

Urologix BPH Guide

A BPH GUIDEBOOK FOR MEN

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About BPH or Enlarged Prostate

BPH is a common condition in which prostate cells begin to increase in number. This growth, part of the aging process, compresses the urethra making it difficult or painful to urinate. Although it is not known exactly what causes an enlarged prostate, the majority of all men will experience it as they age. It is important to note that benign prostatic hyperplasia is not cancerous and is not life threatening, but it does affect your day-to-day life in inconvenient and unpleasant ways.



Millions of men worldwide experience moderate to severe symptoms of enlarged prostate - medically known as benign prostatic hyperplasia. In fact, more than half of men in their 50s and up to 90% of men in their 70s and 80s experience symptomatic BPH.^{1,2}

A normal prostate gland is about the size and shape of a walnut. Located just below the bladder, the prostate gland produces seminal fluid, the fluid that carries sperm. The prostate surrounds a portion of the urethra, which is the tube that carries urine out of your body.

Common BPH Symptoms

- Frequent and urgent need to urinate, getting up at night
- Difficulty starting urination
- Weak urine flow
- Stopping and starting of urine flow
- Feeling of being unable to completely empty the bladder
- Urinary incontinence (involuntary urination)
- Interference with sexual activity

1 National Institute of Diabetes and Digestive and Kidney Diseases. Prostate enlargement: benign prostatic hyperplasia. NIH Publication No. 07-3012. June 2006.

2 Carter HB. Prostate Disorders: The Johns Hopkins White Papers. Baltimore, MD: Johns Hopkins Medicine; 2013:1-25.

Recognizing the Signs of BPH

Some men with BPH have no symptoms. When symptoms (known as lower urinary tract symptoms, or LUTS) occur, they may range from mild and barely noticeable to severe and disruptive. The amount of prostate enlargement is not always related to the severity of the symptoms. Some men with only slight enlargement have severe symptoms, and some men with a great deal of enlargement have few symptoms.

Symptom severity may vary over time. Your symptoms may become worse during cold weather or as a result of physical or emotional stress. Some medicines can make your symptoms worse. These include over-the-counter cold medicines such as certain antihistamines, decongestants and nasal sprays and prescription medicines. Please discuss your current medications with your urologist.

The symptoms of BPH may involve problems emptying the bladder or other problems with bladder function.

Symptoms Related to Bladder Emptying

- Difficulty starting a urine stream (hesitancy and straining)
- Decreased strength of the urine stream (weak flow)
- Dribbling after urination
- Feeling that the bladder is not completely empty
- An urge to urinate again soon after urinating

Symptoms Related to Bladder Storage

- Waking at night to urinate (nocturia)
- Frequent urination
- A sudden, uncontrollable urge to urinate

It is important to note that these symptoms are not always related to prostate enlargement and may indicate a different condition such as urinary tract infections, prostatitis, prostate cancer, diabetes, heart failure, or neurologic diseases. If you are experiencing these symptoms, you should be assessed by a urologist.



BPH Symptom Score Test

The American Urological Association Symptom Score (AUASS) is a simple questionnaire. It contains seven questions intended to classify the severity of your enlarged prostate symptoms. Select the response for each question that most closely corresponds to your recent experiences.

Mark your response in the column which best describes your BPH symptoms. After you answer these seven questions, you may calculate your score. Contact your doctor for any questions that you have about the prostate test score results.

	<i>not at all</i>	<i>less than one time in five</i>	<i>less than half the time</i>	<i>about half the time</i>	<i>more than half the time</i>	<i>almost always</i>	<i>YOUR SCORE</i>
Over the past month, how often have you had the sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5	
Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	
Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5	
Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5	
Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0 times	1 time	2 times	3 times	4 times	5 or more times	
Total Score:							
0 to 7 = Mild Symptoms 8 to 19 = Moderate Symptoms 20 to 35 = Severe Symptoms							

