

REZŪM

This booklet has been provided to help answer the questions you may have with regards to your enlarged prostate and the Rezūm procedure that is being offered to you. It explains what Rezūm is, what treatment options are available, as well as what can happen if you choose to undergo a Rezūm procedure.

We will ask you to sign the consent form before the procedure if you decide to go ahead with surgery.

What is BPH?

Benign prostatic hyperplasia (BPH) with associated lower urinary tract symptoms (LUTS) is a common medical condition in the aging male. The incidence has been estimated to increase from 50% among men between the ages of 50 and 60 years, to 90% for men older than 80 years of age. In 2016, it is estimated that up to 3 million men in the UK have lower urinary tract symptoms suggestive of BPH. Traditionally the options have included making life-style changes for mild symptoms as well as medication and surgical procedures such as TURP or laser prostatectomy (HoLEP) for men with more severe symptoms or complications of prostate enlargement such as urinary infections or a complete stoppage (urinary retention).

What other treatment options are available?

- **Life-style changes and reassurance**

For men with concerns about prostate enlargement and mild symptoms reassurance and advice regarding food and drinks is usually all that is required. This “watch and wait” approach is employed for many men diagnosed with BPH. Treatment usually occurs once the symptoms of bladder outlet obstruction and bladder irritability interfere significantly with quality of life.

Traditionally, the primary objective of treatment has been to alleviate bothersome LUTS that result from prostatic enlargement.

- **Medication**

For many men, medications such as alpha blockers are the first line approach to control mild-to-moderate symptoms of BPH. These symptoms include frequent urination and getting up at night as well as a deterioration in the flow of urine often with hesitancy and sometimes with a feeling of incomplete emptying. Choosing the correct medical treatment for BPH symptoms is often complex and ever changing.

- **Issues**

Many men begin medical therapy but have:

Inadequate or short-lived improvement in their symptoms and quality of life

Undesirable side-effects that lead to discontinuation such as light headedness and sexual problems

Increasingly, men do not want to commit to lifetime pharmaceutical treatment, particularly as they are often taking other medication and there can be concerns relating to interactions between tablets.

Remembering to take the tablets can also be an issue.

The most economical way of treating troublesome symptoms due to BPH is still not entirely clear but many men take medication for several years before going on to have surgery. Increasingly minimally invasive surgical treatments are being offered to men with moderate symptoms, a reluctance to take/continue medication and a desire to return to normal activities quickly.

- **Minimally Invasive Procedures:**

At the present time there are other options. The results with Transurethral microwave thermotherapy (TUMT) and Transurethral needle ablation using radiofrequency thermotherapy (TUNA) are at best modest and prostatic stents continue to cause problems.

The use of Implants to retract enlarged prostate tissue (UroLift®) is gaining popularity but not all prostates are suitable for this procedure, which depends on the size and shape of the prostate gland. It can also make the interpretation of future MRI difficult due to artefact at the site of implants.

- **Endoscopic surgery**

The removal of prostate tissue is called a prostatectomy and when there is benign (non cancerous) prostate tissue causing a blockage the central component of the prostate is removed one way or another, in order to allow urine to flow more easily from the bladder.

For men with severe BPH symptoms including retention of urine, Transurethral resection of the prostate (TURP) has been the gold standard for a long time but increasingly men are looking at the alternatives which include Holmium laser enucleation of the prostate (HoLEP) or vaporization (PVP using the 180W greenlight laser). These laser technologies remove prostate tissue by different means.

With all surgical procedures there are complications, side effects and risks as outlined below. *Bachmann A, Hindley R et al – The Goliath Study, Eur Urol 2013* demonstrated that the percentage of unplanned readmission rates following a TURP procedure was 13.5%.

The other recognised side effects are listed below for endoscopic surgery:

- Retrograde ejaculation (dry ejaculation)
- Erectile dysfunction (impotence)
- Urethral strictures or scarring
- Bleeding (occasionally requiring a transfusion, rare for HoLEP)
- Urinary infection (UTI)

There are also other issues including a Hospital stay:
(usually 2 days after TURP and 1 day for HoLEP).

