

**Unsatisfied with your  
enlarged prostate medication?**

Individual depicted is a model used for illustrative purposes only



# You're not alone.

It has been estimated that there are over 3 million men in the United States who are taking medication for their enlarged prostates. In a 100 patient market research study, **21%** of patients reported that they were not satisfied with their enlarged prostate medication.<sup>1</sup>

## Primary reasons given include:

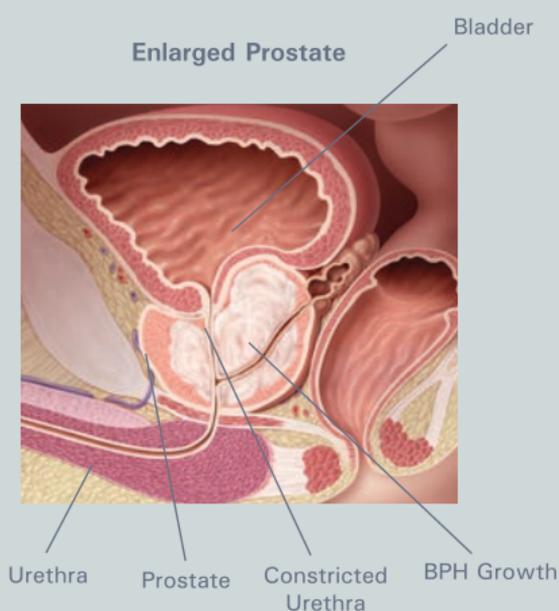
- General feelings that the medications were ineffective
- Frequently awakening at night to urinate
- Concerns regarding sexual side effects
- High cost of drugs
- The need to take drugs every day for the rest of one's life

“ Medications for BPH can be fairly expensive, and there can be side effects. For many patients, there is an additional consideration of interactions with other medications they have to take, not to mention the inconvenience of having to pick up medication and deal with insurance regularly. And they need to be taken for life: if you stop taking them, then your symptoms recur. ”

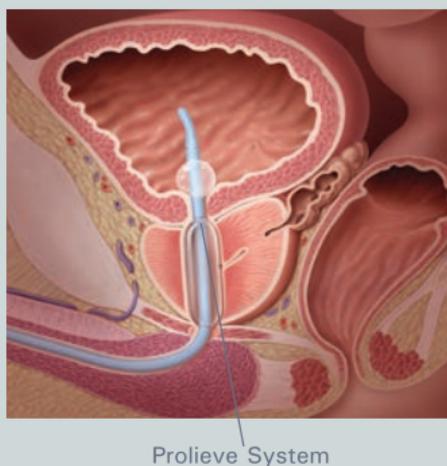
– Dr. Harvey Schonwald

## What is the Prolieve<sup>®</sup> System Treatment?

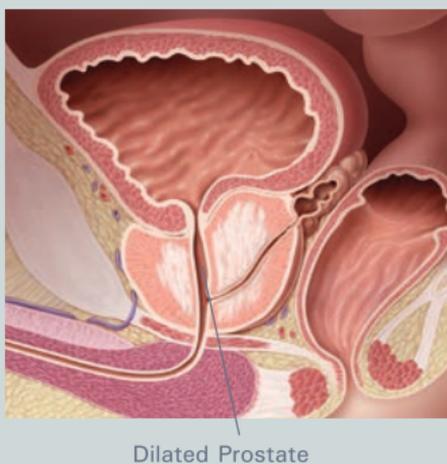
The Prolieve System is a treatment designed to address the symptoms of an enlarged prostate. It may be an alternative to drug therapy. It uses a technology that heats and dilates (opens) the prostate.



### Prolieve System Treatment



### After Prolieve System Treatment



## Potential Benefits of the Prolieve<sup>®</sup> System

- May alleviate the need to take daily medication
- Can be cost effective compared to medication
- In a clinical study demonstrated effective, symptom relief<sup>1</sup>
- Few side effects reported (see below)
- Generally, a 45-minute treatment performed at the physician's office
- Less invasive procedure
- FDA approved

## Potential Side Effects of the Prolieve System

Patients typically go home shortly after treatment. You should have someone drive you home after the procedure.

Some patients have experienced side effects following treatment.

The most common side effects are:

- Bladder spasm
- Pain
- Soreness
- Blood in the urine

These side effects generally clear within a few days.

Other side effects that have been reported:

- urinary urgency
- urinary retention

**Please see the back page of this brochure for a complete list of potential adverse effects, warnings, and contraindications. Ask your physician for the Prolieve System patient brochure for complete information on the treatment or visit [www.prolieve.com](http://www.prolieve.com) to request a complete patient information pack.**

The Prolieve System is not recommended for certain patients.

