

Rezūm™

Water Vapour Therapy



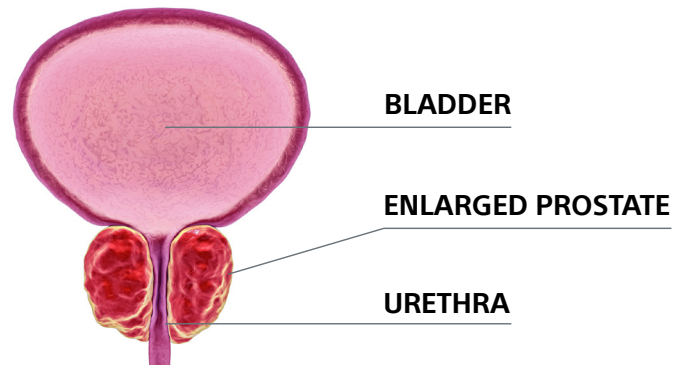
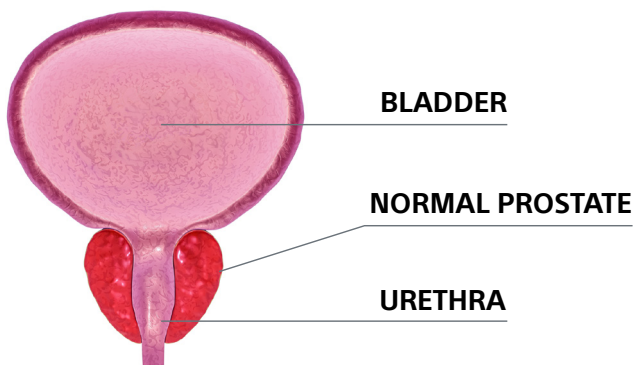
Benign Prostatic Hyperplasia (BPH) | Media Fact Sheet

About Benign Prostatic Hyperplasia (BPH)

Commonly known as an 'enlarged prostate'

A condition in which the prostate becomes enlarged and can obstruct the flow of urine¹

More common in older people: affects about 50% of men by age 60, and up to 90% of men by age 85*²



Symptoms¹:



A weak, interrupted urine stream



Difficulty starting and stopping urination



Frequent or urgent need to urinate and nocturia



Inability to completely empty the bladder

*Studies referenced are binary. For more information on BPH in the trans community, visit: <https://prostatecanceruk.org/prostate-information/further-help/other-prostate-problems-in-trans-women>



Common treatment options:



Behavioral modifications, such as reduction of fluid intake and moderation of intake of caffeine or alcohol to avoid worsening symptoms³

Potential risk factors of behavioral modifications⁵: Untreated BPH can lead to complications including urinary tract infections, kidney or bladder stones and kidney damage⁴



Medication to manage symptoms⁵

Potential side effects⁵: Dizziness, erectile dysfunction, lowered sex drive, retrograde ejaculation (a condition where semen goes into the bladder)³



Surgery to remove tissue blocking the urethra or to widen the urethra⁵

Potential side effects⁵: Difficulty emptying the bladder, urinary leakage, urgency to urinate, discomfort during urination, erectile dysfunction, bleeding⁶



Minimally invasive therapies that reduce, remove or lift and hold prostate tissue adjacent to the urethra, leading to increase in urinary flow rate^{3,5}

Potential side effects⁵: Painful or frequent urination, blood in the urine, and urgent need to urinate^{5,7}

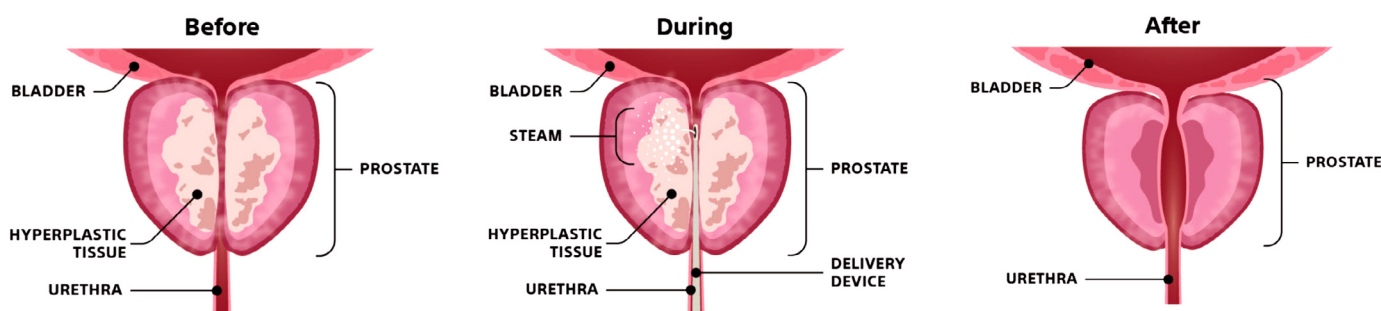
⁵This is not a complete list of side effects associated with each treatment. You should speak with your doctor about the risks associated with each treatment option

