

Information Sheet

UroLift CUP/12 2014

The Prostatic Urethral Lift Procedure (UroLift® System)

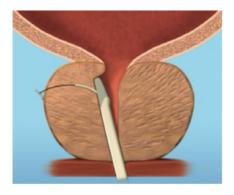
Which patients are the UroLift system suitable for?

The UroLift is suitable for patients who are suffering from symptoms of an enlarged prostate, where medication has been tried but has not been tolerated or has not been effective. Typically it is suitable for patients who are suffering these symptoms from a prostate gland which is not very enlarged, and may be also suitable for younger patients who require some surgery to the prostate for whom the possibility of sexual side effects from medication or the conventional surgery offered for this condition are unacceptable.

What does the procedure involve?

This procedure involves passing a fine telescope-like instrument into your urethra, or waterpipe. This device enables the surgeon to deploy a small implant between the inner and outer surfaces of the prostate, rather like a small treasury tag. This implant retracts the enlarged prostate lobe without the need for any cutting or burning of tissue The number of implants required varies according to the size and shape of the prostate, and usually between 2 and 4 implants need to be deployed. After the implants have been placed, most patients will be able to pass urine without the need for a catheter.

The operation can be performed under sedation or under a general anaesthetic, which means you will be asleep for the entire procedure. Typically, you will go home on the same day as the surgery.





What are the benefits of treatment?

In most cases, urination improves immediately, and risks of adverse effects on ejaculatory or erectile function are extremely small.

How will I know if the procedure is suitable for me?

Individual assessment for UroLift will required, including voiding function, prostate size and shape, and evaluation for prostate cancer. You may also require a telescope inspection of the bladder prior to the procedure. You will be able to discuss whether UroLift is suitable for you with your surgeon, who will discuss the alternatives with you. At Cambridge Urology Partnership we have considerable experience with other techniques of removing the prostate, by conventional TURP and laser removal of the prostate, or HoLEP. There is more information about these on our website. If we think that these might be more suitable procedures for you, then we will discuss this with you.

What are the alternatives to UroLift?

There are several alternative treatment options outlined below, although some may not be appropriate for you. Your consultant will discuss these with you if they are suitable for you:

Lifestyle advice:

For some men altering the amount they drink, or cutting back on caffeinated drinks can improve their urinary symptoms such that they do not wish to have an operation.

Medication: There are two types of medicines available.

They either shrink your prostate or relax the muscles in your prostate and bladder to improve the flow of urine. However, the effects only last as long as you take the medicines. You may have already tried this option without success, or have side effects from these tablets.

Transurethral resection of the prostate (TURP).

This is an operation to remove the parts of your prostate that are pressing on your urethra, to make it easier for you to pass urine. It involves a surgeon inserting a special telescope-like instrument into your urethra, which has a heated wire at one end that is then used to cut away the prostate tissue. There is more information about this on our website.

HoLEP.

This operation uses a laser to peel out all of the obstructing tissue from within your prostate. It causes less bleeding, and is associated with a shorter hospital stay than TURP. It is more durable than any other telescopic operation for enlarged prostates. Unlike the other available procedures it is suitable for men with prostates of any size, and is more successful at freeing men who are urinary retention from the need for a catheter. There is more information about HoLEP on our website. At Cambridge Urology Partnership we have three of the most experienced HoLEP surgeons in the country.



Use of a catheter:

Catheterisation is an option for men who do not want, or who are not considered suitable for any of the treatments above. Either you can pass a sterile catheter yourself, in and out, to empty the bladder periodically (depending on how often it is necessary). These catheters are much more slippery than standard catheters to make them slide very easily. Alternatively, a permanent catheter can be fitted, which either goes through the penis or through the lower abdomen. A permanent catheter can be used with a permanent drainage bag (e.g. a bag which attaches to the leg during the daytime, and a larger floor standing one at night), or a valve, which works like a tap, is fitted to the end of the catheter, avoiding the need for a bag.

What happens during the procedure?

You will be admitted on the same day as your surgery. You may receive an appointment for preassessment before your admission, to assess your general fitness, to screen for the carriage of MRSA and to perform some baseline investigations.

You will be asked not to eat or drink for 6 hours before surgery and, immediately before the operation.

A full general anaesthetic (where you will be asleep throughout the procedure) will usually be used.

Are there any side effects?

- Sensitivity when passing urine, urinary frequency, urgency, bleeding, pelvic discomfort or pain, and can be experienced in the first few weeks from surgery, typically settling within a month. Urinary leakage or infection can occur but are relatively uncommon.
 - Later, there is a small risk that encrustation could develop on exposed parts of the implant, which would then need to be removed. The implant can be removed easily if necessary by a procedure similar to that used for its placement. The implant does not prevent or interfere with subsequent prostate surgery should it be required.
- Urinary tract infection. This can cause symptoms such as pain or burning when passing urine, but can be treated with antibiotics. This happens to about 5% of patients. You may need to contact your surgeon or GP to check that you do not have a urinary infection. If you have symptoms that are very troublesome, not settling, or getting worse, you should contact your surgeon.
- Bleeding is usually minimal, and much less than for other more major surgical procedures for enlarged prostate. It may be aggravated by blood thinners and physical overexertion. If you take aspirin or blood thinners and have bleeding, you should seek advice from your doctor.
- Difficulty passing urine. Most patients will pass urine with immediate improvement in the flow and emptying.
 In the occasional case where there may be difficulty passing urine, or in situations where the surgeon feels it
 necessary, a catheter may be required, for instance if there were bleeding from the prostate. If your bladder
 is weak as a long term result of your enlarged prostate gland, you may still need to use a catheter on a long
 term basis.



