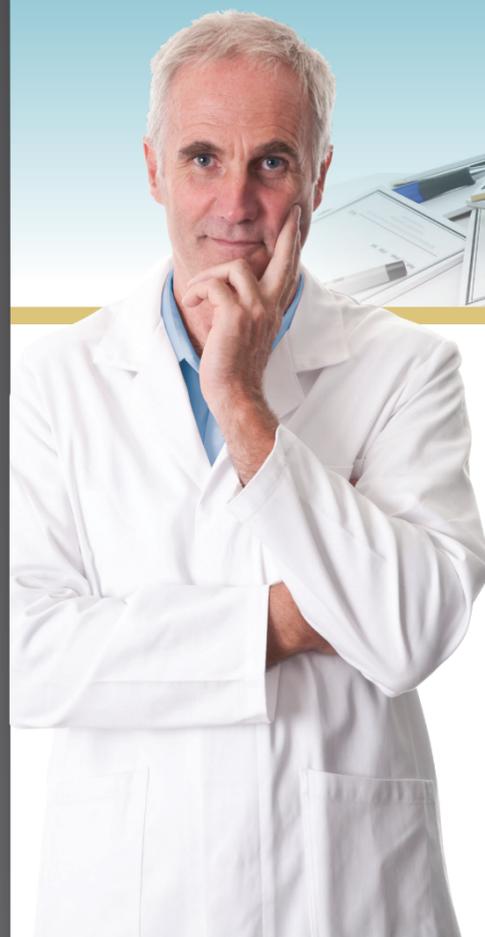


# UROLOGIX®

## The Leader for In-Office BPH Therapy

### THINK OUTSIDE THE Rx



#### Patients are asking for an alternative to medications

- 48% of patients on BPH medications do not have clinically significant symptom improvement<sup>1</sup>.
- Drugs can have serious side effects. Clinical results show a 14%, 19% and 23% increase in impotence for Doxazosin, Finasteride and Combination Therapy, respectively<sup>4</sup>.
- 77% of all patients surveyed are interested in having an in-office procedure<sup>5</sup>.

#### Urologix has the answer with Cooled ThermoTherapy™ and Prostiva® RF Therapy

- Both procedures provide clinically significant QOL, flow rate and symptom score improvement with greater than an 11 point improvement in AUASS in the first year<sup>2,3</sup>.
- Cooled ThermoTherapy and Prostiva provide durable results without retreatment at 5 years in over 90% and 86% of patients, respectively<sup>2,3</sup>.
- Between the two Urologix therapies, most prostate anatomies can be treated including prostate sizes up to 100g with Cooled ThermoTherapy and asymmetric glands, median lobes, and short lobes with Prostiva.

To learn more about Urologix products and services, please call us at  
**(888) 229-0772** or visit [www.urologix.com](http://www.urologix.com)

<sup>1</sup>Wei, et al. High Rates for Continued BPH Medical Therapy Among Non-Responders, Abstract 498, AUA Annual Meeting 2010.

<sup>2</sup>Myrders, L., et al. 5-Year Results of a Multi-Center Trial of a New Generation Cooled TUMT for BPH, Journal of Urology, May 2011.

<sup>3</sup>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

<sup>4</sup>McConnell JD, Roehrborn CG, Bautista OM, et al. Medical Therapy of Prostatic Symptoms (MTOPS) Research Group. The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. N Engl J Med 2003; 349: 2387-98.

<sup>5</sup>Data from online survey conducted by Harris Interactive, August 2007 sponsored by Medtronic, Inc. Survey included 206 qualified respondents.

**Indications:** The Targis System/Cooled ThermoTherapy is indicated to relieve symptoms and obstruction associated with BPH in men with prostatic urethra lengths greater than or equal to 2.5 cm. **Contraindications:** This treatment is contraindicated for patients with a prostatic urethra <2.5 cm in length as measured from the bladder neck to the verumontanum, with urethral stricture (unable to pass 22F urethroscope), peripheral arterial disease with intermittent claudication or Leriche Syndrome (i.e. claudication of the buttocks or perineum); patients who have undergone pelvic radiation therapy or have implanted active devices, including pacemakers or defibrillators within 2.6 inches (6.5 cm) of the prostatic urethra.

**Caution:** Federal (U.S.A.) law restricts this device to use by or on the order of a physician trained and/or experienced in the use of this device. For more complete information about the benefits, risks and contraindications associated with this procedure, please refer to the Instructions for Use and Users Manual. Indications, contraindications, warnings and instructions for use can be found with the product labeling packaged with this device. Cooled ThermoTherapy is a trademark of Urologix, Inc.

**Indications:** For complete indications, contraindications, and precautions for Prostiva RF Therapy, please refer to the Prostiva System Manual at [www.urologix.com](http://www.urologix.com).