What is Rezūm™ Water Vapour Therapy?⁷

- A minimally invasive procedure to treat BPH, not just the symptoms
- The Rezūm System utilises 'wet' thermal energy in the form of water vapour, that is injected into the prostate tissue, to reduce the size of the prostate and provide lasting relief, while preserving sexual and urinary functions
- Proven also suitable for patients with a median lobe⁸

How does Rezūm Therapy work?⁷

- Water vapour is released into the prostate and targets excess tissue surrounding the urethra
- Energy from the water vapour targets the excess tissue cells and over time, the body's healing response removes the treated tissue, relieving pressure on the urethra



The images above are illustrative, not an actual depiction of patient results



Where and how is the procedure performed?⁸

- Depending on the country and the facility, in the operating room or day-case of ambulatory setting
- Physician will evaluate if general anaesthesia or local anaesthesia is required for the patient

How soon can I return to regular activities following the procedure?⁸

- Most patients can go home same day after treatment⁹
- Each experience depends on the individual patient's healing response, and should be discussed with a doctor
- It has been demonstrated that 3 months after treatment there is a reduction in overall prostate and transition zone volumes¹⁰

What value could Rezūm provide to treatment centres?

- With its durable clinical benefits, short procedural time and short length of stay, Rezūm may lead to cost savings as well as capacity impact reduction vs standard of care^{**7, 8, 9, 11, 12}
- The NHS Med Tech Funding Mandate supports Rezūm in the UK for 2022/23[†]

What research has been done?^{8, 13, 14, 15}

- Extensive clinical research has demonstrated the safety, durability and efficacy of the treatment, proving:
 - Pivotal trial shows sustained symptom relief, and a low surgical retreatment rate of 4.4% out to five years and preserves sexual function⁸
 - The ability to treat prostates with hyperplasia of the central zone, lateral lobe and/or median lobe

How has Rezūm adoption been progressing worldwide?

- More than 160,000 devices sold to date worldwide[‡]:
 - Cleared by the FDA in 2015
 - CE marked in 2013
 - Recommended by the American Urology Association, NICE guidance and DGU^{11, 16, 17}

What are the potential risks?

Potential risks associated with Rezūm Water Vapour Therapy include but are not limited to painful or frequent urination, blood in the urine or semen, decrease in ejaculatory volume, urinary tract infection (UTI), inability to urinate or completely empty the bladder, and urgent need to urinate.

Visit myprostateinfo.co.uk for a complete list of risks, and talk to your doctor about the benefits and risks before moving forward with any treatment option^{8, 14}.

^{**}Results from different clinical investigations are not directly comparable. Information provided for education purposes only

[†]<https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/the-medtech-funding-mandate/>

