



Rezūm treatment for BPH (Benign prostatic hyperplasia)

Information for patients, relatives and carers

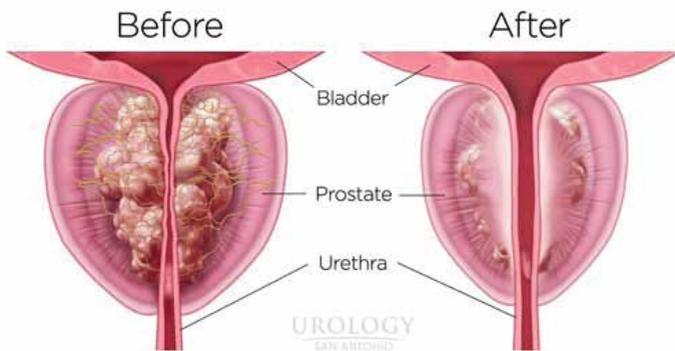
This booklet has been provided to help answer some of the questions you may have about your enlarged prostate and the Rezūm procedure we are offering you. It explains what Rezūm is, what other treatment options are available, as well as what to expect before, during and after the Rezūm procedure.

rezūm[®]
THE NEW WAVE IN BPH TREATMENT

What is BPH?

Benign prostatic hyperplasia (BPH) is a non-cancerous enlargement of the prostate gland. BPH with associated lower urinary tract symptoms (LUTS) is increasingly common as men get older. It is estimated to increase from 50% among men between 50 and 60 years old, to 70% for men older than 70.

Treatment options usually include making lifestyle changes for mild symptoms, as well as medication and surgical procedures such as TURP (transurethral resection of the prostate) or laser prostatectomy for men with more severe symptoms or complications of prostate enlargement, such as urinary infections or an inability to pass urine (urinary retention).



What is Rezum?

Rezum is a surgical treatment which involves a special machine using steam to ablate (remove) the particular part of the prostate that enlarges (this is called the transition zone) and causes symptoms due to BPH.

The machine consists of a portable radiofrequency (RF) generator and delivery device that is passed into the body via your urethra (water pipe). A telescopic lens within the device allows us to guide the treatment to where it is needed. The number of treatments delivered at the time of the procedure depends on how large your prostate is.

RF energy from the generator is applied to an inductive coil in the delivery device to heat up a measured amount of water outside of the body, which then converts the water into vapour or steam. This is then passed into the prostate tissue via a tiny needle with emitter holes to ablate the area which causes BPH. Please note that no RF energy is delivered into the body.

The procedure takes approximately three to seven minutes to complete and patients are normally able to go home the same day. Rezum is often done under a local anaesthetic (you will be awake but the urethra and prostate will be numbed) but it can be done while you sleep under a general anaesthetic. The procedure takes in total between 20-25 minutes.

In comparison with other treatments, which have a longer recovery period, you should be able to resume normal activities within a few days. You should notice improvements within three weeks, although it may take up to six months to obtain the full effect.

Is it safe?

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. The temperature of the vapour/steam is monitored throughout and the person operating the device is in full control of delivering the treatment to the targeted area.

Throughout the procedure, saline (salty water) is running to help the surgeon obtain a better view inside of your body.

Rezum does now have NICE (National Institute for Health and Clinical Excellence) approval as an intervention (granted in August 2018). It is continuing to be assessed as part of



the normal NICE process, in order that recommendations can be made as to who are the patients most likely to benefit, as well as the cost implications. Basingstoke is one of several centres in the UK that were offered the opportunity to start using this technology before the NICE approval and we have now performed over 400 cases since March 2017.

There have been several clinical studies on the benefits of the Rezum system and we can give you details of them on request.

Are there any risks associated with having Rezum?

There are of course risks with all procedures on the prostate gland including Rezum. These include the risks associated with the anaesthetic as well as the procedure. Bleeding and urinary tract infections after the procedure are not uncommon, as well as discomfort passing urine. It does take up to 3 months to notice an improvement in symptoms. This is not the case with some of the other options where the improvement is often noticed within the first few days after catheter removal.