**UROLOGIX®**

# SOME LIKE IT HOT...

## Prostiva® RF Therapy

Reaches intraprostatic temperatures of 110°C allowing it to create a lesion in the tissue, causing effective tissue ablation, in just 2 minutes and 20 seconds while preserving the urethra.<sup>1</sup>

- Experienced physicians have stated that they achieve excellent patient tolerability when utilizing recent advances in prostate block techniques<sup>2</sup>
- Direct visualization and precision allows treatment of median and lateral lobes as well as asymmetrical prostates<sup>1</sup>
- Ability to create a predictable prostate defect without resection of tissue<sup>3</sup>
- Effective therapy – clinically significant improvements in IPSS, peak uroflow, and quality of life at five years<sup>4</sup>
- Durable results – reintervention not necessary in over 86% of patients at five years<sup>4</sup>
- Low rate of side effects<sup>1</sup>

*“Prostiva is a safe, durable, minimally invasive office procedure with a very high patient satisfaction rate. Patients are very happy to get off BPH medication and are well pleased with their voiding patterns following the procedure. Patient referrals indicate to me how very satisfied men are with the results.”* – J. Randolph Beahrs, MD



# OTHERS LIKE TO CHILL.

## Cooled ThermoTherapy™

Reaches intraprostatic temperatures of 80°C causing effective tissue ablation in just a 28.5 minute treatment while preserving the urethra.<sup>5</sup>

- Advanced three chamber proprietary cooling technology provides enhanced urethral preservation and patient comfort.<sup>5</sup>
- Multiple catheter sizes and a high-energy delivery system provide physicians with customizable treatment options for glands up to 100 gm<sup>5</sup>
- Ability to create a predictable prostate defect without resection of tissue<sup>3</sup>
- Effective therapy – clinically significant improvements in IPSS, peak uroflow, and quality of life at five years<sup>6</sup>
- Durable results – reintervention not necessary in over 90% of patients at five years<sup>6</sup>
- Low rate of side effects<sup>5</sup>

*“The strength of the CTT lies in its ability to treat prostate glands of any size, including those that are up to 100g, with higher energy levels and with excellent durability of symptom relief. The tolerability, minimal side effect profile, and improvement of lower urinary tract symptoms have made CTT the top minimally invasive therapy option in my office.”* – Harold H. Tsai, MD

### REFERENCES

- <sup>1</sup>Data derived from the Prostiva RF Therapy System User Guide 8930 CRMRef\_R06
- <sup>2</sup>Physician statements are anecdotal and not based on clinical study results. Physician reports are on file at Urologix.
- <sup>3</sup>Data on file at Urologix, Inc.
- <sup>4</sup>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, J Urol. 2004;171(6 Pt 1):2336-2340
- <sup>5</sup>Data derived from the CTC Advance® Instructions for Use, 250348 Rev D 08/10
- <sup>6</sup>Mynderse, L., et al. 5 year Results of a Multi-Center Trial of a New Generation Cooled TUMT for BPH, J Urol. 2011; 185(5):1804-1810

### INDICATIONS

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# UROLOGIX®

The Leader for In-Office BPH Therapy

# pace SETTERS

Featuring Advances in BPH Treatment

## A Growing Problem

As the world continues to grow and age, BPH is becoming a much more prevalent issue for our male population. Urologix is leading the way toward in-office therapies with Cooled ThermoTherapy™ (CTT) and Prostiva® RF Therapy, providing real alternatives to traditional medication-based options.

Benign Prostate Hyperplasia (BPH) is a common and costly condition impacting millions of men worldwide. Nearly 50% of men over the age of 50 report symptoms of BPH, and occurrence increases with advancing age.<sup>1</sup> Today, medical management is by far the most prevalent treatment of choice. However, if you look at BPH drugs objectively, they may not be the best option for men experiencing moderate to severe lower urinary tract symptoms. Medications have to be taken daily and indefinitely and are not as effective as in-office and surgical therapies.<sup>2</sup> Drugs also have been shown to cause significant side effects including fatigue, dizziness, ejaculation disorders, impotence, loss of sex drive, or breast disorders.<sup>3,4</sup> In fact, treatment efficacy rarely leads to a level of improvement the patients would rate as excellent or very good. It is not surprising that with less than ideal efficacy and common side effects, compliance with medication is a serious concern.<sup>5</sup>

So what other treatment options may be a better choice for the BPH Patient? Let's consider In-Office BPH Therapy.