[‡]Number of patients is based on units shipped and a BSC proprietary algorithm



References and Disclaimers

1. Mayo Clinic. Benign prostatic hyperplasia. Available at: <https://www.mayoclinic.org/diseases-conditions/benign-prostatic-hyperplasia/symptoms-causes/syc-20370087>. Accessed December 2021
2. Harvard Health. The growing problem of an enlarged prostate gland. Available at: <https://www.health.harvard.edu/mens-health/the-growing-problem-of-an-enlarged-prostate-gland>. Accessed December 2021
3. S. Gravas (Chair), J.N. Cornu, M. Gacci, C. Gratzke, T.R.W. Herrmann, C. Mamoulakis, M. Rieken, M.J. Speakman, K.A.O. Tikkinen Guidelines Associates: M. Karavitakis, I. Kyriazis, S. Malde, V. Sakalis, Guidelines Office: N. Schouten, E.J. SmithEAU Guidelines on Management of Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS), incl. Benign Prostatic Obstruction (BPO), © European Association of Urology 2022
4. UCLA Health. Clinical Programs. Available at: <https://www.uclahealth.org/urology/body.cfm?id=478&action=detail&ref=21>. Accessed March 2022
5. Cleveland Clinic. Benign Prostatic Enlargement/Hyperplasia (BPE/BPH). Available at: <https://my.clevelandclinic.org/health/diseases/9100-benign-prostatic-enlargement-bph>. Accessed December 2021
6. Medical News Today. What happens if you have prostate surgery? Available at: <https://www.medicalnewstoday.com/articles/321190>. Accessed December 2021
7. Westwood J, Geraghty R, Jones P, et al. Rezūm: a new transurethral water vapour therapy for benign prostatic hyperplasia. *Ther Adv Urol*. 2018 Nov;10(11):327–333
8. McVary KT, Gittelman MC, Goldberg KA, et al. 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. *J Urol*. 2021 Sep;206(3):715-24
9. NICE Guidance on Rezūm <https://www.nice.org.uk/guidance/mtg49/chapter/1-Recommendations>
10. Dixon C, Cedano ER, Pacik D, Vit V, Varga G, Wagrell L, Tornblom M, Mynderse L, Larson T. Efficacy and Safety of Rezūm System Water Vapor Treatment for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *Urology*. 2015 Nov;86(5):1042-7. doi: 10.1016/j.urology.2015.05.046. Epub 2015 Jul 26. PMID: 26216644
11. James C Ulchaker, Melissa S Martinson, Cost-effectiveness analysis of six therapies for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia, *ClinicoEconomics and Outcomes Research* 2018:10 29–43
12. Blissett *et al*. 2022 Transurethral water vapor therapy for treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: a cost-minimization and budget impact analysis from an Italian healthcare perspective <https://www.minervamedica.it/it/getfreepdf/YU5zODNWRXgxmJlMjjiS0pLMIFORm12b0RRbk1TcU5kV0ZHa2NOUzcydTNCWnlzekhLcDF2UINDbnc4eGtVdA%253D%253D/R19Y9999N00A22122301.pdf>
13. Bausch K, Zahiti L, Schruft M, Wetterauer C, Halbeisen FS, Ebbing J, Seifert HH, Water vapor thermal therapy of lower urinary tract symptoms due to benign prostatic obstruction: efficacy and safety analysis of a real-world cohort of 211 patients, *World Journal of Urology*, 24 January 2023
14. Danielle Whiting, Mohamed Noureldin, Yehia Abdelmotagly, Maximilian J. Johnston, James Brittain, Govindaraj Rajkumar, Amr Emara, Richard Hindley, Real-world Early Outcomes and Retreatment Rates Following Water Vapour Ablative Therapy for Symptomatic Benign Prostatic Hyperplasia, *EUROPEAN UROLOGY OPEN SCIENCE* 39 (2022) 72 – 78
15. Cindolo L, Campobasso D, Conti E, Uricchio F, Franzoso F, Maruzzi D, Viola L, Varvello F, Balsamo R, Ferrari G, Morselli S, Siena G, Do Patients Treated with Water Vapor Therapy and Meeting Randomized Clinical Trial Criteria Have Better Urinary and Sexual Outcomes Than an Unselected Cohort?, *JOURNAL OF ENDOUROLOGY*, Volume 37, Number 3, March 2023
16. Deutsche Gesellschaft für Urologie. V. (Hrsg.): S2e-Leitlinie Diagnostik und Therapie des Benignen Prostata-Syndroms (BPS), Langversion 5.0, 2023, AWMF Registernummer: 043-034, https://register.awmf.org/assets/guidelines/043-034_S2e_Diagnostik_Therapie_benignes_Prostata-syndrom_2023-04.pdf
17. Lerner LB, McVary KT, Barry MJ, Bixler BR, Dahm P, Das AK, Gandhi MC, Kaplan SA, Kohler TS, Martin L, Parsons JK, Roehrborn CG, Stoffel JT, Welliver C, Wilt TJ. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART II-Surgical Evaluation and Treatment. *J Urol*. 2021 Oct;206(4):818-826. doi: 10.1097/JU.0000000000002184. Epub 2021 Aug 13. Erratum in: *J Urol*. 2022 Mar;207(3):743. Erratum in: *J Urol*. 2022 Oct;208(4):939. PMID: 34384236

For more information about BPH and Rezūm Water Vapour Therapy,
visit myprostateinfo.co.uk

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