It is important to be aware that a catheter will be required for a few days after the operation. The duration will depend on the size of your prostate gland but it can commonly be left in for 3-10 days and sometimes longer. It is possible that the first time the catheter is removed it may not be possible to pass urine initially. We recommend that any prostate medication be continued for the first month after the treatment in order to reduce the likelihood of difficulties in the first few weeks. It can take over 4 weeks for the majority of the swelling to settle. We would also recommend abstaining from ejaculating for 4-6 weeks after the procedure, to reduce the risk of bleeding.

The attraction of Rezum is that it can be performed under local anaesthetic (LA) or with sedation and the procedure takes 20 minutes to perform. Furthermore, it is very unlikely to upset the sexual function or ejaculatory function. Our early feedback has suggested that 5% (1 in 20) men will have drier ejaculation after the procedure but problems with the erections are rare. We don't know how long the benefits of the procedure will last in the long term as this treatment has only been available for 5 years in the US and 2 years in the UK. We suspect that the likelihood of further prostate surgery being required in the long term to be higher than for TURP or laser treatments. Incontinence is very rare but will also need to be discussed as part of the consent process. A small proportion of men will require a second procedure in the first year (2%), in order to obtain the maximum benefit. The overall re-treatment rate from the US data is 4.4% at 4 years.

What other treatment options are available?

Lifestyle changes and reassurance

For men with concerns about prostate cancer and mild symptoms, reassurance and advice on diet is usually all that is required. This is known as a 'watch and wait' approach and is used with many men diagnosed with BPH. Treatment usually occurs once bladder symptoms interfere significantly with quality of life. A small proportion of men will require a second procedure in the first year (2%), in order to obtain the maximum benefit. The overall re-treatment rate from the US data is 4.4% at 4 years.

Medication

For many men, medications such as alpha blockers are used to control mild to moderate symptoms of BPH. These symptoms include frequent urination and getting up at night,

as well as deterioration in the flow of urine often with hesitancy and sometimes with a feeling of incomplete emptying. Choosing the correct medication for BPH is often complex. Tablets that shrink the prostate are also an option (eg. Finasteride), but these can upset sexual function in a minority.

Disadvantages of treatment with medication

- Inadequate or short-lived improvement in symptoms and quality of life
- Undesirable side effects, such as light-headedness or sexual problems.

You may not want to commit to lifetime treatment with drugs, particularly if you are already taking other medication. Remembering to take the tablets can also be an issue.

Minimally invasive procedures

There are options other than Rezum and these include

- Prostate Artery Embolization (PAE) which is performed by a radiologist (not a urologist). It tends only to be reserved for those with extremely large prostates, or who are too frail to be considered for other options.
- Urolift, a procedure that uses implants to retract (lift) parts of the enlarged prostate out of the way and thereby prevent it from blocking the urethra. However, not all prostates are suitable for this procedure as it depends on the size and shape of the prostate gland.

These and other even newer minimally invasive options are currently under evaluation. There are now therefore several options for men looking for an alternative to medication, or wishing to avoid the side-effects of bigger procedures such as TURP.

Laser treatments

Patients are increasingly considering treatments using lasers to remove excess prostate tissue, which include procedures known as enucleation (usually Holmium laser) or vaporization (PVP using Greenlight laser). Again the risks and side-effects include infection and bleeding, although this is less likely with the Greenlight laser as the laser seals blood vessels during the procedure. Generally this is a day case procedure although some patients require an overnight stay in hospital. The chances of a deterioration in sexual function after the procedure are less than for a TURP (1-3%), but retrograde (dry) ejaculation is still common (up to 50%). Incontinence is again unusual (1%). A man with a large gland over 100 mls in volume would very likely be better suited to a laser procedure, as the symptoms are slow to improve after Rezum if the gland is large.