It is often 6 weeks before patients can return to normal activities and regular exercise.

What is Rezūm?

Rezūm is a method by which steam energy is used to ablate (or remove) the particular part of the prostate that enlarges and causes symptoms due to BPH. Specific technical information is explained below.

This system consists of a portable radiofrequency (RF) generator and delivery device that is introduced into the body via the urethra (transurethral approach) and guided by direct visualization through a telescopic lens placed within the delivery device.

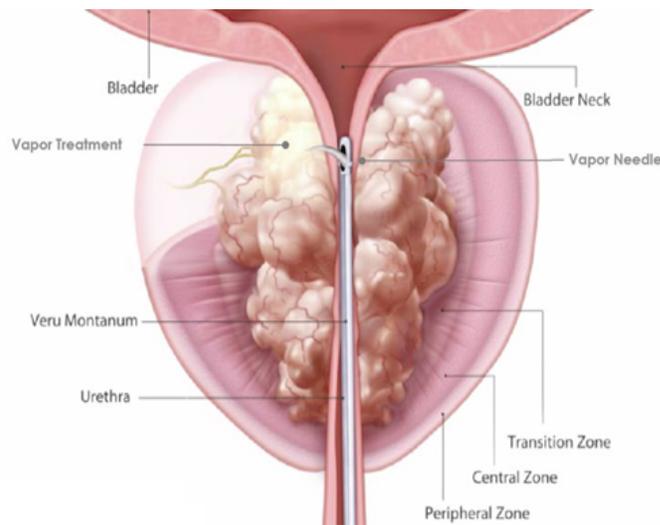
RF energy from the generator is applied to an inductive coil in the delivery device to heat up a controlled amount of water outside of the body, converting the water into vapour or steam. The thermal energy created outside the body is delivered into the prostate tissue through a tiny needle with emitter holes to ablate the targeted obstructive prostate tissue that causes BPH. The procedure takes approximately 3 - 7 minutes and can be performed in a Day Surgery setting. No RF energy is delivered into the body.

Throughout the insertion of the device and during the treatment saline (salty water) is running to help ensure better views and to prevent the urethra from overheating.

The generator has a number of safety features to ensure proper heating and thermal ablation of the targeted prostate tissue, while protecting the urethra during treatment. Thermocouples in the delivery

device monitor temperatures to ensure consistent delivery of thermal energy into the ablation region. The length of the vapour needle is fixed and the operator controls all functions of the device. Placement of the vapour needle within the prostate is done under direct visualization through the telescopic lens, which is in the urethra inside the prostate.

The Rezūm System is intended to relieve the symptoms of obstruction and prostate tissue associated with BPH and is indicated for men with prostatic urethra lengths >2.0 cm and prostate volumes >20 cm³. The Rezūm System also is indicated for treatment of prostates with a median lobe or elevated central zone tissue.



What approvals does Rezūm have?

The Rezūm System received CE Mark on 8th July 2013 and FDA clearance for use in the USA on 27th August 2015.

Rezūm received NICE approval in August 2018 and it has advised that the procedure may also be effective for patients with an enlarged median prostatic lobe.

What evidence of the benefits of Rezūm are available?

There have been several clinical studies undertaken on the benefits of the Rezūm System and we can give you details if you would like to review them.

Rezūm provides the following benefits:

Potential alternative to BPH medications

Relieves symptoms safely and effectively¹

Provides noticeable symptom improvement within two weeks ¹, maximum benefit 1-3 months

Preserves sexual and urinary functions¹

Allows patients to return to regular activities within a few days¹

What happens next?

You will be offered a date for the procedure and also for a pre-operative assessment if a general anesthetic is going to be used. If you have not already done a flow test, this will be performed as well as completing the questionnaires. If you are on blood thinners, you may be asked to stop taking them for a period prior to your treatment.

