

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia (Guidance update)

1 Technology

1.1 *Description of the technology*

The UroLift system (NeoTract) is used to perform a prostatic urethral lift, a procedure that is an alternative to current standard surgical interventions such as transurethral resection of the prostate (TURP) and holmium laser enucleation (HoLEP). The UroLift system uses adjustable, permanent implants to pull excess prostatic tissue away so that it does not narrow or block the urethra. In this way, the device is designed to relieve symptoms of urinary outflow obstruction without cutting or removing tissue.

The UroLift system comprises 2 single-use components: a delivery device and an implant. The delivery device consists of a hand-held pistol grip to which a needle-shaped probe is attached. Each UroLift implant consists of a superelastic nitinol capsular tab, a polyethylene terephthalate monofilament, and a stainless steel urethral end-piece. The surgeon inserts the probe into the urethra until it reaches the prostatic urethra (the widest part of the urethral canal); a fine needle at the end of the probe deploys and secures an implant in a lobe of the prostate. One end of the implant is anchored in the urethra and the other is attached to the firm outer surface of the prostatic capsule, so pulling the prostatic lobe away from the urethra. This is repeated on the other lobe of the prostate. Typically about 4 implants are used. The procedure can

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be done with the patient under local or general anaesthetic and may be done either on an in-patient or day-case basis.

1.2 Relevant diseases and conditions

Urolift is intended for use for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia [2020], in men 45 years of age or older. It should not be used for men who have a prostate volume of more than 100 ml, or those who have a urinary tract infection, urethral conditions that prevent the insertion of the delivery system into the bladder, urinary incontinence due to incompetent sphincter, or current gross haematuria. The company states that UroLift can be performed under local anaesthetic, without an anaesthetist present, with light sedation if needed [2020].

The prevalence of BPH increases with age. The first pathological signs of BPH are seen in men aged 31-40, although prevalence is typically only 8%. This rate increases rapidly with age: around 60% of men aged 60 or older will experience some degree of prostate enlargement ([NHS Choices](#)), and over 80% of men aged 70 or older ([Woo, 2012](#)). BPH is the most common cause of lower urinary tract symptoms (LUTS), although the two are not necessarily synonymous.

The effect of LUTS on quality of life can be assessed using the International Prostate Symptoms Score (IPSS). A score of 8-19 is classified as moderate, 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 ([Patient UK](#)). Moderate to severe LUTS are estimated to affect up to 3.4 million men in the UK (Rees, 2014), and up to 15,000 men undergo TURP annually in England and Wales to relieve symptoms ([NHS Direct Wales](#)).

1.3 Current management

NICE CG97 Lower urinary tract symptoms in men: management (2010) recommended surgical interventions for men with BPH only when LUTS are severe or drug treatment and conservative management have been

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unsuccessful or are not appropriate. If symptoms worsen over time, or if conservative management or drug treatment options are inappropriate or unsuccessful, surgical options may be considered.

For voiding LUTS, options include monopolar or bipolar TURP, transurethral vaporisation of the prostate (TUVP) or holmium laser enucleation of the prostate (HoLEP). Transurethral incision of the prostate (TUIP) may be offered if the prostate is estimated to be smaller than 30 g. Open prostatectomy should only be offered if the prostate is estimated to be larger than 80 g.

These treatments may be unsuitable for some people, due to the size and width of the prostate, size of the median lobe or position of the bladder neck. If the prostate is too large for transurethral surgical interventions, an open prostatectomy may be offered. All surgical comparators (except TUIP) functionally reduce prostate tissue volume by destroying tissue and debulking the prostate, to relieve LUTS.

Minimally invasive treatments such as transurethral needle ablation (TUNA), transurethral microwave thermotherapy (TUMT), high-intensity focused ultrasound (HIFU), transurethral ethanol ablation of the prostate (TEAP) and laser coagulation are not recommended by NICE for people with lower urinary tract obstructive symptoms ([NICE guideline lower urinary tract symptoms in men: management](#)). The clinical guideline recommends offering adjustable prostatic implants (such as the UroLift system) for the treatment of storage symptoms only as part of a randomised controlled trial. [Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia](#) (NICE interventional procedure guidance 475) concluded that there is 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.

1.4 Regulatory status

The UroLift system received a CE mark in November 2009 as a prostatic retraction implant for use in treating urinary outflow obstruction secondary to benign prostatic hyperplasia. The instructions for use specify that it is indicated for use in men aged 50 years and older and is contraindicated in men that have prostates larger than 100 ml.