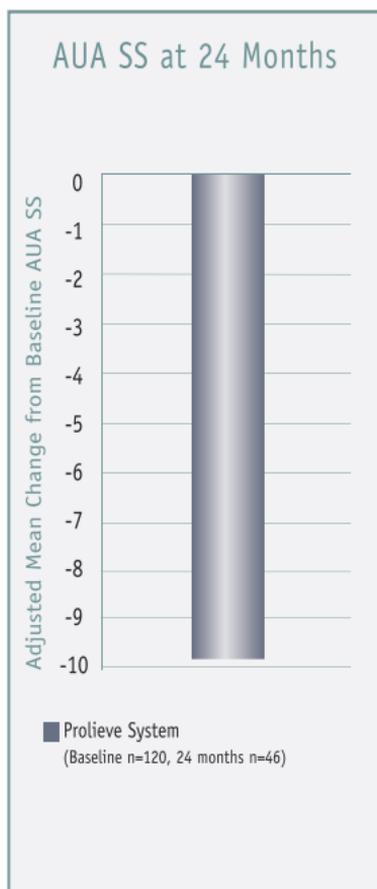
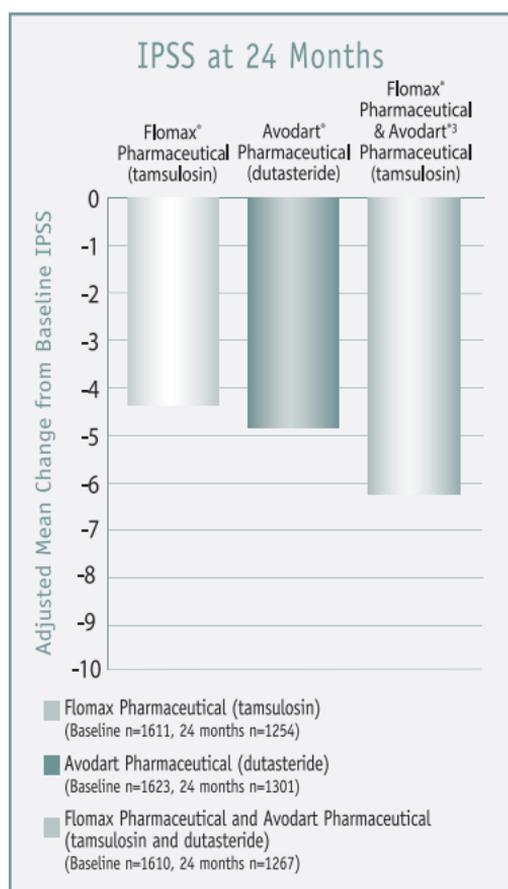
## The AUA Symptom Score

One way to evaluate the effectiveness of enlarged prostate therapy is by measuring a patient's American Urological Association (AUA) symptom score before and after therapy. A greater difference in scores generally indicates a more effective treatment. A symptom score is determined by adding the responses of a set of questions related to the patient's experience with enlarged prostate.

To use this symptom scorecard: Circle one number in each line and add up all the circled numbers to get the total score. The total runs from 0 to 35 points with higher scores indicating more severe symptoms. Scores less than seven are considered mild.

	not at all	less than 1 time in 5	less than half the time	about half the time	more than half the time	almost always
1. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
2. 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
3. Over the past month, how often have you stopped and started again several times when you urinated?	0	1	2	3	4	5
4. Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
5. Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5
6. Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
7. 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	1	2	3	4	5
<b>TOTAL SYMPTOM SCORE</b>						

# Change in Prostate Symptom Scores of Drug Therapy & Prolieve® System Treatment\*



In the study cited above, drug therapy resulted in a 4.3 to 6.2 point improvement in the International Prostate Symptom Score.<sup>2</sup> In an independent study, the Prolieve System treatment provided a 9.8 point improvement in the AUA Symptom Score.<sup>4</sup> Improvement in these scores typically indicates improved symptoms such as interrupted sleep from the urge to urinate, repeated feeling of urination, weak stream, and the feeling of incomplete emptying of the bladder.

\*Because the data for the Prolieve System was not collected in a head-to-head study vs. pharmaceuticals, direct comparisons between the Prolieve System and pharmaceutical therapy cannot be made. The AUA and International Prostate Symptom Scores are derived from a similar set of standardized questions recognized globally.