TURP (transurethral resection of the prostate)

This is a type of endoscopic (keyhole) surgery can be used when there is benign (non-cancerous) prostate tissue causing a blockage. The central part of the prostate is removed, which will allow urine to flow more easily from the bladder. For men with severe BPH symptoms, including retention of urine, TURP has been commonly used for a long time. This uses electricity and a wire to scoop out prostate tissue and is the most common procedure offered to men in the UK. Increasingly men are put off having this procedure as there is a small risk of major complications (1%) as well as a risk of requiring a blood transfusion (1-2%). It can also upset the sexual (erectile) function in 5-10% and will cause a drier ejaculation in over 75%. Scarring of the urethra afterwards is also more common after this procedure. Incontinence is uncommon. This hospital stay is usually 2-3 days and so is seldom possible as a day case procedure. It is often six weeks before men can return to normal activities and undertake regular exercise after having TURP. A bipolar TURP we believe is better than a monopolar TURP because of the reduced likelihood of bleeding.

What happens if I decide to have Rezum?

We will offer you a date for the procedure, and an appointment for the pre-assessment clinic. If you have not already had a urine flow test, we will arrange this. If you are currently taking blood-thinning medication (such as warfarin), we may ask you to stop taking it for a few days before your treatment.



On the day of surgery

We will ask you to come in on the day of your operation. Although the procedure only takes a few minutes, you should expect to be at the hospital for a few hours, longer if you are having a general anaesthetic. It is very likely that you will be able to go home the same day. We will discuss the procedure with you in detail and ask you to sign a consent form. In theatre before the operation, we will give you some strong painkillers as well as antibiotics which you will need to continue at home. You will then be given a general anaesthetic if you are having one. We recommend to keep the bowel motions soft after the procedure for 3-5 days.

The prostate is measured with the use of an ultrasound probe via your back passage. This may feel a bit uncomfortable, but the more relaxed you are, the easier it will be.

We will then pass the Rezum equipment through your urethra (water pipe) using plenty of anaesthetic gel, which may momentarily sting. After a quick inspection of the bladder, we will start the Rezum treatment.

At the end of the procedure, we will insert antibiotics and pain killers (this may include a pain killing suppository into your rectum). You will have a catheter left within your bladder for a few days to drain the urine away without the need for you to pass urine yourself and also allow the prostate to adjust to the treatment and for any swelling to go down. You may be given a tap or valve to attach to the catheter.

When can I go home?

After the procedure, a member of the urology team will discuss the operation with you. They will give you a date to return to hospital for removal of your urinary catheter, as well as advise you on how to look after yourself at home. You are usually in the hospital for less than 6 hours.

You should be discharged home with at least 5 days of antibiotics as well as some painkillers. You are unlikely to have any pain once the catheter has been removed.

Is there anything I need to watch for at home?

It is normal to have some pain and discomfort after surgery, and we will advise you on the most appropriate pain killers to use.

If you have a temperature after the procedure with shivers and shakes you may require antibiotics and so we would advise you to contact the hospital where you had the procedure. If there is bleeding and blood clots we would also ask you to seek help.

When can I get back to normal?

You can return to work as soon as you feel comfortable to do. If you need a sick certificate or have any queries about this, please speak to your surgeon before we discharge you home. Some patients have returned to work within a few days. Most will take 1 week off, some longer.

You should be able to resume most of your usual activities within a few days. It is normal to see a small amount of blood in the urine after this procedure for 4-6 weeks. Burning when passing urine can come and go. This responds well to anti-inflammatory painkillers.

You can resume sexual activity 4 weeks after the catheter has been removed and you feel comfortable to do so. Please do not worry if you see blood in your semen which may also be visible for a long as 3 months.

Will I need to return to hospital?

Yes, we will ask you to return to have your catheter removed. This appointment will be arranged when you come in for your procedure. Please try to have a full bladder when you come for this appointment, so that your stay will be as short as possible.