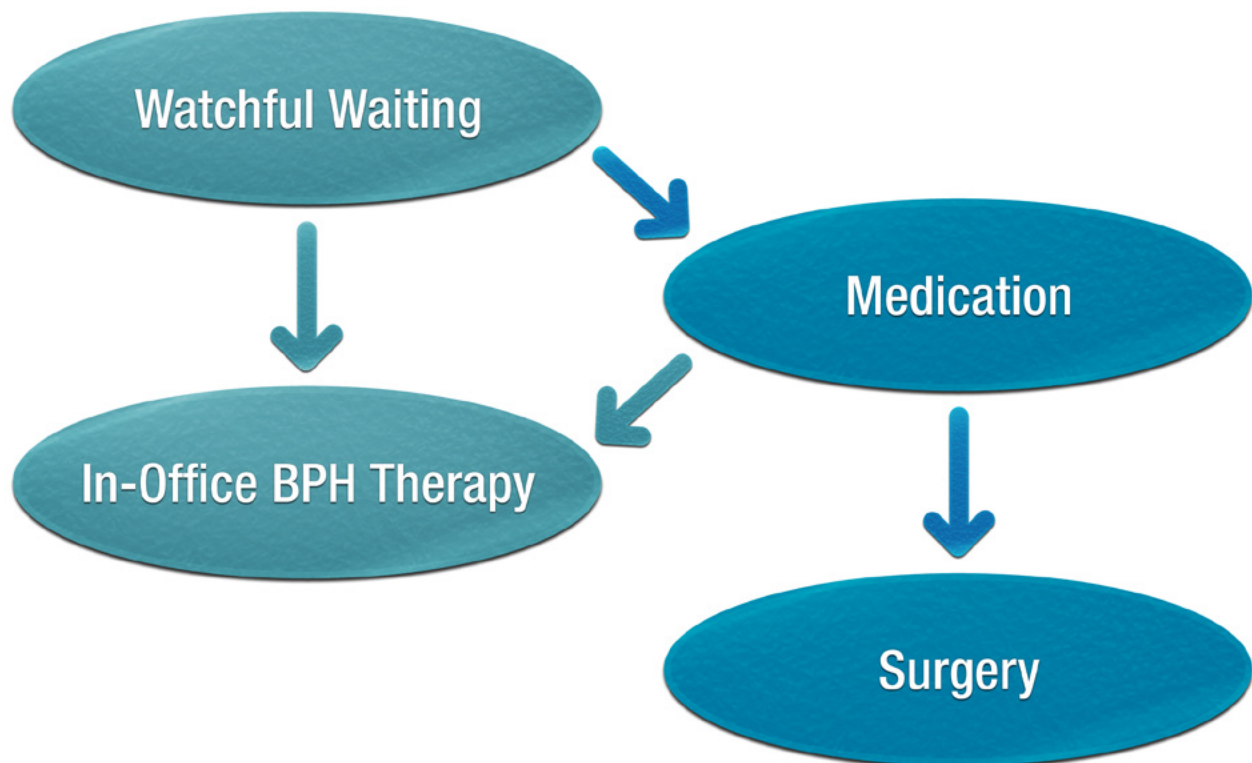
This test can also be taken online at www.urologix.com

Treatment Options

In the past, the primary focus of BPH treatment was to alleviate the bothersome lower urinary tract symptoms that result from prostatic enlargement. However, more recently, urologists have expanded their treatment goals to not just alleviate the symptoms of the disease, but also to slow the progression of the gland enlargement to prevent complications and further disease progression.

A variety of BPH treatment options are available ranging from pharmacologic treatments to surgery. It is important to talk to your doctor about the multiple treatments available and to fully understand all options, including the benefits and risks of each. This approach allows you and your physician to determine the safest and most effective treatment together, based on your individual medical condition and preferences.

Treatment Alternatives



Medication for BPH

Several different types of medications are available to treat the symptoms of enlarged prostate. Many physicians still prescribe medication as the primary treatment option for patients. However, drugs must be taken daily for the rest of your life, and have been shown to cause significant side effects. Also, medication is not effective for all men – as many as 48% do not show clinically significant symptom improvement.¹

Benefits

- Simple to use
- Does not require surgery or a hospital stay
- Fast symptom relief (alpha blockers)

Side Effects²

- Fatigue
- Headache
- Dizziness
- Impotence
- Chronic sinus congestion
- Low blood pressure
- Loss of sex drive

Limited Durability: While medications can provide initial relief from BPH symptoms, some men find that the drugs aren't effective or their effectiveness decreases over time and their symptoms return. In fact, over 50% of patients who start a regimen of medications for BPH discontinue the treatment within three years.³

Cost: The ongoing prescription costs of BPH medications can be an expensive and inconvenient burden. BPH drugs must be taken daily so those costs will be incurred for the rest of your life.

1 Wei, et al, High Rates for Continued BPH Medical Therapy among Non responders, AUA2010 Abstract 498

2 Flomax®, Tamsulosin hydrochloride, Patient Information About Flomax Capsules, Table 3, Treatment Emergent Adverse Events Occurring in ≥2% of Flomax (tamsulosin hydrochloride) capsules or placebo patients in the U.S. short-term placebo-controlled clinical studies, Page 14, July 17, 2006. *Flomax is a registered trademark of Astellas Pharma Inc.*

3 de la Rosette JJ, Kortman BB, Rossi C, et al. Long-term risk of re-treatment of patients using alpha-blockers for lower urinary tract symptoms. J Urol. 2002;167:1734–1739.

