

## **Rezūm™ Water Vapor Therapy Media Fact Sheet**

### **What is benign prostatic hyperplasia?**

Benign prostatic hyperplasia (BPH) is a condition in which a man's prostate becomes enlarged and obstructs the flow of urine. It causes frustrating symptoms, including frequent urination; weak, interrupted urine stream; difficulty starting and stopping urination; feeling a sudden urge to urinate; inability to urinate when needed; and lack of control over urination.

### **How prevalent is it?**

BPH is more common in older men, affecting about 50% of men by age 60, and up to 90% of men by age 85.<sup>1</sup>

### **What is Rezūm™ Water Vapor Therapy?**

- Rezūm Therapy is an in-office treatment for men looking to treat BPH, not just the symptoms. It uses natural water vapor to reduce the size of the prostate and provide lasting symptom relief from BPH symptoms without invasive surgery or the potential side effects of prescription drugs.<sup>2</sup>
- Rezūm Therapy was cleared by the FDA in 2015 and is currently being used in many leading urology practices throughout the United States and around the world. To date, more than 55,000 patients have been successfully treated with Rezūm Therapy.<sup>3</sup>

### **Is Rezūm Therapy covered by insurance?**

- Rezūm Therapy is considered a covered benefit by Medicare and most private insurance.\* Patients should verify their benefits with their insurance company in advance of the scheduled procedure.

### **How does Rezūm Therapy work? What is the procedure like?**

- During the Rezūm Therapy, natural water vapor is released throughout the targeted prostate tissue. When the steam contacts the tissue and turns back into water, all the stored energy is released, killing the excess prostate cells. Over time, the body's natural healing response absorbs the dead cells and shrinks the prostate. With the extra tissue removed, the urethra opens, relieving BPH symptoms.
- Without the need of a permanent implant, this natural treatment option removes the excess BPH tissue and thereby treats the disease and not just the symptoms.
- Rezūm Therapy can be performed in a doctor's office, clinic or other outpatient setting. It can be performed under oral sedation or local anesthesia.<sup>4</sup> There are options available for maximizing comfort during the procedure that will be determined by the physician.

## What research has been done?

- Rezūm Therapy has undergone extensive clinical trials to evaluate the safety and efficacy of the treatment.<sup>2</sup> It is now included in the American Urological Association's BPH treatment guidelines and has four-year follow-up data showing its ability to treat prostates with hyperplasia of the central zone, lateral lobe and/or median lobe.<sup>4</sup>
- Clinical studies support the following:
  - Rezūm Therapy relieves BPH symptoms safely and effectively, eliminating the need for BPH medications while also preserving sexual function.<sup>2,4</sup>
  - Most men experience symptom relief as soon as two weeks after treatment with Rezūm Therapy, and maximum benefit may occur within three months. As with any procedure, patient responses can vary.<sup>4\*\*</sup>
  - Following treatment with Rezūm Therapy, most men return to regular activities within a few days.<sup>4\*\*</sup> The patient's physician will make personal recommendations on resuming activity.
  - Over the course of four years, sustained symptom improvement and a surgical retreatment rate of just 4.4%. Studies are ongoing to determine longer term patient outcomes.<sup>2</sup>

## Are there any side effects?

- All treatments have inherent and associated risks. The Rezūm System is intended to relieve symptoms and obstructions, and reduce prostate tissue associated with BPH. It is indicated for men  $\geq 50$  years of age with a prostate volume  $30\text{cm}^3 \leq 80\text{cm}^3$ . The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe. Potential risks include but are not limited to painful urination (dysuria), blood in the urine (hematuria), blood in the semen (hematospermia), decrease in ejaculatory volume, suspected urinary tract infection (UTI), and urinary frequency, retention or urgency. Patients should talk with their doctor about benefits and risks before moving forward with any treatment option.

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

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<sup>1</sup> What is BPH? Urology Care Foundation website. [https://www.urologyhealth.org/urologic-conditions/benign-prostatic-hyperplasia-\(bph\)](https://www.urologyhealth.org/urologic-conditions/benign-prostatic-hyperplasia-(bph)).

<sup>2</sup> McVary KT, Rogers T, Roehrborn CG. Rezūm water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study. *Urology*. 2019 Apr;126:171-9.

<sup>3</sup> Data on file at Boston Scientific.

<sup>4</sup> McVary KT, Gange SN, Gittelman MC, et al. Minimally invasive prostate convective water vapor energy ablation: A multicenter, randomized, controlled study for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol*. 2016 May;195(5):1529-38.

\*It is the responsibility of the patient to contact their insurance provider for specific coverage information.

\*\*Dependent on individual clinical situation and healing response.

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