

## Rezūm™ Water Vapor Therapy | Media Fact Sheet

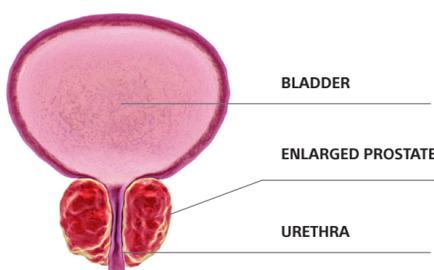
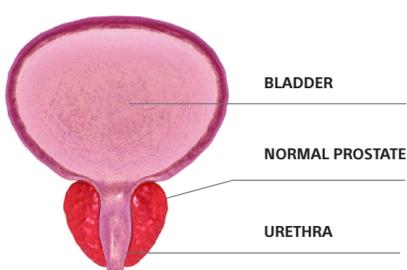
Rezūm

### About Benign Prostatic Hyperplasia (BPH)

Commonly known as an “enlarged prostate”

A condition in which the prostate becomes enlarged and obstructs the flow of urine<sup>1</sup>

More common in older people: affects about 50% of men by age 60 and up to 90% of men by age 85<sup>\*2</sup>



### Symptoms:<sup>1</sup>



Weak, interrupted urine stream



Difficulty starting and stopping urination



Frequent or urgent need to urinate



Inability to completely empty the bladder

### Common Treatment Options:



Behavioral modifications, such as drinking less caffeine, to avoid worsening symptoms<sup>3</sup>

**\*\*Potential dangers of behavioral modifications:** Untreated BPH can lead to complications including urinary tract infections, kidney or bladder stones and kidney damage<sup>4</sup>



Medication to manage symptoms<sup>5</sup>

**\*\*Potential side effects:** Dizziness, erectile dysfunction, lowered sex drive, retrograde ejaculation (a condition where semen goes into the bladder)<sup>5,6</sup>



Surgery to remove tissue blocking the urethra or to widen the urethra<sup>5</sup>

**\*\*Potential side effects:** Difficulty emptying the bladder, urinary leakage, urgency to urinate, discomfort during urination, erectile dysfunction, bleeding<sup>7</sup>



Minimally invasive treatments to remove tissue blocking the urethra or lift and hold the tissue out of the way<sup>5</sup>

**\*\*Potential side effects:** Painful or frequent urination, blood in the urine, and urgent need to urinate<sup>5,8</sup>

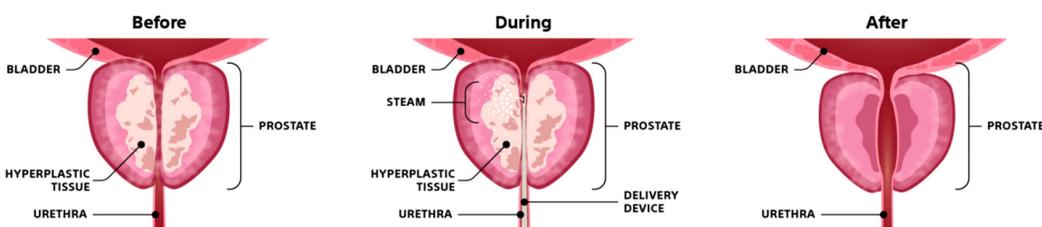
**\*\*This is not a complete list of side effects associated with each treatment. You should speak with your doctor about the risks associated with each treatment option.**

### What is Rezūm™ Water Vapor Therapy?<sup>8</sup>

- A minimally invasive procedure to treat BPH, not just the symptoms
- Uses the energy stored in water vapor to reduce the size of the prostate and provide lasting relief, while preserving sexual and urinary functions

### How Does Rezūm Therapy Work?<sup>8</sup>

- Water vapor is released into the prostate and targets excess tissue surrounding the urethra
- Energy from the water vapor 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 is the Procedure Performed?<sup>9</sup>

- In a doctor’s office, clinic or other outpatient setting
- No general anesthesia required