Once we have removed the catheter, we will ask you to empty your bladder. We monitor how much you void and then do a bladder scan to detect any urine remaining in your bladder. If the nurse is happy with the results, we will discharge you from the ward. However, if there are any problems, we may need to recatheterize you for a further period.

We will be asking you to complete some questionnaires before and after the procedure.

What to expect following the catheter removal (Trial WithOut Catheter - TWOC)

After catheter removal once you have been discharged home it is important to be aware of the following;

- For 24-48 hours the flow may deteriorate before it starts to improve
- Blood in the urine is normal particularly for the first few days
- Increasing fluid intake can help the urine to clear
- Avoiding heavy lifting or straining is sensible
- Burning when passing urine is not uncommon and this can occur at any time in the first 6 weeks – this responds well to anti-inflammatory painkillers and avoiding drinks which irritate the bladder such as fruit juices and caffeine containing drinks
- Please try not to get constipated – straining to open the bowels can trigger bleeding and the passage of blood clots

Blood at the start of the urinary stream is normal particularly in the first few weeks. This can last as long as 6 weeks. If the urine becomes a dark rose colour or red with clots it is important to rest and take fluids, and if this doesn't settle within 24 hours please contact the ward.

It is normal to pass some debris in the first few weeks – $\frac{1}{3}$ of men will pass small bits of prostate tissue in the urine. This is more common if the median lobe has been treated (not all men have a median prostate lobe).

It is possible that pads may be required to absorb any potentially embarrassing leakage particularly in the first 2-3 weeks. This is something that will settle over time.

Continue to look out for the following;

- If you get a fever (high temperature) in the first few weeks – please consult the ward or contact your local GP. Further antibiotics may be required to treat a urinary tract infection.
- If you are unable to pass urine and it becomes painful at any time in the first week you may need another catheter for a few days. This doesn't happen very often.
- If there is dark blood passing from the urethra with clots and it is uncomfortable you may require urgent review if it is not settling.

After 4 weeks

You no longer need to avoid heavy lifting or sexual intercourse.

It is normal for the improvement in the urinary symptoms to be quite slow but usually some improvement in the flow has occurred by this stage. ¼ of men will still be having some difficulties with increased urinary urgency and frequency at 6 weeks.

To get the full benefit of Rezum can take as long as 6 months.

Frequently asked questions

When should I stop my prostate medication?

It is sensible to stop the medication 4 weeks after the procedure. If the prostate is very large then this may be extended to up to 3 months.

Is it normal to have blood in the ejaculation fluid?

Yes this is normal and can take several weeks for ejaculations to settle.

Is it likely to be a slower recovery if my prostate was large before the procedure?

The bigger the prostate the longer it can take to see an improvement and it can be a bit more uncomfortable in the first week or two. As additional injections of steam are required for a bigger gland it will be more swollen to start with.

What happens if my symptoms initially improve and then deteriorate within the first 3-6 months?

Occasionally this can happen in the first few months following the Rezum procedure. This can be due to the healing process and sometimes a piece of dead prostate tissue can cause a partial blockage. This is not difficult to deal with but it is important to notify your Urologist if this occurs.

Is there a limit to the size of gland treated?

We would recommend gland volumes are less than 100mls in size ideally. The data would suggest that the best results are for those with a gland volume of less than 80 mls. This will be assessed before your procedure. We can treat larger glands but there are usually other options which may be superior for very large prostates.

How much time will I need off work?

This does depend on the type of work. If there is quite a lot of travelling and exercise we would recommend 2 weeks from the time of surgery. Some men are able to return to a desk job within 2-3 days of the procedure whilst others will prefer to wait until after the catheter has been removed.

Your feedback is important to us

Comments, concerns, compliments and complaints

If you have any comments, concerns, compliments or complaints about your care, please let us know as soon as possible. Please speak to the urology specialist nurse so that we can help to resolve your concerns quickly.