

Rezūm Patient Information Leaflet

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如有需要,本传单可提供其他语言/版式 此單張的其他語言/格式版本可按要求提供 Na żądanie ta ulotka może zostać udostępniona w innych językach/formatach.

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Discharge Information

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 for men with more severe symptoms or complications of prostate enlargement such as urinary infections or a complete stoppage (urinary retention). Sanderson Suite - 01744 646098/646089

Ward 4A - 0151 430 1420

Ward 4B - 0151 430 1637

Ward 4C - 0151 430 1643

Who can I contact for more help or information?

Best Health (prepared by the British Medical Association)

NHS Clinical Knowledge Summaries (formerly known as Prodigy)

NHS Direct

Patient UK

Royal College of Anaesthetists (for information about anaesthetics)

Royal College of Surgeons (patient information section)

You will be given an appointment to attend for your 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.

Who can I contact if I have a problem when I get home?

If you experience any problems related to your surgery or admission once you have been discharged home, please feel free to the numbers below for advice from the nurse in charge. They will assist you via the telephone, advise you return to your GP or ask you to make your way to the Emergency Department at Whiston Hospital depending upon the nature of your concern.

What other treatment options are available?

Lifestyle changes and reassurance

For men with concerns about prostate cancer 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.

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 anaesthetic you will be sent to sleep. The majority of men will be awake for the procedure.

Antibiotics will be given directly into your vein. Local anaesthetic will then be administered around the prostate gland with the use of an ultrasound probe via the back passage. This may feel a bit uncomfortable, but the more relaxed you are the easier it will begin.

The Rezūm equipment is then passed through the urethra using plenty of anaesthetic 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. An antibiotic and pain killing suppository will be inserted into your rectum at the end.

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 to return for the catheter Removal. As well as the care required whilst at home, we will advise you on painkillers to help keep this 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.

It is normal to have some pain or discomfort after operations.

What approvals does Rezūm have?

The Rezūm System received CE Mark on 8th July 2013, FDA clearance for use in the USA on 27th August 2015 and NICE approval in August 2018.

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.

What happens next?

You will be offered a date for the procedure and also for a pre-operative assessment if a general anaesthetic is going to be used. If you have not already done a flow test, this will be performed as well as completing 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 anaesthetic used. It is very likely that you will be discharged home the same day.

Minimally Invasive Procedures

At the present time there are other options. The results with Transurethral microwave thermotherapy (TUMT) and Transurethral needle ablation using 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.

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 laser enucleation (Holmium laser) 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 (a study which Basingstoke participated in) demonstrated that the percentage of unplanned readmission rates following a TURP procedure was 13.5%.

The other recognised side effects are listed below:

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

There are also other issues including a Hospital stay of several days (usually 3 days after TURP).

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 on the next page.

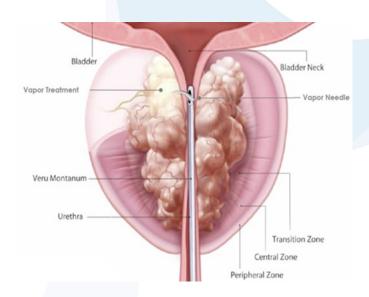
This system consists of a portable radiofrequency (RF) generator and delivery device that is introduced into the body via the urethra (transurethral approach) and guided by direct visualisation through a telescopic lens placed within the delivery device.

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 visualisation 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.



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