



**For more information, contact:**

Michael Kujak  
NxThera, Inc.  
(763) 515-2901  
[mkujak@nxthera.com](mailto:mkujak@nxthera.com)

**NxThera Announces *In Press* Publication of  
Rezūm II 2-Year Clinical Study Data in *The Journal of Urology***

*Two-Year Data Demonstrates Durable Outcomes; Convective Thermal Therapy with Rezūm System Significantly Improves LUTS Symptoms and Preserves Sexual Function in BPH Patients*

Maple Grove, Minn.,--December 21, 2016 — [NxThera, Inc.](http://www.nxthera.com), a medical device company pioneering the application of its convective radiofrequency water vapor thermal therapy platform technology to treat endourological conditions, today announced the *in press* publication of the [2-year data](#) from the Rezūm II pivotal study in *The Journal of Urology*. The Rezūm II clinical study enrolled 197 patients in this randomized, controlled trial across 15 centers in the United States and documents the durable symptom reduction and preserved sexual function in patients who underwent the treatment with Rezūm. Of the 61 patients in the original control arm, 53 elected and qualified for crossover active treatment.

The Rezūm System convectively and uniformly disperses the thermal energy created with RF current through the tissue interstices to disrupt the tissue cell membranes to effect tissue cell death and necrosis. The body's immune system then simply resorbs the dead tissue cells, thereby removing the obstructive prostate tissue to successfully treat Lower Urinary Tract Symptoms (LUTS) secondary to Benign Prostatic Hyperplasia (BPH).

“One of the primary factors in considering BPH therapies for our patients is durability,” said Dr. Claus Roehrborn, co-principal investigator and Professor and Chair, Division of Urology at University of Texas Southwestern Medical Center. “This important data demonstrates that BPH treatments with the Rezūm System provides clinically significant symptom relief out to 2 years while preserving sexual function. Given its strong safety profile and sustained outcomes, Rezūm warrants consideration as a first-line therapeutic alternative to medical therapy for the treatment of BPH.”

Key published findings of the study include:

- Clinically significant and durable urinary symptom improvement as measured by the International Prostate Symptom Score (IPSS) through two years;
- Durable outcomes at 2 years with an IPSS improvement of -11.2 (-51%) and a flow rate improvement of +4.2 mL/sec
  - For patients with a baseline IPSS  $\geq 19$ ; mean IPSS improvement was -13.0 points at 2 years;

- Without exception, the seven individual IPSS domains, including urgency and nocturia, reflected the significant relief of symptoms over 2 years,  $p < 0.0001$ ;
- Overactive bladder bother and impact on quality of life improved significantly through 2 years,  $p < 0.0001$ ;
- ICS male incontinence scores improved significantly through 2 years,  $p < 0.0001$ ;
- At 1 year, IPSS of the crossover subjects, together with flow rate and quality of life measures were markedly improved after thermal therapy compared to their prior control procedure,  $p = 0.0024$  to  $p < 0.0001$ ;
- In a subset of crossover subjects with median lobe treatments, the mean IPSS decrease was -13.1 at 1 year;
- Preserved sexual function.

“We are excited about the sustained clinical and sexual health benefits out to two years for both clinicians and their patients,” said Bob Paulson, President & CEO of NxThera. “The sustained and compelling clinical results from our Rezūm II pivotal study demonstrate a minimally invasive treatment option that can be performed in a variety of clinical settings, including as an in-office procedure. We are committed to provide urologists with world-class clinical training and patient education to support them in their efforts to improve the lives of men suffering from BPH.”

### **About NxThera**

NxThera pioneered its convective radiofrequency water vapor thermal therapy platform technology to treat a variety of endourological conditions beginning with BPH. The Company is furthering the application of the technology platform through advanced research and development targeting the treatment of prostate cancer and kidney cancer. NxThera’s FDA cleared Rezūm System to treat BPH uses radiofrequency energy to create sterile water vapor, or steam, to convectively deliver targeted, precise thermal energy treatments in a simple procedure with minimal discomfort, and provide improvements in LUTS symptoms, urine flow and quality of life. Founded in 2008, NxThera is located in Maple Grove, Minnesota.