In-Office Therapy

In-Office BPH Therapies are non-surgical treatment options that are performed in the urologist's office, generally in less than one hour. These procedures do not require general anesthesia and allow the patient to return home after the treatment has been performed. Research has proven that Urologix's minimally invasive treatments are a safe, effective and durable option for BPH with a low rate of side effects.^{1,2} These therapies are ideal for patients who do not want to take daily medications for the rest of their lives, dislike the side effects and ongoing costs of medication or do not want the risks, side effects, or high costs of invasive surgery.

Benefits:

- Convenient treatment completed in your doctor's office in less than an hour
- Minimally invasive procedure which does not require general anesthesia
- Quick return to your normal activities often within just a few days of the treatment^{3,4}
- Significant improvement of urine flow and relief of urinary symptoms
- Clinically proven results which typically last more than five years^{1,2}
- Low rate of side effects^{5,6}
- Treatment which is covered by Medicare, as well as most private insurance companies

As with any medical procedure, there are potential risks and side effects that can occur with in-office medical procedures. We're committed to providing you with the information you need to make a well-informed decision about your treatment options. Although these problems rarely occur, we want you to know the facts. Please refer to the Cooled ThermoTherapy and Prostiva RF Therapy sections to learn about the benefits and risks specifically associated with these procedures.

If you're considering an in-office procedure, we encourage you to watch our online educational seminar at www.urologix.com. You'll learn about BPH, treatment options, and the benefits and risks of each of the treatment alternatives. You will also hear more about in-office BPH therapies such as Cooled ThermoTherapy and Prostiva RF Therapy.

1 Mynderse LA, Roehrborn CG, et al. Results of a 5-Year Multicenter Trial of a New Generation Cooled High Energy Transurethral Microwave Thermal Therapy Catheter for BPH. *Journal of Urology*. Vol. 185, 1804-1811, May 2011

2 Hill, B., et al Transurethral Needle Ablation vs TURP for the Treatment of Symptomatic BPH: 5 Year Results of a Prospective, Randomized, Multicenter Clinical Trial, *Journal of Urology* Vol 171, 2336-2340, June 2004

3 Ramsey, E., et. al., A Novel Transurethral Microwave Thermoablation System to Treat Benign Prostatic Hyperplasia? Results of a Prospective Multicenter Clinical Trial. *The Journal of Urology*, vol. 158, 112-119, July 1997.

4 Parrott EK. TUNA of the prostate in an office setting: nursing implications. *Urol Nurs*. 2003;23(1):33-40.

5 Data derived from the CTC Advance® Instructions for Use - 250348 (www.urologix.com)

6 Data derived from the Prostiva System User Guide 250369-001 (www.urologix.com)

Surgical Procedures

Surgery is generally considered when symptoms have not improved with another non-surgical BPH treatment. Surgical procedures typically remove large amounts of prostate tissue and are performed in a hospital or surgical center. These operations are done under anesthesia and most patients will spend 1-2 nights in the hospital. Typically, the patient can expect a 3-6 week recovery period where they need to maintain reduced physical activity.

The most commonly performed surgical option is a Transurethral Resection of the Prostate (TURP). This involves the insertion of a small rigid metal instrument through the urethra to cut away the enlarged prostate tissue. Another alternative surgical procedure uses a laser to ablate prostatic tissue in much the same manner. Surgery, specifically the TURP procedure, is typically successful in resolving the patient's BPH symptoms, but unfortunately involves a number of risks and side effects including a very high rate of retrograde ejaculation.

Benefits

- Effective for treatment of BPH symptoms
- Most common surgery used to remove part of an enlarged prostate
- Long track record of success

Perioperative and Short-Term Risks^{1,2}

- General anesthesia
- Bleeding
- Perforation of the prostate wall
- TUR syndrome
- Transfusions
- Urinary retention
- Urinary tract infection

Longer Term Complications^{1,2}

- Urethral stricture
- Bladder neck stenosis
- Retrograde ejaculation
- Erection problems
- Painful urination
- Incontinence



1 AUA Treatment Guidelines: BPH (2010)

2 Carter HB. Prostate Disorders: The Johns Hopkins White Papers. Baltimore, MD: Johns Hopkins Medicine; 2013:1-25.

Cooled ThermoTherapy™

Cooled ThermoTherapy is a safe, non-surgical 30-minute in-office therapy which provides long-term relief from BPH symptoms and urinary obstruction without the side effects and limited effectiveness of chronic medication or the risks and high costs associated with invasive surgery. This treatment option delivers targeted heat to reduce excess prostate tissue and includes an advanced urethral cooling system providing enhanced protection for the healthy urethra as well as increased patient comfort. The treatment typically results in significant improvement from bothersome symptoms such as persistent daytime urination as well as reduction in how often you have to get up at night to urinate.^{1,2}

