

## Benign Prostatic Hyperplasia (BPH) + Rezūm™ Water Vapor Therapy Key Messages and Q&A

### Key Messages

- Benign prostatic hyperplasia (BPH) is a condition in which a man's prostate enlarges and squeezes the urethra, causing frustrating symptoms such as frequent or urgent urination, a weak or interrupted urine stream, and the need to get up several times a night to urinate.
- Treatment options for BPH range from behavior modification to medications, minimally invasive procedures and surgery. Medications may not work for everyone, and may have undesirable side effects such as dizziness, sexual dysfunction.<sup>1</sup> Some minimally invasive procedures may only treat BPH symptoms, not the underlying condition.
- Rezūm™ Water Vapor Therapy is a minimally invasive in-office procedure for men looking to treat their BPH, not just the symptoms. It uses natural water vapor to reduce the size of the prostate and provide lasting symptom relief from BPH without invasive surgery or the potential side effects of prescription drugs.<sup>2</sup>
- Clinical studies support that Rezūm Therapy relieves BPH symptoms safely and effectively, eliminating the need for BPH medications while also preserving sexual function.<sup>2,3</sup> It helps most men see symptom improvement within a few weeks and return to regular activities within a few days after treatment.<sup>3\*</sup>
- Men with BPH who are dissatisfied with their current treatment, including prescription drugs, should consider Rezūm Therapy — a minimally invasive in-office procedure that treats the underlying condition, not just the symptoms. For more information about BPH and Rezūm Water Vapor Therapy, visit [Rezum.com](http://Rezum.com). Patients should talk with their doctor before moving forward with any treatment option.

### Frequently Asked Questions

#### 1) **What is the cause of BPH?**

As many men get older, their prostate gland enlarges, which may squeeze the urethra and obstruct the flow of urine. Other risk factors for BPH include family history, obesity, heart disease and diabetes.<sup>1</sup>

#### 2) **How is BPH treated?**

A wide variety of treatment options are available for BPH, including watchful waiting, behavioral modification, medication, minimally invasive therapies and surgery. Medication is the most common first-line treatment for mild to moderate symptoms of enlarged prostate. Minimally invasive or surgical treatment might be recommended if symptoms are moderate to severe, medication doesn't relieve the symptoms, or the patient has other health issues.

#### 3) **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 without invasive surgery or the potential side effects of prescription drugs.<sup>2</sup>

Clinical studies support that Rezūm Therapy relieves BPH symptoms safely and effectively, eliminating the need

for BPH medications while also preserving sexual function.<sup>3</sup> It helps most men see symptom improvement within a few weeks and return to regular activities within a few days after treatment.<sup>3\*</sup>

**4) Who may benefit from Rezūm Water Vapor Therapy?**

Clinical studies show that Rezūm Therapy provides significant lasting, improvement in symptoms and quality of life.<sup>2</sup> It may be an option for those who have given up on watchful waiting and lifestyle changes, men who are dissatisfied with, have stopped or don't want to start taking BPH medications, and men not interested in other minimally invasive or surgical BPH procedures. Rezūm Therapy removes excess prostate tissue with water vapor, thereby treating the disease while also relieving symptoms and preserving sexual function.<sup>3</sup>

**5) Why is Rezūm Water Vapor Therapy an important option?**

For years, the primary options for treating BPH were through medications or invasive surgery. Rezūm Therapy is a natural, in-office therapy option for men who do not want to take medication or are dissatisfied with medication symptom relief and want to avoid invasive surgery or implants to treat their BPH.

Market research indicates that preserving sexual function is a priority for men when it comes to BPH treatments.<sup>4</sup> Clinical studies show Rezūm Therapy treats the cause of BPH symptoms while preserving sexual function.<sup>2</sup>

**6) How is the Rezūm Water Vapor Therapy procedure performed? Is the patient awake during the procedure?**

The procedure takes place during one short office visit and does not require general anesthesia.<sup>3</sup> During each 9-second treatment, 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, reducing BPH symptoms. Depending on the size of the prostate, the number of water vapor treatments vary.

**7) Where is the Rezūm Water Vapor Therapy procedure performed?**

Rezūm Therapy can be performed in a doctor's office, clinic or other outpatient setting.

**8) Is the procedure painful?**

Rezūm Therapy can be performed under oral sedation or local anesthesia and doesn't require general anesthesia.<sup>3</sup> There are options available for maximizing comfort during the procedure that will be determined by the physician.

**9) Is Rezūm Water Vapor 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.

**10) How quickly do patients experience symptom relief?**

Clinical studies show that most men experience symptom relief as soon as two weeks after treatment with Rezūm Therapy, and maximum benefit may occur within three months.<sup>1</sup> As with any procedure, patient responses can vary.

**11) How soon can patients return to regular activities?**

Clinical studies show that following treatment with Rezūm Therapy, most men return to regular activities within a few days.<sup>3\*</sup> The patient's physician will make personal recommendations on resuming activity.