IPSS = International Prostate Symptom Score  
AUA SS = American Urological Association Symptom Score

# The Prolieve® System Can Provide Cost Savings Over Drug Therapy

Patients have to take enlarged prostate medication everyday. For many people, these drugs can be very costly and pose an ongoing financial burden. This is in addition to the other daily medication that may be necessary as men age. As these costs add up, patients may spend thousands of dollars on medication over their lifetime. This is the financial reality faced by many men across the country. Treatment with the Prolieve System may cost much less than drug therapy—in some cases almost **9 times less** than that of combination Flomax Pharmaceutical and Avodart Pharmaceutical drug therapy over a two year period.

## 2-Year Costs to Patients<sup>5</sup>

BPH Treatment	
Flomax® Pharmaceutical Only	\$870
Combination Therapy Flomax® Pharmaceutical & Avodart® Pharmaceutical	\$1,388
Prolieve System	\$155

\*Costs derived from Medicare analysis for patients with supplemental coverage (Part D\* and MediGap coverage).

### ASSUMPTIONS

- Flomax Pharmaceutical cost is 75/month (at Walmart, Northeast)
- Avodart Pharmaceutical cost is 96/month (at Walmart, Northeast)
- Part D plans with negotiated 10% pharmacy discounts
- Patient has no additional medications
- Monthly premiums not included

\*90% of Medicare subscribers also carry Medicare Part D, or other comparable drug coverages, as of March 2010. MEDPAC March 2010 Report to Congress.

<sup>1</sup>Cogent Research Report, December 2007: Are BPH Medications Effectively Treating Patients?

<sup>2</sup>The Journal of Urology, February 2008, Vol. 179, 616-621, "The Effects of Dutasteride, Tamsulosin, and combination Therapy on Lower Urinary Tract Symptoms in Men with Benign Prostatic Hyperplasia and Prostatic Enlargement: 2-Year Results from the CombAT Study". Number of patients followed out to 24 months were: 1267 for Combination therapy, 1301 for Dutasteride, and 1254 for Tamsulosin.

<sup>3</sup>Flomax Pharmaceuticals is a registered trademark of Astella Pharma, Inc. Avodart Pharmaceuticals is a registered trademark of GlaxoSmithKline.

<sup>4</sup>Data on file at Medifocus, Inc., PMA030006

<sup>5</sup>Health economic and reimbursement information provided by Medifocus, Inc. is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Medifocus, Inc. encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services and to submit appropriate codes, charges, and modifiers for services that are rendered. Medifocus, Inc. recommends that you consult with your payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters.

Medifocus, Inc. does not promote the use of its products outside their FDA-approved label.



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**Ask your physician for the Prolieve System patient brochure for complete information on the treatment or visit [www.prolieve.com](http://www.prolieve.com) to request a complete patient information pack.**

**INDICATIONS** The Prolieve Thermilatation® System is a transurethral microwave therapy device for the treatment of symptomatic Benign Prostatic Hyperplasia (BPH) in men with a prostate size of 20 to 80 grams and prostatic urethra length between 1.2 cm and 5.5 cm and in whom drug therapy (finasteride or Proscar®) is typically indicated.

**CONTRAINDICATIONS** Patients who have significantly decreased pain responses, severe urethral stricture prohibiting catheterization, current urinary or prostatic infection, penile or urinary sphincter implants, prostate sizes <20 g or >80 g, peripheral arterial disease with intermittent claudication or Leriche's Syndrome, protruding median lobe with obstruction, metallic implants, implanted cardiac pacemakers or defibrillators, previous transurethral prostatectomy, renal impairment, coagulation disorders, neurological disorders that may affect bladder function, bladder stones, evidence of prostate or bladder cancer or have an interest in the preservation of future fertility.

**WARNINGS AND PRECAUTIONS** All components of the Prolieve System must be used in accordance with the User Manual. The emission of microwave energy must be off during placement and removal of the catheter. Patient comments of pain or excess heat should be investigated. Failure to monitor adequately and deliver the procedure per User Manual may lead to decreased patient safety and/or reduced clinical effectiveness. A single high dose of microwave radiation to the testes, or testicular heating for a prolonged period, may result in temporary or permanent sterility. No anesthetic other than aqueous-based topical intraurethral anesthetic used for catheter placement is recommended. The safety and effectiveness of the Prolieve System for men <50 and >80 years old has not been established in clinical studies. If procedure kit seal or internal sterile packaging seals are damaged or broken, the contents may not be sterile and could cause infection.

**POTENTIAL ADVERSE EFFECTS** that may occur include but are not limited to bleeding, bowel irritation, urethral injury (irritation), chronic pain at site, bladder spasms, urinary retention (complete or incomplete), urinary incontinence, prostatitis, pressure sensation, urinary urgency, urinary tract infection, anal irritation, retrograde ejaculation, erectile dysfunction, and urinary clot retention.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.