Benefits

- Minimally invasive procedure which does not require general anesthesia
- Quick return to your normal activities often within just a few days of the treatment³
- Significant improvement of urine flow and relief of urinary symptoms as early as 6 weeks post treatment³
- Proven safe, effective and durable results¹
- Low rate of side effects⁴
- Treatment which is covered by Medicare, as well as most private insurance companies

Risks⁴

- Blood and/or clots in urine
- Painful or difficult urination
- Rectal irritation
- Temporary inability to control urination
- Brief inability to achieve or maintain an erection
- Inability to discharge semen during orgasm



The benefits and risks listed above do not represent a comprehensive list. For more complete information about the benefits and risks associated with Cooled ThermoTherapy, you should discuss this treatment option and your specific medical condition with your physician.

1 Mynderse LA, Roehrborn CG, et al. Results of a 5-Year Multicenter Trial of a New Generation Cooled High Energy Transurethral Microwave Thermal Therapy Catheter for BPH. *Journal of Urology*. Vol. 185, 1804-1811, May 2011

2 Eyre, S., Brafman, A. et al. Medication vs. Microwave: A comparison of Nocturia, Voiding Symptom Improvement and Cost. *Journal of Urology*; Vol. 187, No. 4S, Supplement, May 20, 2012

3 Ramsey, E., et. al., A Novel Transurethral Microwave Thermoablation System to Treat Benign Prostatic Hyperplasia? Results of a Prospective Multicenter Clinical Trial. *The Journal of Urology*, vol. 158, 112-119, July 1997.

4 Data derived from the CTC Advance® Instructions for Use - 250348 (www.urologix.com)

Prostiva[®] RF Therapy

Prostiva RF Therapy is a safe, effective, non-surgical in-office therapy which provides long-term relief from BPH symptoms and urinary obstruction without the side effects and high cost of chronic BPH medication or the risks and high costs associated with invasive surgery. This treatment option delivers precisely targeted low-level radio frequency (RF) energy that produces heat to destroy the excess prostate tissue. After the treatment, the prostate will heal, allowing the patient to urinate more normally. The treatment should result in a significant improvement from bothersome symptoms such as the frequent need to urinate during the day and night, a sense of urgency to urinate, and low urine flow.¹

Benefits

- Convenient treatment completed in your doctor's office in less than an hour
- Minimally invasive procedure which does not require general anesthesia
- Quick return to normal activities often within a few days of treatment²
- Progressive improvement of urinary symptoms often within 2-6 weeks following treatment³
- Proven safe, effective and durable results¹
- Low rate of side effects⁴
- Treatment which is covered by Medicare, as well as most private insurance companies



Risks⁴

- Obstruction (blockage)
- Bleeding
- Blood in urine
- Pain/discomfort
- Urgency to urinate
- Increase urinary frequency
- Urinary tract infection

The benefits and risks listed above do not represent a comprehensive list. For more complete information about the benefits and risks associated with Prostiva RF Therapy, you should discuss this treatment option and your specific medical condition with your physician.

1 Hill, B., et al Transurethral Needle Ablation vs TURP for the Treatment of Symptomatic BPH: 5 Year Results of a Prospective, Randomized, Multicenter Clinical Trial, Journal of Urology Vol 171, 2336-2340, June 2004

2 Parrott EK. TUNA of the prostate in an office setting: nursing implications. Urol Nurs. 2003;23(1):33-40.

3 Naslund, M., Transurethral Needle Ablation of the Prostate, Urology, 50 (2) 1997

4 Data derived from the Prostiva System User Guide 250369-001 (www.urologix.com)

About Urologix

Urologix, Inc. is the market leader for in-office BPH therapy. The company, based in Minneapolis, develops, manufactures, markets and distributes minimally invasive medical products for the treatment of obstruction and symptoms due to BPH. Urologix's Cooled ThermoTherapy produces targeted microwave energy combined with a unique cooling mechanism to protect healthy tissue and enhance patient comfort. The Prostiva RF Therapy System, delivers radio frequency energy directly into the prostate destroying prostate tissue, reducing constriction of the urethra, and thereby relieving BPH voiding symptoms. Both of these products provide safe, effective and lasting relief of the symptoms and obstruction due to BPH.

Contact Us

To contact the Urologix Customer Service Department, please use the following contact information:

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www.beatbph.com

You can find a urologist near you at www.urologix.com. 

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