**12) How long do improvements last?**

Current clinical studies demonstrate that, following treatment with Rezūm Therapy, symptom improvement is sustained through four years, and studies are ongoing to determine longer-term patient outcomes.<sup>2</sup>

**13) Can Rezūm Water Vapor Therapy cause erectile dysfunction, or ED?**

Clinical studies have demonstrated that Rezūm Therapy preserves erectile and urinary functions. There were no

reports of erectile dysfunction (ED) as a result of treatment with Rezūm Therapy.<sup>3</sup> However, there is a possibility that an underlying condition may surface following treatment. Each patient should speak with a physician about their individual health situation.

**14) Can Rezūm Water Vapor Therapy cause urinary incontinence?**

In Rezūm Therapy's clinical studies, there were no reports of post-procedure urinary incontinence as a result of treatment with Rezūm Therapy.<sup>3</sup>

**15) What are the risks of Rezūm Water Vapor Therapy?**

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.

**16) Has Rezūm Water Vapor Therapy been clinically tested?**

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>3</sup> Over the four years, the trial showed a surgical retreatment rate of only 4.4% and no new adverse events noted between years three and four.<sup>2</sup>

**17) How long has Rezūm Water Vapor Therapy been available?**

Rezūm Therapy was cleared by the FDA in 2015 and is currently being used in many leading urology practices. To date, more than 55,000 patients in the United States have been successfully treated with Rezūm Therapy.<sup>5</sup>

**18) Can patients be treated with Rezūm Water Vapor Therapy while on their current BPH medication?**

During the Rezūm Therapy pivotal study, all patients discontinued their BPH medication to ensure the efficacy seen was from Rezūm Therapy alone. As such, there has been no randomized clinical data collected on using Rezūm Therapy at the same time as BPH medications.<sup>2</sup>

**19) Can post-radiation patients be treated safely with Rezūm Water Vapor Therapy?**

Post-radiation patients were not included in the Rezūm Therapy pivotal study. As such, there has been no data collected for this subset of patients.

**20) How is Rezūm Water Vapor Therapy different than the UroLift™ System?**

Rezūm Therapy is an in-office treatment for men looking to treat their BPH, not just the symptoms. It uses natural water vapor to reduce the size of the prostate and provide lasting symptom relief from BPH without invasive surgery, reliance on implants or the potential side effects of prescription drugs.<sup>2,3</sup> Surgical retreatment rates for Rezūm Therapy are just 4.4% at four years.<sup>2</sup>

The UroLift System involves permanent implants that remain inside the body and treat the symptoms of BPH, not the underlying disease. Results from the L.I.F.T. study show surgical retreatment rates for the UroLift System are 13.6% at four years.<sup>6</sup>

**21) How is Rezūm Water Vapor Therapy different than laser therapy?**

Laser therapy is an important option for patients who may not be appropriate candidates for Rezūm Therapy. Laser therapy may involve a short hospital stay and has been associated with shorter catheterization time, less bleeding and a faster recovery than traditional surgery.<sup>7-11</sup> The individual's medical history, health condition and other factors will influence treatment decisions.

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- <sup>1</sup> Roger K and Gilling P. Fast Facts: Benign Prostatic Hyperplasia, 7th edition. Health Press. 2011.
- <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> McVary KT, Gange SN, Gittelman MC et al. Minimally invasive prostate convective water vapor energy (WAVE) 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.
- <sup>4</sup> Boston Scientific Market Research: Understanding Today's BPH Patient, August 30, 2018.
- <sup>5</sup> Data on file at Boston Scientific.
- <sup>6</sup> Roehrborn CG, Barking J, Gange SM, et al. Five-year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. *Can J Urol*. 2017 Jun;24(3):8802-13.
- <sup>7</sup> Bachmann A, Tubaro A, Barber N, et al. 180-W XPS GreenLight laser vaporization versus transurethral resection of the prostate for the treatment of benign prostatic obstruction: 6-month safety and efficacy results of the European multi-centre randomized trial – The GOLIATH Study. *Eur Urol*. 2014 May;65(5):931-42.
- <sup>8</sup> Lukacs B, Loeffler J, Bruyère F, et al. Photoselective vaporization of the prostate with GreenLight 120-W laser compared with monopolar transurethral resection of the prostate: A multicenter randomized controlled trial. *Eur Urol*. 2012;61(6):1165-73.
- <sup>9</sup> Capitán C, Blázquez C, Martin MD, et al. GreenLight HPS 120-W laser vaporization versus transurethral resection of the prostate for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia: A randomized clinical trial with 2-year follow-up. *Eur Urol*. 2011 Oct;60(4):734-9.
- <sup>10</sup> Al-Ansari A, Younes N, Sampige VP, et al. GreenLight HPS 120-W laser vaporization versus transurethral resection of the prostate for treatment of benign prostatic hyperplasia: a randomized clinical trial with midterm follow-up. *Eur Urol*. 2010 Sep;58(3):349-55.
- <sup>11</sup> Bouchier-Hayes DM, Van Appledorn S, Bugeja P, et al. A randomized trial of photoselective vaporization of the prostate using the 80-W potassium titanyl-phosphate laser vs transurethral prostatectomy, with a 1-year follow-up. *BJU Int*. 2010 Apr;105(7):964-9.

\*Dependent on individual clinical situation and healing response.

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

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

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