

Ordering Number	Product or Service	Description	Units
D2201-003	Rezūm™ Delivery Device	<ul style="list-style-type: none"> • Sterile Delivery Device with cable and tubing • Sterile Syringe • Sterile Spike Adaptor • 50 ml Sterile Water Vial 	1
G2200-0031	Rezūm Generator	<ul style="list-style-type: none"> • Portable Generator • Power Cord 	1

Other materials that are typically required for the Rezūm System procedure include, but are not limited to, the following items:

- Saline supply at room temperature (1L recommended)
- 4mm, 30 degree, 30cm Storz or Richard-Wolf rigid cystoscope lens
- Light source and cord
- 240V socket

Please see the Rezūm System Instructions for Use for the full list of materials.

* Dependent on individual clinical situation and healing response.

1 Roehrborn CG, Gange SN, Gittelman MC, et al. Convective water vapor energy (WAVE) ablation therapy: durable two-year results and prospective blinded crossover study for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. J Urol 2017; 197: 1507.

2 McVary KT, Gange SN, Gittelman MC, et al. Minimally invasive prostate convective water vapor energy (WAVE) ablation: A multicenter, randomized, controlled study for treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Urol 2016; 195: 1529.

3 McVary KT, Rogers T, Roehrborn CG. REZUM™ water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. This material not intended for use in France.

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Rezūm™

Water Vapor Therapy



Rezūm™ Water Vapor Therapy

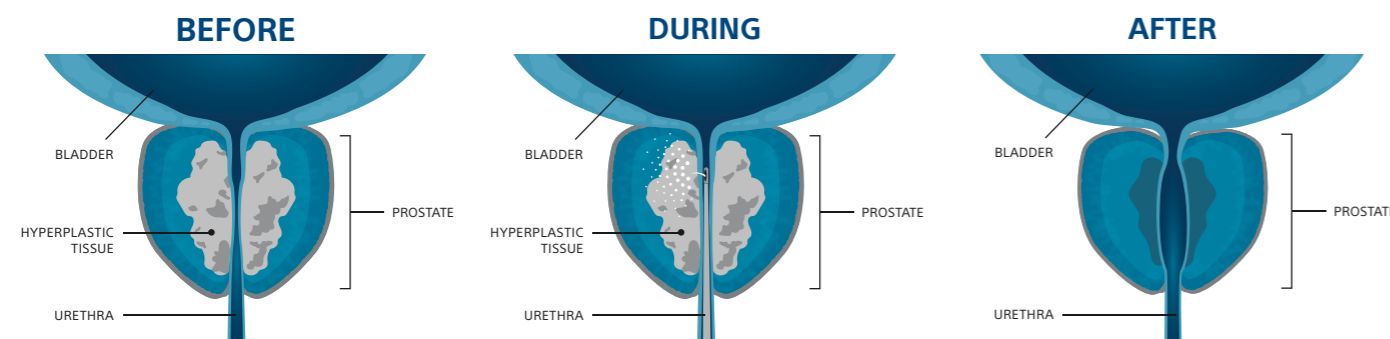
Powered by convective water vapor energy, the Rezūm™ System delivers targeted, controlled doses of the stored thermal energy in water vapor directly to the region of the prostate gland with the obstructive tissue causing the lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).

Each 9-second treatment uses 0.42ml of heated sterile water vapor which rapidly and uniformly disperses through the tissue interstices. The condensation of water vapor releases stored thermal energy. Cell membranes are denatured, thereby causing immediate cell death, the vasculature is closed, and there is denervation of the alpha-adrenergic nerves within the treatment zone providing you with a uniform, predictable treatment.

Over time, this ablated tissue is reabsorbed by the body's natural healing response, reducing the volume of tissue allowing the urethra to open relieving LUTS.



Model G2200
Rezūm Generator



The appropriate Rezūm Therapy patients are the following:

- Men who have chosen not to take BPH medications, are taking them but are dissatisfied, or have discontinued them
- Men who are not receptive to surgical BPH procedures
- Men who are unable to have general anesthesia

The Rezūm Therapy procedure provides the following benefits to men suffering from BPH:

- Alternative to BPH medications¹
- Studies support Rezūm relieves symptoms safely and effectively²
- Most patients see symptom improvement within two weeks²
- Does not require general anesthesia²
- Preserves erectile and urinary functions²
- Ability to return to regular activities within a few days^{2*}

Indications

The Rezūm System is indicated to relieve symptoms, obstructions and reduce prostate tissue associated with BPH in men with:

- Prostates ≥ 30 cm³
- Prostates with hyperplasia of the central zone and/or a median lobe

Contraindications

The use of the Rezūm System is contraindicated for patients:

- With a urinary sphincter implant
- Who have a penile prosthesis

Key Efficacy Results

IPSS outcomes are consistent and durable across all studies.

Rezūm Therapy demonstrated durable outcomes at 4 years with an IPSS improvement of 10.1 (46.7%) and flow rate improvement of +4.2 ml/sec.³