- Prostate enlargement and formation of scar tissue. Your prostate continues to enlarge even after surgery and in the future. Occasionally another procedure may become necessary if your symptoms return. Surgery does not protect against or diagnose prostate cancer.
- While there have not been any reported side effects related to dry orgasm or erectile problems to date, there is a very small risk of this occurring after any surgery on the prostate, but the risk is extremely low with this type of surgery, and much lower compared to other types of prostate operation.

In addition, if you have an anaesthetic, there are some complications which can occur as a result of this.

Very common (1 in 10) and common (1 in 100) side effects

Feeling sick and vomiting after surgery Sore throat

Dizziness, blurred vision Headache

Itching

Aches, pains and backache Pain during injection of drugs bruising and soreness

Confusion or memory loss

Uncommon side effects and complications (1 in 1000)

Chest infection Bladder problems Muscle pains

Slow breathing (depressed respiration) Damage to teeth, lips or tongue

An existing medical condition getting worse Awareness (becoming conscious during your operation)

• Rare (1 in 10,000) or very rare (1 in 100,000 or less) complications

Damage to the eyes

Serious allergy to drugs

Nerve damage Death

Equipment failure

What happens immediately after the procedure?

There is minimal downtime post-treatment and patients may experience symptom relief as early as 2 weeks after the procedure. You may experience urinary discomfort during the recovery period. The most common adverse events reported include blood in the urine, burning or stinging when passing urine, a strong urge to pass urine at times, pelvic pain, and leakage of urine due to having a strong urge to urinate and not being able to reach a toilet in time. Most symptoms reported in studies so far were mild to moderate in severity and resolved within two to four weeks after the procedure. Your doctor will discuss with you how quickly you can return to your daily activities.

You can safely undertake light exercise after the operation, but you must avoid heavy lifting, straining, long journeys and sexual activity in the first month. You should maintain a good fluid intake of 1.5 - 2 litres a day, drink steadily throughout the day, and avoid taking too much tea, coffee, fizzy drinks and alcohol as these may irritate your bladder. You should pass urine according to how you feel the need to do so.

You may need to have two weeks off work. It is sensible to avoid driving in this period. You must absolutely not drive within 24 hours of sedation or anaesthetic.

It is common to have less control passing urine for a short time after surgery. If you experience this, please tell your nurse, who will explain how to perform pelvic floor exercises to improve your control.

You will be seen in clinic by either a doctor or nurse specialist 2-3 months after your surgery.



What is the evidence for UroLift

UroLift received FDA approval in 2013 and NICE approval in January 2014.

The published evidence shows that in men treated with Urolift, the flow rate improved by 50% (up to twice that of drugs but less than TURP and HoLEP), symptoms improved by 50% (up to 2-3 times that seen with drugs, but less than TURP or HoLEP) and no sexual dysfunction has been reported yet. Currently follow-up data is published up to two years. There was no incidence of sexual dysfunction in any of the studies.

More information is available on www.urolift.co.uk

Frequently asked Questions

1. What is the UroLift® System?

The UroLift[®] System is a new minimally invasive treatment designed to treat lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).

2. How does the UroLift System work?

The UroLift System consists of a delivery device and permanent implants. The implants are delivered during a minimally invasive treatment and act like window curtain tie-backs, holding the lobes of the enlarged prostate open to relieve obstruction. No cutting, heating, or removing prostate tissue is involved.

3. Is UroLift System treatment right for me?

The UroLift System is a treatment option for BPH patients who are looking for an alternative to drugs or more major surgery. You may be considering or scheduled for a TURP/Laser treatment, or are unhappy with or have stopped taking medications. The UroLift System is appropriate for patients seeking a minimally invasive treatment and who are concerned about preserving their sexual function and their quality of life, post-treatment, so long as the prostate is not too large.

4. What should I expect during the UroLift System treatment?*

If you and your doctor decide that the UroLift System treatment is right for you, your doctor will provide the specific, detailed information relating to your condition. In general, the UroLift System is a minimally invasive treatment that entails minimal downtime. Your doctor will use the UroLift Delivery Device to deploy permanent implants to relieve obstruction caused by the enlarged prostate. The procedure may be performed under local or general anesthesia and you may be given medication to feel comfortable during the treatment. Typically, no catheter and no overnight stay is required post-treatment. Your doctor will discuss with you how quickly you can go home.

5. What happens during the recovery period?*

There is minimal downtime post-treatment and patients may experience symptom relief as early as 2 weeks. You may experience urinary discomfort during the recovery period. The most common adverse events reported include: blood in the urine, burning or stinging when passing urine, a strong urge to pass urine at times, pelvic pain, and leakage of urine due to having a strong urge to urinate and not being able to reach a toilet in time. Most symptoms were mild to moderate in severity and resolved within two to four weeks after the procedure. Your doctor will discuss with you how quickly you can return to your daily activities.

6. How soon will I feel better after UroLift System treatment?*

While results vary with each patient, many men experience improvement in their lower urinary tract symptoms as early as 2 weeks after the treatment.

7. Will it affect my sexual function?*

There have been no reports of erectile dysfunction or ejaculatory dysfunction to date as a result of the UroLift System treatment.

8. Is clinical data available for the UroLift System?*

Clinical data supports the safety and effectiveness of the device, including a large pivotal study conducted in the U.S. It is approved by the FDA in the USA and NICE in the UK.

9. Who performs the UroLift System treatment?

A urologist, a doctor who specializes in the treatment of diseases of the urinary system and sex organs, uses the UroLift System to treat urinary symptoms due to BPH. The urologist must be trained prior to using the UroLift System.

10. Where is the UroLift System available?

The UroLift System is available in the United States, Europe, Canada and Australia



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