

Clinical Study Overview



Are Urinary Symptoms Interfering with Your Life? Do You Suffer from the Following?

- Frequent need to urinate during the day and at night
- Weak or slow urinary stream
- A sense that you cannot completely empty your bladder
- Difficulty or delay in starting urination
- Urgent feeling of needing to urinate
- A urinary stream that stops and starts

What is BPH?

If you suffer from these symptoms, you are not alone. Millions of men in the world have a condition called benign prostatic hyperplasia (BPH), or enlargement of the prostate. The prostate is a walnut-shaped gland that surrounds the urethra, the tube that drains urine from the body. As you age, the prostate grows and presses on the urethra causing bothersome urinary symptoms.

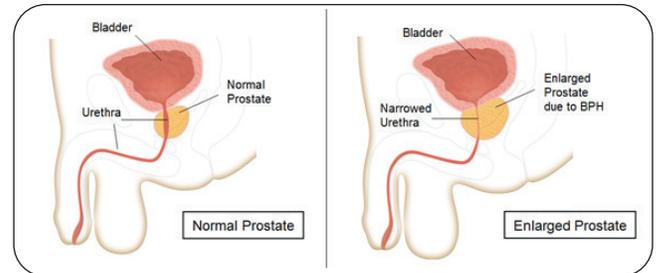


Figure 1. Normal Prostate and Enlarged Prostate due to BPH

What is the BREEZE Clinical Study?

If you are living with symptoms of BPH and are 45 years or older, you may qualify for the BREEZE Clinical Study. This study will evaluate a new treatment, the Zenflow Spring System, to relieve symptoms of an enlarged prostate. The *Spring*[®] Treatment is intended to provide a patient-friendly alternative to current treatment options that require piercing or cutting of prostate tissue. Participation in this study is free of charge for the patient and you will be reimbursed for your time.

What is the Spring[®] Treatment and How Does it Treat the Symptoms of BPH?

The Zenflow Spring is an investigational device designed to relieve the symptoms associated with an enlarged prostate. This minimally invasive treatment can be performed as an outpatient procedure and patients typically return home the same day. The Spring props open the narrowed urethra (Figure 2), improving urinary flow. Although the Spring is designed to be permanent, it can be removed at any time. Clinical studies to date have had promising outcomes with respect to patient symptom relief, urinary flow rates, and preservation of sexual function.

Additional Study Detail:

Your urologist is participating in a research study to evaluate the safety and effectiveness of the Zenflow Spring System in relieving the symptoms of obstructive BPH. This is a randomized clinical trial. If you choose to participate, you have a two in three chance of receiving the Spring Treatment. If you are in the the group not treated, you may be offered treatment with the Spring after you complete your three-month follow up. This is a research study and your participation is voluntary. The study device is “investigational”, which means that FDA has approved this device for research use only. Participation in the study lasts up to 5 years.

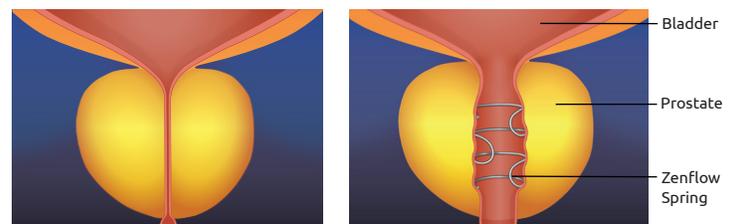


Figure 2. Zenflow Spring in the Prostatic Urethra (Pre-treatment and Post-treatment)

If you are interested, please ask your Urologist if you are a candidate for the BREEZE Clinical Study. You may also find additional information at www.zenflow.com.

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