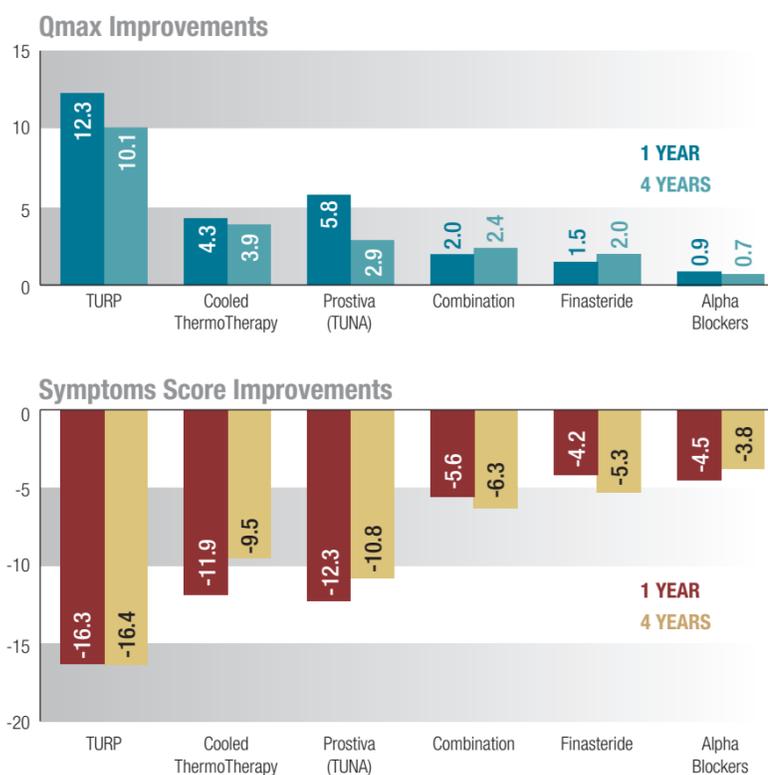
### Do Patients Want In-Office Therapies?

Research shows that BPH patients aren't satisfied with taking chronic BPH medication for life. The Prostate Research Study completed by the Harris Interactive Group in 2007 showed that of patients surveyed:

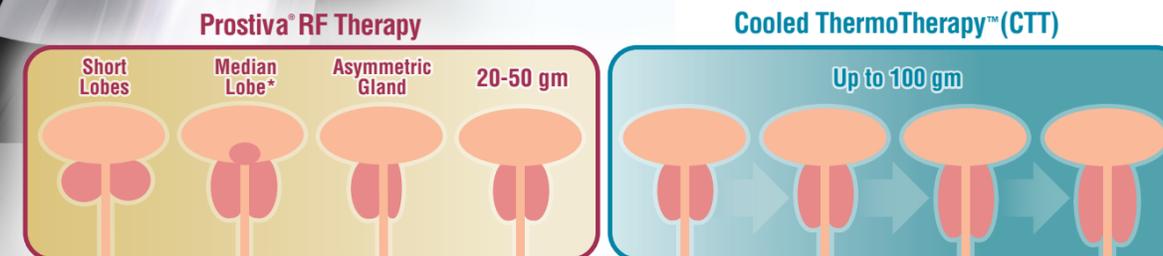
- 50% are not satisfied with the effectiveness of their medication<sup>6</sup>
- 77% of BPH patients are interested in having an in-office procedure<sup>6</sup>
- 61% of patients currently on medication would actually prefer an in-office procedure<sup>6</sup>

### Is BPH In-Office Therapy Effective?

Clinical research has demonstrated that both CTT and Prostiva are effective in the treatment of BPH.<sup>7,8,9</sup>



It is important to note that these data points were not collected in a head-to-head study; therefore, direct comparisons cannot be made. BPH Medication data is derived from the CombAT Study (see reference 7); Cooled ThermoTherapy data is derived from Mynderse, et al. 2011 (see reference 8); and Prostiva RF Therapy data is derived from Hill, et al. 2004 (see reference 9).



\*Excluding a ball valve median lobe that grows up into bladder and obstructs opening.

### Is BPH In-Office Therapy Durable?

CTT and Prostiva are proven to be durable with no retreatment needed at five years in over 90% and 86% of patients, respectively.<sup>8,9</sup> This is in part due to the high temperatures used in these therapies. Permanent cell death is a product of time and temperature. As a baseline, 50°C is required to permanently ablate tissue in 60 minutes. CTT reaches intraprostatic temperatures of 80°C for effective tissue ablation in just a 28.5 minute treatment while preserving the urethra and providing increased patient comfort through its advanced three chamber catheter and proprietary cooling technology.<sup>11</sup> Prostiva reaches intraprostatic temperatures of 110°C allowing it to create a lesion in the tissue in just 2 minutes and 20 seconds and also provides urethral preservation and excellent patient tolerability<sup>10</sup> utilizing recent advances in prostate block techniques.

