only suitable for certain age, sex, skin type etc.   |

|                            |   |    |
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| related to equality issues | Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics? | No |
|                            | Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?   | No |
|                            | Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?  | No |

## 4 Related NICE guidance

### Published

- Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia. NICE interventional procedure guidance, IPG475, January 2014. Available from: <http://guidance.nice.org.uk/IPG475>
- Lower urinary tract symptoms in men. NICE quality standards, QS45, September 2013. Available from: <http://publications.nice.org.uk/lower-urinary-tract-symptoms-in-men-qs45#>
- Lower urinary tract symptoms secondary to benign prostatic hyperplasia: tadalafil. NICE Evidence summary: new medicine, ESNM18. Available from: <http://www.nice.org.uk/mpc/evidencesummariesnewmedicines/ESNM18.jsp>
- Prostate Artery embolisation for Benign Prostatic Hyperplasia. NICE interventional procedure guidance, IPG453, April 2013. Available from: <http://guidance.nice.org.uk/IPG453>
- [Lower urinary tract symptoms in men](#). NICE Pathway. October 2012. Available from: <http://pathways.nice.org.uk/pathways/lower-urinary-tract-symptoms-in-men>
- Lower urinary tract symptoms: Evidence Update March 2012. A summary of selected new evidence relevant to NICE clinical guideline 97 'The management of lower urinary tract symptoms in men' (2010). Available from: <https://www.evidence.nhs.uk/about-evidence-services/bulletins-and-alerts/evidence-updates>

- LUTS in men, age-related (prostatism). NICE Clinical Knowledge Summary, August 2010. Available from: <http://cks.nice.org.uk/luts-in-men-age-related-prostatism>
- [The management of lower urinary tract symptoms in men](#). NICE clinical guideline, CG97, May 2010. Available from: <http://www.nice.org.uk/cg97>
- Laparoscopic prostatectomy for benign prostatic obstruction. NICE interventional procedure guidance. IPG275, November 2008. Available from: <http://publications.nice.org.uk/laparoscopic-prostatectomy-for-benign-prostatic-obstruction-ipg275>
- Holmium laser prostatectomy. NICE interventional procedure guidance, IPG17, November 2003. Available from: <http://www.nice.org.uk/guidance/IPG17>
- [Transurethral electrovaporisation of the prostate](#). NICE interventional procedure guidance, IPG14, October 2003. Available from: <http://www.nice.org.uk/guidance/IPG14>

### **Under development**

NICE is developing the following guidance (details available from [www.nice.org.uk](http://www.nice.org.uk)):

- The TURis system for transurethral resection of the prostate. NICE medical technologies guidance, publication expected February 2015. <http://guidance.nice.org.uk/MT/217>

## **5 External organisations**

### **5.1 Professional organisations**

#### **5.1.1 Professional organisations contacted for expert advice**

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- The Association for Perioperative Practice



- British Association of Day Surgery
- British Association of Urological Surgeons
- British Prostate Group
- The College of Operating Department Practitioners
- Royal College of Anaesthetists
- Royal College of Surgeons of England

### **5.1.2 Professional organisations invited to comment on the draft scope**

The following societies were alerted to the availability of the draft scope for comment:

- The Association for Perioperative Practice
- British Association of Day Surgery
- British Association of Urological Surgeons
- British Prostate Group
- The College of Operating Department Practitioners
- Royal College of Anaesthetists
- Royal College of Surgeons of England

## **5.2 Patient organisations**

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Bladder and Bowel Foundation
- Everyman
- Men's Health Forum (MHF)
- Orchid (for penile, prostate and testicular cancer)
- Prostate Cancer Network (PCaSO)
- Prostate Cancer UK
- Prostate Help Association
- Sexual Advice Association

- Tackle Prostate Cancer