1.5 Claimed benefits

The benefits to patients claimed by the company 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 company 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

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2 Decision problem

Population	Men with lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) aged 45 or over, and with prostate volumes no greater than 100 ml
Intervention	The UroLift system in inpatient or day case setting
Comparator(s)	<ul style="list-style-type: none"> • Monopolar or bipolar transurethral resection of the prostate (TURP) • Holmium laser enucleation of the prostate (HoLEP) • Transurethral water vapour therapy using Rezum (NxThera Inc)
Outcomes	<p>The outcome measures to consider include:</p> <ul style="list-style-type: none"> • Length of hospital stay • The need for, or duration of, post-operative catheterisation • Number of post discharge follow-on consultations, both in primary and secondary care settings • Time to re-operation and re-operation rates • Symptoms of BPH (using the International Prostate Symptom Score [IPSS]) • Changes in ejaculatory or sexual function • Time to return to normal activities • Quality of life • Hospital-acquired infection • Theatre and staff time • Incidence of chronic atonic bladder, detrusor sphincter dyssynergia, chronic urinary infection, chronic renal failure • Device-related adverse events • Number of implants
Cost analysis	<p>Comparator(s): Monopolar or bipolar TURP, HoLEP and Rezum</p> <p>Costs will be considered from an NHS and personal social services perspective.</p> <p>The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared.</p> <p>Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers of implants and combinations of devices are needed.</p>
Subgroups to be considered	Men for whom TURP or HoLEP is unsuitable because of operative risk including risks of blood loss or anaesthesia.
Special considerations, including those related to equality	Men who wish to preserve sexual function and fertility.

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Special considerations, specifically related to equality	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 characteristic?	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 the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable	

3 Related NICE guidance

Published

- Northampton General Day Case BPH service evaluation – adoption of Urolift. Shared learning, January 2020. Available here: <https://www.nice.org.uk/sharedlearning/northampton-general-day-case-bph-service-evaluation>
- Lower urinary tract symptoms in men. NICE pathway, last updated April 2020. Available from: <https://pathways.nice.org.uk/pathways/lower-urinary-tract-symptoms-in-men>
- Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia. NICE interventional procedures guidance IPG641. January 2019. Available here: <https://www.nice.org.uk/guidance/IPG641>
- Urolift – a community-based alternative treatment for Benign Prostatic Obstruction (BPO). Shared learning, November 2019. Available from: <https://www.nice.org.uk/sharedlearning/urolift-a-community-based-alternative-treatment-for-benign-prostatic-obstruction-bpo>
- Prostate artery embolisation for lower urinary tract symptoms caused by benign prostatic hyperplasia. NICE interventional procedure guidance,

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IPG611, April 2018. Available from:

<https://www.nice.org.uk/guidance/ipg611>

- Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia, NICE interventional procedures guidance IPG629, September 2018. Available from:
<https://www.nice.org.uk/guidance/ipg629>
- Transurethral water vapour ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia, NICE interventional procedures guidance IPG625, August 2018. Available from:
<https://www.nice.org.uk/guidance/ipg625>
- Rezum for treating benign prostatic hyperplasia, NICE medtech innovation briefing MIB158, August 2018. Available from:
<https://www.nice.org.uk/advice/mib158>
- Memokath-028, 044 and 045 stents for urethral obstruction. NICE medtech innovation briefing MIB123, October 2017. Available from:
<https://www.nice.org.uk/advice/mib123>
- Adoption of UroLift procedure, an ambulatory pathway for patients suffering from Lower Urinary Tract Symptoms of Benign Prostatic Hyperplasia. Shared learning, November 2016. Available from:
<https://www.nice.org.uk/sharedlearning/adoption-of-urolift-procedure-an-ambulatory-pathway-for-patients-suffering-from-lower-urinary-tract-symptoms-of-benign-prostatic-hyperplasia>
- Insights from the NHS: adoption of UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia at St Helens and Knowsley Teaching Hospital NHS Trust. NICE shared learning, September 2016. Available from: <https://www.nice.org.uk/sharedlearning/insights-from-the-nhs-adoption-of-urolift-for-treating-lower-urinary-tract-symptoms-of-benign-prostatic-hyperplasia-at-st-helens-and-knowsley-teaching-hospital-nhs-trust>
- Insights from the NHS: adoption of UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia at Frimley Park Hospital. NICE shared learning, August 2016. Available from:
<https://www.nice.org.uk/sharedlearning/insights-from-the-nhs-adoption-of->

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[urolift-for-treating-lower-urinary-tract-symptoms-of-benign-prostatic-hyperplasia-at-frimley-park-hospital](#)

- GreenLight XPS for treating benign prostatic hyperplasia. NICE medical technologies guidance MTG29, June 2016. Available from: <https://www.nice.org.uk/guidance/mtg29>
- 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: 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>

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- 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>

In development

NICE is developing the following guidance:

- Rezum for treating lower urinary tract symptoms secondary to benign prostatic hyperplasia. NICE medical technology guidance. Expected publication date 24th June 2020.
- Guidance update to MTG23: The PLASMA system for transurethral resection of the prostate. (The PLASMA system was formerly known as TURis). NICE medical technology guidance update. Publication date to be confirmed.

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

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

4.2 Patient

NICE's [Public Involvement Programme](#) contacted the following organisations for patient commentary and asked them to comment on the draft scope:

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