### How Can Patient Comfort Be Handled in the Office Setting?

Thanks to shorter treatment times and improved cooling technologies, controlling the patient's comfort level has greatly improved over the past 10 years. However, it is important to use a thoughtful pain management approach when performing in-office treatments. Many experienced physicians use pre-procedure oral

### Is One Therapy Better Than the Other?

Utilizing both CTT and Prostiva offers greater versatility within your practice. Prostiva provides the physician with direct visualization, 360 degrees of precision, and the ability to treat the median and lateral lobe as well as asymmetrical prostates up to 50 gm.<sup>10</sup> The CTT family of catheter sizes and high-energy delivery system allows physicians to customize treatment for glands up to 100 gm.<sup>11</sup> Between these two therapies, urologists are able to treat most prostate anatomies.<sup>10,11</sup>

medications, local anesthesia, and prostatic blocks to maximize patient comfort.

In a recent clinical study, pain levels were measured using a 0-10 VAS score and demonstrated an average score of <3 throughout the Cooled ThermoTherapy procedure.<sup>8</sup>

### What are the Benefits of In-Office BPH Therapy?

In-Office BPH Therapy provides significant benefits to both the healthcare professional and the patient.

- Minimally invasive treatment which does not require general anesthesia
- Convenient treatment completed in your office in less than an hour
- Clinically proven results which typically last up to 5 years<sup>8,9</sup>
- Durability with very small retreatment rates<sup>8,9</sup>
- Low rate of side effects<sup>10,11</sup>
- Established reimbursement

### Is BPH In-Office Therapy Difficult to Integrate into My Practice?

In today's busy practices, introducing a new technology into your office can be a daunting task. Urologix provides services and tools that can make that integration seamless.

*"Minimally invasive therapies are significantly more effective for relief of lower urinary tract symptoms than pharmacologic therapy as demonstrated in randomized clinical trials. Moreover, durability for both Cooled ThermoTherapy and Prostiva are well documented in the literature. Since 1988, I have treated more than 800 patients with Cooled ThermoTherapy and the retreatment rate for my patients after 14 years is only 14%. I believe that minimally invasive therapies for patients with symptomatic BPH should be the primary therapy because they provide more significant symptom relief and have durable results."* — Robert G. Pugach, MD

A critical step to successful integration of these procedures is educating patients. We understand that finding the time to thoroughly inform your patients about BPH and its treatment options can be challenging for your busy practice. That's why Urologix has developed first-rate educational materials and programs to assist you in providing the best information to your patients in a timely and cost effective manner. In addition, Urologix has sponsored many highly successful and well attended BPH patient educational seminars across the country. These events provide a great opportunity to educate existing patients on the benefits of non-surgical treatment alternatives. Urologix also offers a completely turnkey mobile solution, delivering safe, durable, and versatile solutions for in-office BPH treatment right to your door.

### How can I learn more about In-Office Therapy?

Urologix offers several different resources available online and in person that will help you learn more about Cooled ThermoTherapy™ and Prostiva® RF Therapy to determine if these options would be a beneficial addition to your current BPH treatment protocol. Urologix has an extensive online educational resource center which includes procedure videos, animations, physician testimonials, and peer lectures located at [www.urologix.com](http://www.urologix.com) In addition, we sponsor a large number of preceptorships and educational events across the country.

For more information, please call the Urologix Customer Support team at (888) 229-0772 or visit [www.urologix.com](http://www.urologix.com)

References: 1. Napalkov P, Maisonneuve P, Boyle P. Worldwide patterns of prevalence and mortality from benign prostatic hyperplasia. *Urology*. 1995;46(suppl 3A):41-46. 2. AUA Clinical Guidelines on the Management of BPH (Revised, 2010) 3. Jaly labeling, [www.fda.gov](http://www.fda.gov), October, 2010 4. Proscar labeling, [www.fda.gov](http://www.fda.gov), June, 2011 5. Roehrborn, CG. Current Medical Therapies for Men With Lower Urinary Tract Symptoms and Benign Prostatic Hyperplasia: Achievements and Limitations. *Rev Urol*. 2008 Winter; 10(1): 14-25. 6. Data from online survey conducted by Harris Interactive, August 2007 sponsored by Medtronic, Inc. Survey included 206 qualified respondents. 7. Roehrborn CG, et al. The Effects of Combination Therapy with Dutasteride and Tamsulosin on Clinical Outcomes in Men with Symptomatic Benign Prostatic Hyperplasia: 4-year Results. *Eur Urol*. 2010 Jan; 57(1):123-31 8. Mynderse, L., et al. 5 year Results of a Multi-Center Trial of a New Generation Cooled TUMT for BPH. *J Urol*. 2011; 185(5):1804-1810 9. 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. *J Urol*. 2004;171(6 Pt 1):2336-2340 10. Data derived from the Prostiva RF Therapy System User Guide 8930 CRMRef\_R06 11. Data derived from the CTC Advance® Instructions for Use, 250348 Rev D 08/10