### How Soon Can I Return to Regular Activities Following the Procedure?<sup>9</sup>

- Most patients return to regular activities within a few days after treatment and see symptom improvement within two weeks
- Each experience depends on the individual patient’s clinical situation healing response, and should be discussed with a doctor

### Is Rezūm Therapy Covered by Insurance?<sup>10</sup>

- Rezūm Therapy is considered a covered benefit by Medicare and most private insurance – It is the responsibility of the provider to confirm specific payer coverage and reimbursement

### What Research Has Been Done?<sup>11</sup>

- Extensive clinical research has confirmed the safety and efficacy of the treatment and has demonstrated:
  - Sustained symptom relief, and a low surgical retreatment rate of 4.4% out to five years, without impacting sexual function
  - The ability to treat prostates with hyperplasia of the central zone, lateral lobe and/or median lobe

### How Many Patients Have Been Treated With Rezūm Therapy?

- More than 70,000 patients to date and growing in the United States<sup>\*\*12</sup>
  - Cleared by the FDA in 2015
  - Included in the American Urological Association’s (AUA) BPH treatment guidelines
  - Only minimally invasive BPH treatment recommended by the AUA for prostate median lobe obstructions<sup>13</sup>

### What Are the Potential Risks?

Potential risks associated with Rezūm Water Vapor Therapy include but are not limited to painful or frequent urination, blood in the urine or semen, urgency in ejaculation, urinary tract infection (UTI), inability to urinate or completely empty the bladder, and urgent need to urinate. Visit rezum.com for a complete list of risks, and talk to your doctor about the benefits and risks before moving forward with any treatment option.<sup>12</sup>

\*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>

\*\*Number of patients based on units shipped to 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. UpToDate. Patient education: Benign prostatic hyperplasia (BPH) (Beyond the Basics). Available at: [https://www.uptodate.com/contents/benign-prostatic-hyperplasia-bph-beyond-the-basics?search=%20benign-prostatic-hyperplasia-bph-beyond-the-basics&source=search\\_result&selectedTitle=1-150&usage\\_type=default&display\\_rank=1](https://www.uptodate.com/contents/benign-prostatic-hyperplasia-bph-beyond-the-basics?search=%20benign-prostatic-hyperplasia-bph-beyond-the-basics&source=search_result&selectedTitle=1-150&usage_type=default&display_rank=1). Accessed December 2021.
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. WebMD. Managing Sexual Concerns if You Have BPH. Available at: <https://www.webmd.com/men/prostate-enlargement-bph/features/managing-sexual-concerns-if-you-have-bph>. Accessed March 2022.
7. Medical News Today. What happens if you have prostate surgery? Available at: <https://www.medicalnewstoday.com/articles/321190>. Accessed December 2021.
8. Westwood J, Geraghty R, Jones P, et al. Rezum: a new transurethral water vapour therapy for benign prostatic hyperplasia. *Ther Adv Urol*. 2018 Nov;10(11):327-333.
9. McVary KT, Gange SN, Gittelman MC, et al. Minimally invasive prostate convective water vapor energy ablation: A multicenter, randomized, controlled study of Rezūm water vapor therapy for treatment of moderate-to-severe lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol*. 2016 May;195(5):1529-38.
10. Medicare Coverage Database. Billing and Coding: Rezūm® System for Benign Prostatic. Available at: <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56083>. Accessed March 2022.
11. 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.
12. Data on file with Boston Scientific.
13. Lerner LB, McVary KT, Barry MJ, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline 2021. *J Urol*. 2021 Oct;206:806-26.

Content of this brochure is for Information Purposes only and does not constitute medical advice. Boston Scientific strongly recommends that you consult with your physician on all matters pertaining to your health or to address any questions.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

All images are the property of Boston Scientific. All trademarks are the property of their respective owners.

©2022 Boston Scientific Corporation or its affiliates. All rights reserved. URO-1251804-AA MAY 2022

For more information about BPH and Rezūm Water Vapor Therapy, visit [rezum.com](https://rezum.com)