Treatment day

You will have been given a time to attend the hospital. Even though the procedure only takes a few minutes, you will probably be at the hospital some time before and after the procedure, again depending on the anesthetic used. It is very likely that you will be discharged home the same day.

The treatment

About an hour before, you will be given some strong painkillers as well as some antibiotics which you will continue at home. You will then be accompanied to theatre where the procedure will take place. If you are having a general anesthetic you will be sent to sleep.

The Rezūm equipment is then passed through the urethra using plenty of anesthetic gel, which may momentarily sting. After a quick inspection of the bladder, the treatment will begin.

On completion a catheter will be left within your bladder for a few days prior to voiding as the prostate readjusts to the treatment and the swelling subsides.

When can I go home?

After your procedure, you will be reviewed by a member of the urology team who will discuss the operation, any specific requirements for you at home and a plan for your aftercare.

A date will be given to you as when to return for the catheter removal as well as the care required whilst at home.

It is normal to have some pain or discomfort after operations, and we advise you on painkillers to help keep it under control.

Return to work as you feel comfortable depending on your job. If in doubt please check with your surgeon and obtain a certificate, before you are discharged

When you attend for catheter removal, the tube will be removed and then when you are ready you will be asked to void into the flow machine and the bladder scanner will detect any remaining volume of urine. If the nurse is happy with the results you will be discharged.

If there are any problems you may require a further period of catheterisation or be taught intermittent self catheterisation.

Within a few days you will be able to resume normal activities and should notice improvements within 2 weeks, although it may be 3 months before the full benefit is evident. Blood may be visible in the urine and ejaculation fluid

When can I resume sexual activity?

We recommend you avoid ejaculation for 6-8 weeks following the procedure.

Are there any side-effects?

Most procedures have a potential for side-effects. You should be reassured that, although all these complications are well-recognised, the majority of patients do not suffer any problems after a urological procedure.

Common (greater than 1 in 10)

- Blood in the urine (usually temporary with resolution usually in days)

Occasional (between 1 in 10 and 1 in 50)

- Frequency and urgency to pass urine (usually temporary with resolution usually in days)
- Temporary pelvic discomfort or pain
- Urinary tract infection
- Continuing enlargement of the prostate and need for further prostate surgery

- Failure to resolve symptoms (due to continuing blockage or a bladder problem). Over 95 in 100 patient have a good response to treatment with improvements in their symptoms
- Reduced volume of ejaculation (known as retrograde ejaculation) happens in 5 to 10 people out of 100

Rare (less than 1 in 50)

- Prolonged retention
- Stricture

What should I expect when I get home?

When you leave hospital, you will be given a discharge summary of your admission. This holds important information about your inpatient stay and your operation. You can safely undertake light exercise after the operation, but you must avoid heavy lifting, straining, long journeys and sexual activity for 6-8 weeks. You should maintain a good fluid intake of 1.5 to 2 litres a day, drink steadily throughout the day, and avoid taking too much tea, coffee, fizzy drink and alcohol as these may irritate your bladder. You should pass urine according to how you feel the need to do so. The average return to normal activity is five days. It is sensible to avoid driving in this period. It is common to have less control passing urine for a short time after surgery.

What else should I look out for?

After you have had prostate surgery, contact the ward or our secretary or your GP (general practitioner) if you have any problems such as pain, bleeding or symptoms of urinary infection or feeling generally unwell. If severe, please go to your nearest accident and emergency department.

¹McVary KT, Roehrborn CG. Three-year outcomes of the prospective, randomized controlled Rezūm system study: Convective radiofrequency thermal therapy for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. *Urology*. 111C (2018):1-9.

McVary KT, Roehrborn CG. Final. 5-Year Outcomes of the Multicenter Randomized Sham-Controlled Trial of Rezūm Water Vapor Thermal Therapy for Treatment of Moderate-To-Severe Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *Journal of Urology* 2021. <https://pubmed.ncbi.nlm.nih.gov/33872051/>

Procedure code for insured patients: M6750